STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Veterinary Medical Board
1747 N. Market Blvd., Suite 230, Sacramento, CA 95834
Telephone: 916-515-5220 Fax: 916-928-6849 | www.vmb.ca.gov

MEETING AGENDA

Veterinary Medical Board
1747 N. Market Blvd. – Hearing Room
Sacramento, California
January 20-21, 2016

9:00 a.m. Wednesday, January 20, 2016

1. Call to Order - Establishment of a Quorum

2. Introductions

3. Review and Approval of October 20-21, 2015 Meeting Minutes

4. Election of Officers

5. Review and Discuss Recommendations to Legislature Regarding a Veterinarian's Responsibility to Notify Parties Upon Scanning an Animal with a Microchip

6. Proposed Regulations
   A. Status of Pending Regulations
   B. Review and Discuss Potential Amendments to the Registered Veterinary Technology Approval of Schools Accredited by the American Veterinary Medical Association Regulations [California Code of Regulations Title 16, Division 20, section 2064]

7. Action on Implementation of 2015 Legislation
   A. Assembly Bill 192 - Discuss Implementation of Pet Lover's License Plate Program
   B. Senate Bill 361- Discuss Tracking of Mandatory Continuing Education on Judicious Use of Medically Important Antimicrobial Drugs

8. Multidisciplinary Advisory Committee Report – Dr. Jon Klingborg
   A. Review and Consideration of Multidisciplinary Advisory Committee Items and Recommendations

9. Review and Consider Action on 2016 Legislative Proposals
   A. Sunset Review Provisions
   B. Exemptions for Unlicensed Veterinarians Providing Assistance to California Licensed Veterinarians
   C. Review and Possible Action on Statutory Change Authorizing Veterinarians to Compound Drugs

10. Board Chair Report – Dr. Mark Nunez

11. Review and Discuss Recent Guidance on the *North Carolina State Board of Dental Examiners v. Federal Trade Commission (North Carolina)*

12. Public Comment on Items Not on the Agenda
    Note: The board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. (Government Code Sections 11125, 11125.7(a)).

13. Overview of Complaint Procedures & Expert Opinion Case Review – Diann Sokoloff, Supervising Deputy Attorney General; Kimberly Kirchmeyer, Executive Director, Medical Board of California.

14. Recess until January 21, 2016, at 9:00 a.m.

9:00 a.m. Thursday, January 21, 2016

15. Reconvene - Establishment of a Quorum

16. Introductions

17. Executive Officer & Staff Reports
    A. CURES Update
    B. Administrative/Budget
    C. Enforcement
    D. Licensing/Examination
    E. Hospital Inspection

18. Agenda Items and Next Meeting Dates – April 20-21, 2016; Los Angeles
    A. Agenda Items for Next Meeting
    B. Multidisciplinary Advisory Committee Meetings – April 19, 2016; Los Angeles
    C. Future Veterinary Medical Board Meeting Dates 2016: July 20-21, 2016; Sacramento, October 19-20, 2016; Sacramento

CLOSED SESSION

19. The Board will meet in closed session (pursuant to Government Code Section 11126(c)(3) to discuss and vote on disciplinary matters including stipulations and proposed decisions.

RETURN TO OPEN SESSION

20. Adjournment

This agenda can be found on the Veterinary Medical Board website at www.vmb.ca.gov. Times stated are approximate and subject to change. This meeting will conform to the Open Meeting Act. Agenda discussions and report items are subject to action being taken on them during the meeting by the Board at its discretion. The Board provides the public the opportunity at meetings to address each agenda item during the Board's discussion or consideration of the item. Total time allocated for public comment may be limited.

The Board plans to webcast items 1-18 at this meeting on its website at www.vmb.ca.gov. Webcast availability cannot, however, be guaranteed due to limitations on resources or technical difficulties that may arise. If you wish to participate or to have a guaranteed opportunity to observe, please plan to attend at a physical location.

The meeting locations are accessible to the physically disabled. Other disability-related accommodations or modifications can be provided upon request. Please make your request for disability-related accommodations by contacting the Board at (916) 515-5220 or sending a written request to 1747 N. Market St., Suite 230, Sacramento, CA 95834. Provide at least five (5) business days' notice prior to the meeting to help ensure availability of requested accommodations.

MISSION

The mission of the Veterinary Medical Board is to protect consumers and animals by regulating licensees, promoting professional standards and diligent enforcement of the practice of veterinary medicine.

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MEETING MINUTES

Hilton Garden Inn-San Diego –Rancho Bernardo
17240 Bernardo Center Drive
San Diego, CA 92128
October 20-21, 2015

9:00 a.m. Tuesday, October 20, 2015

1. Call to Order - Establishment of a Quorum

Dr. Mark Nunez called the Veterinary Medical Board (Board) meeting to order at 9:04 a.m. Executive Officer, Annemarie Del Mugnaio, called roll; seven members of the Board were present and thus a quorum was established. Elsa Flores was absent.

Dr. Jaymie Noland introduced herself as a new member to the Board and provided a brief background on her experience with veterinary medicine.

Dr. Nunez swore in Dr. Jaymie Noland as a new member on the Board.

2. Introductions

Board Members Present
Mark Nunez, DVM, President
Cheryl Waterhouse, DVM, Vice President
Kathy Bowler, Public Member
Jennifer Loredo, RVT
Judie Mancuso, Public Member
Jaymie Noland, DVM
Richard Sullivan, DVM

Staff Present
Elizabeth Bynum, Associate Enforcement Analyst
Annemarie Del Mugnaio, Executive Officer, Veterinary Medical Board
Nina Galang, Administrative Program Coordinator
Lou Galiano, DCA Television Specialist
Sabina Knight, Legal Counsel
Ethan Mathes, Administrative Program Manager
Diann Sokoloff, SDAG, Board Liaison

Guests Present
Karen Atlas, Physical Therapist, California Association of Animal Physical Therapists
Jeff Backus, CaRVTA
Kellie Boiston, Physical Therapist, California Association of Animal Physical Therapists
Leslie Boudrian, RVT, CaRVTA
Nancy Ehrlich, RVT, CaRVTA
Valerie Fenstermaker, CVMA
Jodi Heaston, Licensed Massage Therapist, CHRB

Jon Klingborg, DVM, Multidisciplinary Advisory Committee
Libby Lucas
Norine Marks, DCA Legal
Elisa Martin
Robert Miller, General Counsel,
John Pascoe, UCD
Trish Penice, Physical Therapist, California Association of Animal Physical Therapists
Daniel Robbins, Physical Therapist, California Association of Animal Physical Therapists
June Sanchez
Marshall Scott, DVM, CVMA
Dan Segna, DVM, California Veterinary Medical Association
Deb Sell, AVCA
Jane Sykes, UC Davis School of Veterinary Medicine
Ron Terra, DVM, Western University of Health Sciences
Erin Troy, DVM
Kim Williams, RVT
Darlene Woodend

3. Review and Approval of July 21-22, 2015 Meeting Minutes

- Dr. Richard Sullivan motioned and Kathy Bowler seconded the motion to adopt the July 21-22, 2015 meeting minutes. The motion carried 6-0-1. Dr. Jaymie Noland abstained.

4. Consider Reappointment of Diversion Evaluation Committee Public Member Jim Weisenberg

- Judie Mancuso motioned and Kathy Bowler seconded the motion to reappoint Jim Weisenberg as a Public Member on the Diversion Evaluation Committee. The motion carried 7-0.

5. Proposed Regulations
   A. Status of Pending Regulations

Dr. Nunez commended staff on the progress made on the pending regulations.

   B. Review and Approval of Updates to Disciplinary Guidelines

Dr. Nunez reviewed the eight changes to the Disciplinary Guidelines, including five changes requiring discussion.

There were no further changes requiring discussion on: No Preceptorships or Supervision of Interns, Supervised Practice, and Tolling of Probation.

The Board discussed the term, No Management or Administration, which restricts respondents from managing any veterinary hospital during the duration of his or her probation. Dr. Nunez clarified that respondents may have administrative responsibilities (i.e. if they are the owner of the practice, they may purchase supplies, pay the bills, etc.), but may not manage aspects of veterinary practice (i.e. establish protocols for the practice of veterinary medicine).

The Board discussed the term, Notice to Employers, Item #7 (Notice to Employers). Dr. Nunez clarified that based on the July 2015 Board meeting, the Board agreed that the previous language for Item #7 (Notice to Licensee Manager/Managing Licensee) and Item #9 [Owners and Officers (Corporations or Partnerships): Knowledge of the Law] could be combined to create the new term. Ms. Del Mugnaio

clarified that it is the managing licensee's responsibility to ensure that the Board has been notified of the work location of all relief veterinarians. This clarification will be included in the final language.

Based on the recommendation of legal counsel, the Board agreed to notice the proposed regulations for 45-days in order to allow the public an opportunity to review, comment, and request a hearing, if necessary. After the 45-day comment period, the proposed language will be brought before the Board for adoption and direction to move forward with the rulemaking file.

- Judie Mancuso motioned and Kathy Bowler seconded the motion to adopt the Disciplinary Guidelines language, post a notice for a 45-day public comment period to review any comments received and agreed not to hold a public hearing unless one is requested. The motion carried 7-0.

C. Review Public Comments on the Animal Rehabilitation Regulations and Consider Modifications to the Proposed Language. [California Code of Regulations, Title 16, Division 20, section 2038.5]

Dr. Nunez reviewed the Animal Rehabilitation supplemental packet and the general comments received from the public and various interested parties. Testimony included, but was not limited to, the following:

- complimentary therapy, such as animal massage, should not be defined as animal rehabilitation
- supervision parameters were overly restricted, level of supervision should be determined by the referring veterinarian
- lack of training defined for animal rehabilitation, which poses a consumer protection issue
- concern that these regulations were an attempt by the Board to restrict business competition
- definition of animal rehabilitation proposed by the Board is too broad
- regulations should protect animal patients from incompetent providers
- musculoskeletal manipulation is not being modified by the proposal
- animals are deemed property, therefore, consumers should have a right to choose complimentary services
- significant negative impact on business and jobs if regulations were to take effect
- lack of veterinarians available to provide supervision services
- proposed regulations potentially drive up costs for consumers

Dr. Nunez presented two options:

1) Pursue regulations, and if the Board decides to proceed with this rulemaking process, it will need to respond to all of the comments.
2) Not pursue a regulatory change and handle animal rehabilitation issues through enforcement on a case-by-case basis.

Dr. Nunez argued that it would be difficult to pursue cases through enforcement since there is currently no clear definition of animal rehabilitation.

Ms. Del Mugnaio clarified that the lack of statutory authority refers to the authority to exempt physical therapists from the Veterinary Medicine Practice Act. Under current law, physical therapists are equivalent to unregistered assistants and are therefore, currently not exempt.

The Board proposed delegating to the Multidisciplinary Advisory Committee (MDC) the task of revising current language with direction on how to address some of the concerns expressed by interested parties. A clear definition of animal rehabilitation must be determined, including more information on what it is doing and how it is being used.

MDC Chair, Dr. Jon Klingborg, walked through the Task Force Report compiled by the MDC. While physical therapists have technical training, they should have anatomical training. Registered Veterinary Technicians (RVTs) have anatomical training but should have some technical training. Dr. Klingborg referenced two specific programs which offer intensive hands-on training on animal rehabilitation techniques and anatomy for both RVTs and physical therapists. However, the Board lacks oversight of physical therapists, therefore, under the current framework, education cannot be required and direct supervision may be the only option.

The Board discussed models used by other states such as Colorado and Nevada. In other states, enforcement of physical therapists is vested with the Physical Therapy Board, and therefore, it may not be possible to emulate other states' models exactly.

Public member, Nancy Ehrlich, questioned why the Board members were not required to attend the hearing. Ms. Del Mugnaio clarified that in the interest of time, it was held outside of an official Board meeting to receive all comments. While not required to attend or take action during the hearing, Board members are required to respond to each of the public comments. Comments were summarized and presented in a more condensed manner due to the large number of comments received.

Mr. James Sims from the Physical Therapy Association expressed that as a physical therapist, he would not feel comfortable performing physical therapy on his own animal, as it is different from human-based physical therapy. Ms. Karen Atlas, physical therapist with a certification in canine rehabilitation, shared that although she works at a premise that is nearly already in compliance with the proposed regulations, she feels the model does not work and expressed opposition to the proposed regulations. Ms. Margaret Nee also added that she studied at a professional school in Colorado, received training in anatomy, and has liability insurance.

Public comment also included support of the proposed regulations and suggestions to make the language more specific. Veterinarians, Dr. Erin Troy and Dr. Jessica Waldmen, shared stories of animals that were harmed or killed during animal rehabilitation without the supervision of a veterinarian.

Norine Marks, supervising attorney with the Department of Consumer Affairs, pointed out that the Board only has authority over veterinarians and RVTs and the proposed regulations should be written with that in mind.

- Judie Mancuso motioned and Dr. Richard Sullivan seconded the motion to refer the issue back to the Multidisciplinary Advisory Committee to redefine animal rehabilitation, to define what animal rehabilitation is doing, to address whether minimum education requirements for individuals who participate in the services of animal rehabilitation is necessary in regulation to address the possible change in level of supervision, to discuss the requirement for a premises permit whenever veterinary medicine is being practiced, and to identify the issue of physical therapists being exempt and how to include or remove from the regulations as a barrier to moving forward. The motion carried 7-0.

Ms. Del Mugnaio noted that the regulations are already in process and need to be withdrawn.

- Dr. Richard Sullivan motioned and Dr. Cheryl Waterhouse seconded the motion to withdraw the Animal Rehabilitation regulations. The motion carried 7-0.

D. Review and Discuss Possible Action on the Proposed RVT Student Exemption Regulation [California Code of Regulations Title 16, Division 20, section 2064]

Dr. Nunez reviewed the proposed RVT Student Exemption regulations.

Mrs. Ehrlich, expressed that she has no objection to the wording, but identified a problem since the only school that is Board approved is San Diego - Mesa College. The remaining colleges throughout California are not Board approved. Ms. Del Mugnaio clarified that colleges accredited by the AVMA are still required to meet reporting requirements to the Board.

- Dr. Richard Sullivan motioned and Dr. Cheryl Waterhouse seconded the motion to adopt the language and delegate to the Executive Officer to notice the regulations for a 45-day public comment period and review any comments received and agreed not to hold a public hearing unless one is requested. The motion carried 7-0.

E. Review and Consider Action to Submit Comments on the Amended California Horse Racing Board's Proposed Regulations on Authorized Bleeder Medication [California Code of Regulations Title 4, Division 4, section 1845]

Philip Laird, Staff Counsel at California Horse Racing Board (CHRB), reviewed the intent of the Authorized Bleeder Medication regulations and provided an update to the timeline and status of the regulations, including further defining "Owner as Veterinarian" and "Furosemide Veterinarian."

The Board noted on page 2 that the types of license referenced needs to be clarified and suggested changing the wording to "not less than" instead of "no later than," in order to clarify which side of four hours the time limitation would apply.

CHRB agreed with the suggested changes and requested a letter of support from the Board, if possible.

- Dr. Richard Sullivan motioned and Kathy Bowler seconded the motion to write a letter of support for the California Horse Racing Board on the amended proposed regulations on Authorized Bleeder Medication. The motion carried 6-1. Judie Mancuso opposed the motion.

6. 2015 Legislation Report

A. AB 12 (Cooley) State government: administrative regulations: review
B. AB 85 (Wilk) Open meetings
C. AB 750 (Low) Business and professions: retired category: licenses.
D. AB 1060 (Bonilla) Professions and vocations: licensure
E. AB 483 (Patterson) Healing arts: initial license fees: proration
F. AB 316 (Maienschein) Veterinarians
G. AB 317 (Maienschein) Veterinary medicine: temporary shelter facility.
H. SB 27 (Hill) Livestock: use of antimicrobial drugs.
I. SB 361 (Hill) Skilled nursing facilities: antimicrobial stewardship guidelines.
J. SB 800 (BP&E Committee) Clean-up Provisions for VMB
K. AB 192 (Allen) Pet Lovers License Plate

Dr. Nunez updated the Board on the current legislation impacting the Veterinary Medical Board. AB 85 and AB 317 were vetoed by the Governor. AB 1060 has been amended since the last Board meeting and is no longer relevant to the Board. Dr. Nunez reviewed AB 12 and AB 750 and there were no comments received by the Board.

SB 27, SB 361, SB 800, and AB 192 were chaptered by the Governor. AB 316 was also chaptered by the Governor and Dr. Nunez reiterated that the Board is in support of hiring California veterinarians first

before pursuing out-of-state relief veterinarians during emergency situations in which there was a need for additional veterinarians on site when resources are low.

Dr. Nunez reviewed AB 483 and noted that should the bill have passed, it would result in a loss of revenue for the Board.

7. Review and Consider Action on 2016 Legislative Proposals
   A. Adding Resigned and Non-Renewable License Statuses

No information was received from the Medical Board; therefore, the Board will not be discussing the item.

   B. Review and Possible Action on a Statutory Change to Require University Licensure

Dr. Nunez provided background on the research and discussion by the MDC on University Licensure. Veterinarians currently employed at the two universities California in Veterinary Medicine programs are exempt from the requirements to obtain a veterinary license. Legal counsel has recommended removing this exemption and creating a university license, allowing veterinarians employed by the university to provide veterinary care to public animals.

The MDC recommended approving the proposed statutory change as proposed. California veterinary representatives, Dr. Ron Terra of Western University of Health Sciences, College of Veterinary Medicine, and Dr. John Pascoe and Dr. Jane Sykes of University of California, Davis, also spoke in support of the proposed language, which serves as a statutory framework for the Board. The language also provides disclosure and transparency to the public with regards to licensure.

Dr. Nunez noted that further discussion will be forthcoming on a potential "grandfather clause" which affects veterinarians currently employed at the university. Ms. Del Mugnaio clarified that the language proposed a delayed implementation date as opposed to a "grandfather clause," as it provides more time to comply with the requirements, but does not provide an exemption. The only exemption is the continuing education requirement.

Ms. Del Mugnaio noted the universities may be exempt from the premise permit regulations. The Board expressed opposition to the universities being exempt from the premise permit regulations since they are practicing veterinary medicine and working with the public's animals.

- Dr. Richard Sullivan motioned and Judie Mancuso seconded the motion to adopt the proposed University Licensure statutory language and direct staff to research the effective date of the grandfather clause and report back to the Board. The motion carried 7-0.

8. Board Chair Report – Dr. Mark Nunez

Dr. Nunez provided an update on the list of activities, meetings, and workshops that have occurred since the last meeting.

The following is a table of the latest Board activities since the July 2015 meeting:

August 4-7, 2015	Hospital Inspection Training for new and returning hospital inspectors in Sacramento, CA
August 14, 2015	Expert Witness Training in San Diego, CA
September 17-19, 2015	Dr. Nunez attended the American Veterinary Association of State Boards annual meeting in Milwaukee, WI

9. Multidisciplinary Advisory Committee Report – Dr. Jon Klingborg

Dr. Klingborg reported on the work that has been done since the last report received on July 20, 2015 by outgoing MDC Chair, Dr. William Grant. The MDC has five existing priorities, plus animal rehabilitation, which now will be a top priority. Dr. Klingborg will assign an animal rehabilitation task force to work on language.

Ms. Del Mugnaio updated that the Drug Compounding task force is meeting with the Board of Pharmacy on November 12, 2015 to discuss existing language for drug compounding as it relates to the practice of veterinary medicine.

10. Review and Discuss Sunset Review Draft Report and New Issues

Ms. Del Mugnaio updated the Board that she has met with Bill Gage, Chief Consultant of the Senate Business, Professions and Economic Development Committee, who is responsible for review of the Board's Supplemental Sunset Review Report to address the new and existing issues before the Board.

Ms. Del Mugnaio noted that the Board has until December 1, 2015 to submit the final Supplemental Sunset Review Report to the legislature. There will be hearings held in March during which Dr. Nunez will testify before the Legislature, the Executive Officer, and possibly a public member of the Board.

Ms. Del Mugnaio noted that she will report on the staffing changes and the two BCPs that were pursued in attempt to retain the limited-term staff that was hired in 2014/2015. Ms. Del Mugnaio will also report on the projected revenue from the VACSP program, which helps support the new staff positions.

Ms. Del Mugnaio noted that the Board's Strategic Plan will be included as an attachment to the Supplemental Sunset Review Report to expand on the various RVT matters, including the approval of RVT schools and RVT alternate route programs that have been prioritized by the Board. The Strategic Plan will also serve to highlight the 36 Board accomplishments since the 2012-2015 Sunset Review.

Ms. Del Mugnaio noted that in order to make the Diversion Program self-supporting, Board support would need to be eliminated entirely, which is $10,000-$20,000 per participant. Participants currently only pay $2,000 over the course of 3-5 years.

Ms. Del Mugnaio noted that the number of veterinary premise inspections has increased and will be addressed in the Sunset Review Report.

Ms. Del Mugnaio reported that the Citation and Fine regulations were completed in 2014 and have been amended since then and transitioned to the Office of Administrative Law. The regulations should take effect by March 2016. Regulatory language for Disciplinary Guidelines and Consumer Protection Enforcement Initiative (CPEI) has been approved by the Board and is moving through the rulemaking process. Regulations for Animal Dentistry, CCR section 2037, were put forward along with Minimum

Standards, which took effect in January 2014. Uniform Standards for Abuse regulations have been put on hold per the Department of Consumer Affairs' Legal Counsel. Ms. Del Mugnaio reported that the VACSP regulations are moving forward in the rulemaking process and are anticipated to take effect in early 2016.

The staff developed a general customer satisfaction survey on the Board's website. Also, surveys are sent through QR codes during the complaint process which contain a link to the enforcement survey.

Ms. Del Mugnaio stated that the Board has shown vast improvements in curing backlogs in complaint review. One area needing improvement is disciplinary case processing, which includes processes outside the Board's control since the Office of Administrative Hearings has a full calendar and often issues continuances. Ms. Del Mugnaio noted that there are statistics regarding the percentage of cases that are declined by the Attorney General's office and staff has identified the outlier cases that significantly affect the overall processing time.

Ms. Del Mugnaio provided an update on the new issues to address in the Sunset Review and requested input from the Board members on Issue #6, Implementation of SB 27/SB 361.

Ms. Del Mugnaio presented two options: 1) Authorize a Sunset Review Subcommittee to finalize the document or 2) Discuss the report with entire Board via a telephonic meeting. Dr. Nunez suggested going with option #1.

- Judie Mancuso motioned and Kathy Bowler seconded the motion to authorize the approval of the Sunset Review Supplemental Report to the Sunset Review Subcommittee. The motion carried 7-0.

Dr. Nunez appointed Kathy Bowler and himself to form the Sunset Review Subcommittee.

11. Executive Officer & Staff Reports

Ms. Del Mugnaio commended the hospital inspection team on the great work they are doing, receiving positive feedback from the professional community about the education they are receiving on how to improve compliance.

Ms. Del Mugnaio provided additional information regarding the 26 non-compliant hospitals and noted that Patty Rodriguez, from the Hospital Inspection Program, can speak more to this issue at the January 2016 Board meeting. Drug storage, controlled drug logs, and expired drugs tend to be common issues. Reporting to CURES is another common issue that requires education.

Ms. Mancuso recommended adding the Top 3 reasons hospitals are not in compliance to our website or social media.

Ms. Del Mugnaio discussed the issues VMB staff have been having regarding the backlog of non-compliant hospitals.

The Board members requested to go on a hospital inspection to further understand the process. Ms. Del Mugnaio pointed out that if the inspection results in any disciplinary action, the board member that participated in the inspection would need to recuse themselves from voting.

A. Administrative/Budget

Ms. Del Mugnaio noted that the expenditure of $165,000 for our in-house consultants was taken from last year's budget and includes the raise they received. Dr. Lane Johnson has been hired by the University of California, Davis and is leaving the Board.

Administrative Program Manager, Ethan Mathes, noted that the Board is experiencing vacancies. Mr. Mathes clarified that the Board was given 11 new staff positiosn but 6.5 of the positions were limited-term. The current Budget Change Proposal (BCP) includes a request for 5.5 of the positions as full-time permanent. The analysis of fund conditions includes the VACSP revenue.

B. Enforcement

Enforcement Manager, Candace Raney, reviewed the Enforcement Report and highlighted a number of significant improvements that have been made since the last report in July 2015.

Staff has made significant strides to reduce processing times and backlog, specifically in the area of the number of days to complaint intake.

The Board issued the first probationary license to an RVT, which is a new process that aims to save the applicant and Board time and money.

The Board conducted its second expert witness training on August 14, 2015 in San Diego, CA at the Attorney General's Office as presented by Supervising Deputy Attorney General, Diann Sokoloff.

There are currently 19 expert witnesses serving as experts to the Board with regard to complaint investigation. Mrs. Sokoloff inquired about the manner in which the in-house consultants are being used. Ms. Del Mugnaio noted that this needs to be placed on the agenda to be discussed in greater detail.

The Board is currently looking at ways in which to provide guidance to supervisors of probationers regarding their role and expectations as a supervisor. An informational guide will be placed on the Board's website regarding the supervisor's role in reviewing medical records.

Mrs. Raney noted that there are three vacancies in the enforcement unit. The focus over the next month will be Sunset Review and filling the vacant positions.

C. Licensing/Examination

Mr. Mathes updated the Board on the Licensing/Examination Report. Staff has begun User Acceptance Testing (UAT) as of September 2015 with six staff members devoted to UAT. Staff is going through intensive training and organizational change management and has begun outreach through renewal packet inserts and Board website updates. Additional outreach will be communicated to the Board's stakeholders and partner associations.

Mrs. Ehrlich inquired about the costs regarding the California RVT exam and why the exam cost evaluation would not be complete until 2017. Mr. Mathes clarified that there are figures included in the Section 139 report; however, a component necessary for the evaluation is a linkage study, which examines the test equivalency of the national examination compared with the California examination and which is still not available. This study is conducted every 3-5 years and the methodology for the California law exam still needs to be written.

Lastly, Mr. Mathes updated that the number of Diversion Program participants has grown from two to six participants since the implementation of the program.

12. Overview of Continuing Education Audit Program

Mr. Mathes reported on the history of the Continuing Education (CE) Audit Program. An initial rate of two percent and up to 10 percent of licensees may be audited with the help of potential staff. Mr. Mathes noted that all licensees in good standing could be subject to a CE audit.

Mrs. Ehrlich inquired about logs if one attends a multi-day conference. Mr. Mathes clarified that licensees will need to obtain a certificate stating that they attended the course.

Ms. Del Mugnaio added that the CE Audit Porgram is part of a legislative mandate and is included in our strategic plan.

13. Public Comment on Items Not on the Agenda

Valerie Fenstermaker noted that Stephanie Trumm from MAXIMUS wrote a two-page article for CVMA set to publish in their November/December newsletter, focusing on the participant confidentiality of the Diversion Program. The issue will be sent to all of its veterinarian and RVT members in California.

CVMA and CaRVTA offered to include BreEZe information in their website and newsletter.

14. Agenda Items and Next Meeting Dates – January 20-21, 2016; Sacramento
    A. Agenda Items for Next Meeting

- Election of Officers
- Scanning microchips
- Section 2064 changes regarding RVT AVMA approved schools
- Sunset Review follow-up
- Complaint Review - expert testimony and in-house/external consultants
- Regulatory Status Update

The Board agreed on the following Board meeting dates for 2016: January 20-21 (Sacramento), April 20-21, July 20-21, and October 19-20, 2016. The Board is considering Los Angeles for the April meeting and Sacramento for the July and October meetings. Locations will be determined at a later date.

    B. Multidisciplinary Advisory Committee Meetings – January 19, 2016; Sacramento

15. Recess until October 21, 2015, at 9:00 a.m.

9:00 a.m. Wednesday, October 21, 2015

16. Reconvene - Establishment of a Quorum

Dr. Waterhouse called the Board meeting to order at 9:10 a.m. and six members of the Board were present, thus a quorum was established. Dr. Mark Nunez and Elsa Flores were absent.

17. Introductions

Board Members Present
Cheryl Waterhouse, DVM, Vice President
Kathy Bowler, Public Member
Jennifer Loredo, RVT
Judie Mancuso, Public Member
Jaymie Noland, DVM
Richard Sullivan, DVM

Staff Present
Elizabeth Bynum, Associate Enforcement Analyst
Annemarie Del Mugnaio, Executive Officer, Veterinary Medical Board
Nina Galang, Administrative Program Coordinator
Lou Galiano, DCA Television Specialist
Sabina Knight, Legal Counsel
Ethan Mathes, Administrative Program Manager
Diann Sokoloff, SDAG, Board Liaison

Guests Present
Adam L. Berg, Administrative Law Judge
Sunh Hah
Janine Jung, DVM
Daniel Rodriguez
Greta Yang, Court Reporter

18. Petition for Penalty Modification – Dr. Janine Jung, VET 12330

Supervising Deputy Attorney General (SDAG) Diann Sokoloff opened the petition for penalty modification hearing presenting the case against Dr. Janine Jung. Dr. Jung answered questions from SDAG Sokoloff and members of the Board. Administrative Law Judge (ALJ) Adam L. Berg closed the hearing and the Board went into closed session.

19. Petition for Penalty Modification – Dr. Byoung "Bill" Hah, VET 10122

SDAG Sokoloff opened the petition for penalty modification hearing presenting the case against Dr. Byoung "Bill" Hah. Dr. Hah answered questions from SDAG Sokoloff and members of the Board. ALJ Berg closed the hearing.

CLOSED SESSION

20. The Board met in closed session (pursuant to Government Code Section 11126(c)(3) to discuss and vote on this matter and on other disciplinary matters including stipulations and proposed decisions.

Petition for Penalty Modification – Dr. Janine Jung, VET 12330
The Board adopted the penalty modification.

Petition for Penalty Modification – Dr. Byoung "Bill" Hah, VET 10122
The Board rejected the petition modification.

AV 2013 17
The Board adopted the stipulated settlement.

IA 2016 6
The Board adopted the stipulated settlement.

IA 2015 21
The Board adopted the proposed decision.

IA 2015 14
The Board adopted the proposed decision.

IA 2016 2
The Board adopted the proposed decision.

IA 2015 13
The Board adopted the proposed decision.

RETURN TO OPEN SESSION

21. Adjourn

The Board adjourned at 1:30 p.m.

TO SCAN OR NOT TO SCAN, THAT IS THE QUESTION

Gregory M. Dennis[1]

1. AVMA and Microchips

In November 2005, the AVMA's Executive Board approved a policy entitled ***The Objectives and Key Elements Needed for Effective Electronic Identification of Companion Animals, Bird, and Equids***.[2] Two revisions have since happened, most recently in November 2008.

The AVMA's electronic identification policy declares:

> "Scanning of animals for microchips is necessary for the identification system to be effective. Therefore, every companion animal, bird, and equid presented to a veterinarian should be scanned, when deemed necessary, for the presence of a microchip."

Continuing:

> "The veterinarian, or designated staff, should scan the animal and note in the patient's medical record if a microchip is present, and if so, record the microchip number in the patient's medical record."

Further:

> "The routine scanning for a microchip not only aids in the positive identification of an animal, but also provides the opportunity to assess if the microchip is still functioning properly and located appropriately, as well as reminding owners to keep their microchip database contact information current.

The AVMA's electronic identification policy also discusses if the information derived through the microchip is different from the information that had been given by the presenter.

> "In those circumstances that raise suspicion that the presenting person may not actually be the lawful owner of the animal, a veterinarian should ask for documentation of ownership, such as governmental registration, bill of sale, adoption documents, or microchip identification. Documentation of ownership should be required when a client requests that a veterinarian remove a microchip. Where the veterinarian has cause to believe that ownership of the animal is

> unclear, the veterinarian should postpone treatment until evidence of ownership is presented unless, in the judgment of the veterinarian, the treatment is necessary to maintain the health of the animal, or preserve its life, or protect public health."

The AVMA's policy naturally leads to the question of what, if any, obligations do California veterinarians have to scan animals for microchips? Further, what if the chip information does not coincide with the details on the presenter?

2. *California Veterinary Medicine Practice Act* and Scanning for Microchips

In California for ten-years (1987 – 1997), the Veterinary Medical Board's position was that insertion of a microchip was a surgical procedure and, therefore, could only be performed by a licensed veterinarian.[3] Before 1997 the Board's Legal Counsel cautioned the Board that if it changed its position it "might not have jurisdiction to regulate the process at all." In October 1997, the Board changed its position and "concluded that the microchip procedure was not a veterinary treatment over which the VMB had jurisdiction." Other states have come to the same conclusion[4] or hold it as the practice of veterinary medicine.[5]

With the California VMB having taken the position that Microchipping is not the practice of veterinary medicine[6] and, therefore, it does have jurisdiction, the question then arises can it issue policies or regulations pertaining to California veterinarians and microchipping, including whether a California veterinarian has an obligation to *scan* any animal presented to her or him for a microchip?

There are only two California statutes that specifically require animals be scanned for a microchip; neither are in the ***California Veterinary Medicine Practice Act***. ("***CVMPA***"). ***Food & Agriculture Code* § 31108(c)**, concerning impounded dogs at public or private shelters, requires shelters to scan dogs for microchips and make reasonable efforts to contact the owner.

***Food & Agriculture Code* § 31752(c)** does the same for cats.[7]

16 *Code of Regulations* § 2032.3, pertaining to the required contents of veterinary records, does not list as a necessary informational item that a California veterinarian has scanned the patient for a microchip and, if so, was one detected. Further, if a microchip was detected, what was the identification number. While **§ 2032.3(a)(3)** requires a veterinarian to list the "name or identity of the animal, herd or flock," that provision does not require scanning. Also, it is not like the language in either ***Food & Agriculture Code* § 31108(c)** or **§ 31752(c)** that specifically mentions and requires public or private animal shelters to scan dogs and cats for microchips. Indeed, the words "microchip" and "scan" do not appear in the ***CVMPA*** or the companion regulations. Nor, for that matter, are "client" and "owner" defined by the ***CVMPA*** or the regulations.

3. Civil Liability for Failing to Scan?

Is there potential liability if a veterinarian fails to scan an animal for microchip? Depending on the particular facts, maybe. For instance, in 2006 the Washington state Court of Appeals set-aside a trial court's dismissal and reinstated a lawsuit that alleged, among other things, animal shelters were failing to scan cats for microchips resulting in the animals being euthanized rather than returned to the owners.[8]

4. What if the Microchip and the Client do Not Coincide?

The fact that a microchip reading leads to information that the name obtained is not the same name as the person presenting the animal does not mean the presenter is not then the owner of the animal. There can be many reasons other than theft why there are differences. Animals are abandoned, sold, given-away and, of course, lost. Additionally, registry information had not been updated or the person selling or giving away the animal forgot to mention the animal has a

microchip.

Veterinarians should not jump to the conclusion that if there is a difference, the presenter must, therefore, be in unlawful possession of the animal. If a microchip is detected, which the veterinarian does not already know about, he or she or authorized staff should promptly speak with the presenter (client) and ask if they knew about the microchip. If the client does know about the chip and tells the veterinarian or staff member the animal belongs to the client, the veterinarian should be able to rely upon this statement particularly if the client has signed an admission form or is willing to sign a document identifying itself as the owner or the owner's authorized agent.

If the client didn't know there is a microchip in the animal, the veterinarian or staff member should provide the client with written information for how the client can contact the registry company and encourage the client to do so promptly.

In the latter situation, if the client tells the veterinarian to proceed with treatment the veterinarian may decline to do so until the client contacts the registry company and reports to the veterinarian what he or she learned. Alternatively, the veterinarian may decline to proceed with treatment until the client gives him or her permission to contact the registry company.

No matter what happens, the veterinarian or staff member should document in the patient's record they have spoken to the client, what the client told the veterinarian or staff, what documents, if any, they gave to the client, the veterinarian's or staff's name, and the date and time of the conversation.

Finally, if an emergency, the veterinarian should be able to proceed with treatment to stabilize the animal. Once again, the veterinarian or staff should appropriately document the patient's records.

5. Other Countries and Microchips

The debate over whether a veterinarian has or should have a duty to scan any animal that he or she sees for treatment is not limited to the United States.[9] For instance, in 2005 while dismissing charges against a British veterinarian who had euthanized an elderly stray cat which post-mortem was found to have a microchip, a Royal College of Veterinary Surgeons'[10] Investigation Committee advised the veterinarian that henceforth when any animals were presented as strays they "should be scanned to see if they are microchipped, so that the owners can be contacted."[11] Additionally, the RCVS's *Microchipping: Ownership Dispute* policy states that if "a client [who has presented an animal] declines to consent to the release of his or her name and contact details of the animal and microchip, a veterinar[ian] should breach client confidentiality to pass the necessary information to the PetLog Reunification Service."[12]

6. Conclusion

While identification microchips are a good, their increasing presence on the veterinary scene should not convert a veterinarian from being a person who treats and cares for animals into an adjudicator of facts and law in resolving ownership disputes.[13] That is not, and should never become, the purpose or role of veterinarians in society.

Editor's Note*:** This article is ***not intended for nor should it be relied upon as legal advice. Any reader of this article should and is fully encouraged to consult with an attorney of their choice for any question they might have or advise they might want to seek on the subject matter of this article.

Footnotes

[1] **Gregory M. Dennis** spoke at the 2008 AVMA Convention, American Veterinary Medical Law Association meeting on veterinary legal and ethical duties pertaining to microchips, lost, stolen and escaped animals, cremation and pet cemeteries. He is a consultant to the AVMA's Electronic ID study group.

Mr. Dennis is Legal Counsel for both the Kansas and Missouri veterinary medical associations. He is also a charter member of the American Veterinary Medical Law Association; from 1995 – 2004 was the Editor of the AVMLA's *Newsletter*; and the AVMLA's president from 2003 - 2004. Mr. Dennis has served on two AVMA Tasks Forces; *first* the *Model Veterinary Practice Act* and, *second*, the Legal Status of Animals. Finally, he has written and spoken extensively on numerous and diverse legal issues and matters affecting the practice of veterinary medicine both in and outside the United States.

[2] www.avma.org/issues/policy/electronic_identification.asp
See also, ***Microchipping of Animals*** (December 3, 2007).
www.avma.org/reference/backgrounders/microchipping_bgnd.pdf
Microchipping animals, Frequently asked questions.
www.avma.org/issues/microchipping/microchipping_faq_pf.asp

[3] See Department of Consumer Affairs, Veterinary Medical Board, **Policy 97/98-1: *Microchip Implantation***.
www.vmb.ca.gov/laws_regs/po197_1.shtml

[4] *E.g.*, ***Georgia Attorney General Opinion 95-3***, 1995 Ga. Atty. Gen. 4, 1995 WL 124592 (February 6, 1995)—"If a microchip is implanted solely for the purpose of identification of an animal, then such a procedure would not constitute the practice of veterinary medicine since it does not involve the diagnosis or treatment of an animal disease, defect, or injury." ***Minutes of the Kansas Board of Veterinary Examiners Meeting, Wednesday, January 30, 2008***, p. 2—"…the consensus of the Board was that micro-chipping does not constitute the practice of veterinary medicine as defined in Kansas statute." www.kansas.gov/veterinary/bdminutes_013008.pdf

[5] *E.g.*, **Florida**—"Florida [animal] shelters can continue to implant microchips in animals up for adoption but can no longer be allowed to provide free or low-cost microchips to pet owners, unless a licensed veterinarian implants the chips." Miller, ***Vets Must Put Microchips in Pets, State Says***, *Palm Beach Post* (March 19, 2008).

The ***New York*** *Veterinary Practice Act* specifically includes "the subcutaneous insertion of a microchip intended to be used to identify an animal" in its definition of the "practice of veterinary medicine." ***N.Y. Education Law* § 6701**.

***South Carolina Code* § 47-3-55(c)** suggests that only a licensed veterinarian or an animal shelter employee can implant a microchip.

[6] ***Business & Professional Code § 4826*** defines the practice of veterinary medicine, surgery and dentistry as, among other things, the diagnosing or prescribing of "a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure or relief of a wound, fracture, bodily injury, or disease of animals." Also, administering "a drug, medicine, appliance, application, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of animals, except where the medicine, appliance, application, or treatment" Further, performing "a surgical or dental operation upon an animal" or "any manual procedure for the diagnosis of pregnancy, sterility, or infertility upon livestock or equidae."

[7] *See generally*, ***People v. Youngblood***, 91 Cal. App.4th 66, 73 – 74, 109 Cal. Rptr.2d 776, 781 (3rd Dist. 2001), discussing ***Food & Agriculture Code* § 31752**.

[8] *E.g.*, ***Wolverton v. Young***, 2006 Wash. App. *LEXIS* 78, 2006 WL 165734 (Div. 3, 2006). *See generally*, ***Minetti v. City of Seattle***, 2005 WL 1532959 (W.D. Wash. June 29, 2005)—police called to resolve a dispute between two individuals about who owned a dog. A microchip indicated the plaintiff was the owner, However, witnesses and the dog tag issued before the microchip's insertion, indicated the other person owned the dog. The police allowed the other person to take the dog. The plaintiff's lawsuit against the city and others was dismissed.

See generally, *Pet's Death Rekindles Electronic ID Debate: New Microchip Raises Doubts About Scanner Reliability*, ***J.A.V.M.A. News*** (July 1, 2004).

[9] *See, e.g.*, ***Australian Veterinary Association***, *Microchip Protocols* (November 12, 2007); ***Canadian Veterinary Medical Association***, *Microchip Implants* (Rev. July 2002).

[10] The veterinary licensing and disciplinary authority in the United Kingdom.

[11] ***Royal College of Veterinary Surgeons Preliminary Investigation Committee Chairman's Report to Council June 2005***, *Stray Animals*, ¶ 18. www.rcvs.org.uk/Shared_ASP_Files/UploadedFiles/E6611C1C-B793-48FA-B65A-25E24B24A829_PIC_CRC_0506.pdf

In 2008 the RCVS dismissed a complaint by a horse owner against a veterinarian who, at the request of a humane society and police had euthanized their horse. The horse had apparently been down on the ground for many

days, in a very poor condition and had tetanus. Neither the society, police nor the veterinarian knew who owned the animal. The complainant's charge was the veterinarian should have attempted to find the owner and he euthanized the animal without the owner's consent. Among the RCVS's reason for dismissal was the veterinarian had scanned the horse for a microchip and found none. ***Royal College of Veterinary Surgeons Preliminary Investigation Committee Chairman's Report to Council November 2008***, ¶ 15, p. 3 & ¶ 19, p. 4. www.rcvs.org.uk/Shared_ASP_Files/UploadedFiles/rcvs/FE756476-0E68-4374-8FA0-B1F7EDB108F0_PIC_CRC_0811.pdf

[12] R.C.V.S. ***Guide to Professional Conduct***, Part 2, ¶ j(6). www.rcvs.org.uk/templates/internal.asp?nodeid=92589&int1stparentnodeid=89642&int2ndparentnodeid=89738

The *PetLog Reunification Service* website is www.microchipping.com/

[13] *See e.g.*, ***Wadsworth v. Olive***, 53 Ga. App. 539, 186 S.E. 590 (1936)—the plaintiff's evidence tended to show his hound dog had been stolen from him while he was hunting. The dog was later in the defendant-veterinarian's possession before he turned him over to another person, also a defendant. Judgment for the plaintiff.

See generally, ***Propes v. Griffth***, 25 S.W.3d 544 (Mo. App. W.D. 2000)—defendant took two of her neighbor's dogs to a local veterinarian and requested he euthanize them. The veterinarian suspected the animals belonged to the neighbor and did not do so. The defendant then took the dogs to a veterinarian in another town. The defendant signed a euthanasia consent form indicating she was the owner. The second veterinarian euthanized the dogs. The dog owner awarded a judgment against the defendant.

Veterinary
Medical Board

Memo

To: All Interested Parties

From: Susan M. Geranen, Executive Officer
Veterinary Medical Board

Date: April 3, 2009

Re: Microchips

The Veterinary Medical Board, in 1997, determined, based on testimony, evidence submitted and a legal opinion from its staff counsel, that microchip implantation was a procedure that could safely be performed by lay persons and, thus, was not considered the practice of veterinary medicine.

Recently a question was posed as to whether a California veterinarian has an obligation to scan any animal presented to him or her for a microchip prior to treating said animal. Since the task of inserting a microchip is not the practice of veterinary medicine, it is not within the jurisdiction of the Board to require veterinarians to insert a chip or to scan for one that may have been inserted. Currently, in California, there is no requirement for veterinarians to scan an animal prior to treatment.

The issue of whether there may be civil, criminal or ethical liability for scanning or not scanning to determine ownership is outside the Board's jurisdiction.

STATE OF CALIFORNIA

Memorandum

To: **SUE GERANEN**
Executive Officer
Veterinary Medical Board

Date: October 17, 1997

Telephone: (916) 445-4216
CALNET: 8-485-4216
FAX: (916) 323-0971

From: **Department of Consumer Affairs**
Legal Office

Subject: Microchip Implants

The Veterinary Medical Board ("Board") has requested an opinion on whether the use of a hypodermic needle to inject a transponder under the skin of an animal, for a fee, by an unlicensed individual who is working independent of a veterinarian or registered veterinary technician is a violation of the Veterinary Medicine Act (Business and Professions Code section 4800 et seq. - hereinafter referred to as "the Act").

Conclusion

It is our opinion that microchip implantation does not fall within the treatments covered by subdivisions (b) and (c) of section 4826. Depending upon the board's review and expert opinion, microchip implantation may constitute a surgical operation which would be deemed the practice of veterinary medicine under subdivision (d) of section 4826. If it is deemed to be a surgical operation, it could be performed only by a licensed veterinarian.

Analysis

Microchip implantation is a technique for identifying animals which has been available for approximately ten years. It uses a hypodermic needle for implanting a transponder just beneath the skin of the subject animal. The transponder is approximately the size of an uncooked grain of rice. The hypodermic needle is a large gauge plastic needle. The plunger in the syringe is modified to include a shaft used to push the transponder through the hypodermic needle and under the skin of the subject animal. Thereafter, scanning devices can be held over the animal which can identify the animal by reading the transponder carried by the animal.

Section 4825 of the Business and Professions Code (all section references are to that Code) makes it unlawful to practice veterinary medicine or any branch thereof without having first obtained a license in accordance with the Act.

Section 4826 defines the practice in veterinary medicine, in part, as follows:

"Any person practices veterinary medicine, surgery, and dentistry, and the various branches thereof when he does any of the following:

* * *

"(b) Diagnoses or prescribes a drug, medicine, appliance or application or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, or bodily injury or disease of animals."

"(c) Administers a drug, medicine, appliance or application or treatment of whatever nature for the prevention, cure or relief of a wound, fracture, or bodily injury or disease of animals..."

* * *

"(d) Performs a surgical...operation upon an animal."

Subdivisions (b) and (c) of section 4826 define the practice of veterinary medicine as including the prescribing, diagnosing or administering of an application or a treatment upon an animal. It requires that the treatment be "for the prevention, cure or relief" of a disease or injury. If a treatment is not administered for the prevention, cure, or relief of a disease or injury, it would not fall within the provisions of subdivisions (b) or (c).

In some instances microchip implantations are used in animal disease control programs to identify individual animals to facilitate tracing diseased animals to their origins. It has been asserted that where microchip implantations are used in such programs, they should be considered as appliances used "for the prevention, cure or relief of ...disease of animals."

The term "for the prevention... of... disease of animals" means that the motive or purpose of a treatment is to keep a disease from happening or existing. That is, the treatment is intended as a precautionary measure.

The purpose of a microchip implantation is to insert a transponder into an animal which is to be used for the identification of the animal recipient. It is a means of transmitting and obtaining information. The information obtained through a transponder is precoded generic information about the animal. It does not transmit diagnostic information about the animal. The microchip implantation is not a prophylactic measure in and of itself.

Microchip implantations are used in a variety of situations. On the one hand, they may be used for information purposes in an animal disease control program. On the other hand, they may be used by a pet owner to facilitate the retrieval of his or her animal from the local animal shelter in the event that the animal is lost. In the latter case, there is no basis to conclude that such a microchip implantation is a preventative treatment. The Board would be placed in a situation where microchip implantation, depending upon its particular application, may or may not be the practice of veterinary medicine. This produces an unequal and inconsistent result. To accomplish a consistent application of the law, microchip implantation must be examined in the context of its fundamental purpose rather than the use to which its information will be applied. As discussed above, the fundamental purpose of microchip implantation is identification of the animal recipient. As a method of animal identification, we do not believe it is a treatment for the prevention of an animal disease.

In addition, if the Board were to accept that the use of microchip implantation in animal disease control programs is a preventative veterinary treatment, it would follow that other methods of animal identification which are used in animal disease control programs, such as branding and tattooing, would also have to be considered a veterinary treatment. Historically, the Board has determined that these practices are not the practice of veterinary medicine because their primary purpose was for animal identification.

It has been also suggested that an Attorney General opinion defining the scope of practice for human medicine supports the Board's jurisdiction over microchip implantation. In 58 Cal.Atty.Gen.Ops. 565, 571, the Attorney General's office concluded that cosmetic procedures were the practice of human medicine if the procedure required a detailed knowledge of medicine which went beyond the mere severance or penetration of tissue. It is suggested that the same rule be applied to veterinary medicine. That is, if a particular procedure requires specialized knowledge of veterinary medicine which is beyond the mere severance or penetration of tissue, it should be considered the practice of veterinary medicine. Based upon this premise, it is proposed that microchip implantation requires specialized knowledge of animal anatomy warranting a finding that its use be deemed a veterinary treatment.

We believe that the cited Attorney General's opinion is inapplicable to the practice of veterinary medicine because there is a significant difference between the definition of human medicine and veterinary medicine. The definition of the practice of human medicine is broader than the definition of the practice of veterinary medicine. Section 2051 is specific as to the purpose for which a physician is authorized to penetrate or sever tissue. It permits a physician to "to sever or penetrate the tissues of human beings...in the treatment of diseases, injuries, deformities, or other physical or mental conditions."(Emphasis added) The purpose for which a veterinarian is authorized to prescribe or administer a treatment is to prevent, cure or relieve diseases or injuries. (Emphasis added) The veterinary definition does not include within its scope of practice

treatments intended to address an animal's physical condition which is not otherwise a disease or injury.

The Attorney General's opinion addressed the question of whether earlobe piercing constituted the practice of medicine. The Attorney General concluded that the mere penetration of tissue for a beauty culture purpose rather than an intent to practice medicine within the traditional and statutory definition, did not constitute the practice of medicine. The opinion included a cautionary note that it was not to be construed to exempt from the practice of medicine other cosmetic procedures. The opinion cited examples of cosmetic procedures such as cosmetic surgery to the eyebrows and silicone injections to enlarge female breasts as practices which "require a detailed knowledge of medicine which goes beyond the mere severance or penetration of tissue." It concluded that such practices when considered "in the total context under which they are performed clearly fall within the traditional and statutory definition" of the practice of medicine. Id at page 570.

The underlying basis for asserting that a cosmetic procedure may be the practice of medicine rests upon the definition of the practice of medicine which specifically includes treatments intended to address "physical conditions."

In contrast, the application of a treatment will constitute the practice of veterinary medicine if the purpose of such treatment is..."for the cure or relief of a wound, fracture or bodily injury or disease of animal." The definition of veterinary medicine does not include treatments intended to address a physical condition which is not otherwise considered a disease or injury. It would be an inappropriate expansion of the statutory definition of the practice of veterinary medicine to hold that treatments not intended to address a disease or injury constitute veterinary medicine because they require specialized veterinary medical knowledge. The Attorney General opinion applied the "specialized medical knowledge" criteria to the definition of the practice of medicine which includes treatments of physical conditions. The definition of veterinary medicine does not have a provision for treatments of physical conditions. Accordingly, the specialized medical knowledge test adopted in the Attorney General opinion is inapplicable to veterinary medicine.

The purpose of a transponder is for identification of an animal rather than the cure or relief of a disease or injury. Accordingly, we do not believe that microchip implantation fall within the treatments covered by subdivisions (b) and (c) of section 4826.

We next consider whether the insertion of a microchip implant constitutes the practice of veterinary medicine because it falls within the provisions of subdivision (d) of section 4826. Subdivision (d) defines the practice of veterinary medicine as including the performance of a "surgical operation" upon an animal. Subdivision (d) does not require that the surgical procedure have as its intended purpose the "cure" or "relief" of a disease or injury. The fact that a

procedure is a surgical operation is a sufficient basis to find that it is the practice of veterinary medicine.

The phrase "surgical operation" is not defined in the Act or the board's regulation. The term "surgery" has been defined to mean the "severing or penetration of tissue of human beings." People v. Fowler (1939) 84 P.2d 326. Application of this definition to veterinary medicine would require that a surgical operation include the "severing or penetration" of animal tissue.

The question posed is whether the application of a hypodermic needle may constitute a surgical operation. In an Attorney General opinion which addressed whether unlicensed persons could perform injections upon animals, there is a statement which implies that the use of a hypodermic needle does not constitute surgery. The opinion states as follows:

> "Under this section [4826], injections may be administered by a layman under the direct supervision of a licensed veterinarian [subdiv. (c)], but only a licensed veterinarian may perform surgery [subdiv. (d)]" 560 Cal.Atty.Gen.Ops. 349

The opinion suggests that the use of hypodermic needles falls within the provisions of subdivision (c) [veterinary treatments] rather than subdivision (d) [surgical operation] of section 4826.

We believe that the Attorney General's opinion may be distinguished from microchip implantation. The Attorney General's opinion addressed injections which used traditional hypodermic needles and injectable media. The hypodermic needle associated with the microchip implant is a much larger gauge needle. The traditional injection introduces a liquid into the body. In contrast, microchip implantation introduces a solid, nondisperable object into the body. Based upon these differences, we believe that the aforementioned Attorney General opinion may be inapplicable to the microchip implantation.

Ultimately, the decision of whether insertion of a microchip implant constitutes a surgical operation is a question of interpretation based upon the Board's expertise in the area of veterinary medicine.

It is noted, that when the Board was first presented with microchip implantation in 1987, it concluded that the procedure was a surgery which could be performed only by a veterinarian. In 1993, the Board again reviewed the microchip implant. The minutes of the Board's November 18, 1993 meeting state, in relevant part, as follows:

> "However, since 1987 this procedure has been used successfully and safely at many locations in California and nationwide. Based on historical data

> and testimony submitted during its meeting, the board determined that the microchip implant procedure could be done as an injection rather than as a surgical procedure..."

Although in 1993, the Board determined that a microchip implant did not constitute a surgical procedure, it may change its interpretation if it has evidence to the contrary that its earlier decision was incorrect.

We note that if the Board were to conclude that the insertion of a microchip implant is a surgical operation, such a procedure could only be performed by licensed veterinarians. Section 4840.2 imposes limitations on the scope of practice for registered veterinary technicians ("RVT") and unregistered assistants ("UA"). It provides in relevant part as follows:

"Registered veterinary technicians and unregistered assistants shall not perform the following health care services:

(a) Surgery"

* * *

Section 4840 makes it clear that if the insertion of microchip implant is deemed to be a surgical operation that a veterinarian cannot delegate that taskto an RVT or a UA.

Based upon the above analysis, it is our conclusion that the insertion of a microchip implant does not fall with the treatments covered by subdivisions (b) and (c) of section 4826. Depending upon the Board's review and expert opinion, the insertion of a microchip implant may constitute a surgical operation which would be deemed the practice of veterinary medicine. If it is deemed to be a surgical operation, it could be performed only by a licensed veterinarian.

We trust that the foregoing is responsive to your inquiry.

DERRY L. KNIGHT
Deputy Director
Legal Affairs

By DONALD CHANG
Supervising Counsel

STATUS OF PENDING VMB REGULATIONS JANUARY 2016			
Subject	**CCR Section(s)**	**Current Status/Action**	**Notes**
BOARD			
Civil Penalties for Citation	2043	Agency Review	3/20/15 – OAL Publication Date 5/4/15 – End of public comment period May 2015 – Submitted to DCA Legal for Review/Approval November 2015 – Submitted to Agency for Review/Approval February 2016 – Submit to OAL for Approval
Veterinary Assistant Controlled Substances Permit (VACSP)	2034 et. seq.	DCA Review	June 2015 – Board approved language 9/4/15 – Published 45-day notice 10/19/15 – End of public comment period 11/5/15 – Publish 15-day Notice of Extension of Public Comment Period November 2015 – Submit to DCA Legal for Review/Approval
Animal Control Officer Training	2039.5	In Progress	July 2014 – Board approved language January 2016 – Publish 45-day notice
CPEI (SB 1111)	TBD	In Progress	October 2014 – Board approved language January 2016 – Publish 45-day notice
Disciplinary Guidelines	2006	In Progress	January 2015 – Board approved language May 2015 – Disciplinary Guidelines Committee Meeting July 2015 – Submit language to Board for review/approval October 2015 – Board approved language January 2016 – Publish 45-day notice
Minimum Standards / Telemedicine	2032.1	In Progress	February 2015 – MDC approved amendments to Minimum Standards language April 2015 – Board approved language
RVT Alternate Route School Approval	2068.5	In Progress	February 2015 – MDC approved amended language and forwarded to Board for discussion. July 2015 – Board approved language
RVT Student Exemption (BPC 4841.1)	TBD	In Progress	July 2015 – MDC approved amended language and forwarded to Board for discussion. October 2015 – Board approved language
Uniform Standards for Abuse (SB 1441)	2006, 2006.5, and 2076	In Progress	October 2014 – Board approved language April 2015 – On hold per Legal

MDC			
Shelter Medicine	TBD	TBD	September 2015 – CVMA task force meetings begin
Animal Rehabilitation	TBD	TBD	November 2015 – Rulemaking file withdrawn from OAL January 2015 – Assign MDC Task Force

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Veterinary Medical Board
1747 N. Market Blvd., Suite 230, Sacramento, CA 95834
Telephone: 916-515-5220 Fax:: 916-928-6849 | www.vmb.ca.gov

MEMORANDUM

DATE	January 4, 2016
TO	Veterinary Medical Board
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Registered Veterinary Technology Approval of Schools Accredited by the American Veterinary Medical Association Regulations**

Regulatory Background:

In January 2006, the Registered Veterinary Technician Committee (RVTC) began discussions regarding using American Veterinary Medical Association (AVMA) approval criteria as a standard for California veterinary school approval. Former Executive Officer, Sue Geranen, noted that Committee members should review the AVMA approval criteria to assure that California schools are meeting a standard that is acceptable to the RVTC and one that is not duplicative with current AVMA processes. The Committee agreed that regulations would need to be developed in order recognize the AVMA accreditation and to maintain oversight over AVMA accredited, California approved veterinary schools with regards to notification of new schools, reporting pass rates to students, and being placed on probation when necessary.

Legal Counsel, Shela Barker, noted that the change to CCR section 2064 is not an across the board exemption, and that the Board still requires AVMA-accredited schools to submit applications to the Board in order for the Board to be notified of the program's existence, as well as to comply with reporting requirements. Ms. Barker also opined that the Board does not have legal authority to defer the Board's approval of a school to another non-governmental agency.

During an RVTC meeting in April 2009, the committee passed a motion to recommend to the Board that a letter is sent to RVT schools notifying them that they need to be approved by the Board by a specified implementation date while the Board moves forward with regulations to revise the school approval process.

On December 7, 2012, the Board noticed proposed regulatory changes to the California Code of Regulations (CCR), sections 2064-2066.1, that make specific that RVT educational programs accredited by the American Veterinary Medical Association (AVMA) are deemed California Board approved. The proposed regulations also exempt AVMA accredited schools from undergoing separate inspections as AVMA already performs facility inspections.

No public comments were received, the modified language and rulemaking file was approved by the Office of Administrative Law (OAL) and the Secretary of State, and the regulations took effect January 1, 2015.

Issues:

On October 20, 2015, the Board discussed clarity issues with the approved regulatory language regarding the reporting requirements for AVMA accredited schools that have been deemed equivalent to California "approved," but have not officially been approved by the Board.

Action(s) Requested

- Consider directing staff to amend existing regulatory language to exempt AVMA schools from specified reporting requirements.

Attachment(s):

- CCR sections 2064-2066.1 - RVT School Approval Regulations

Title 16. Professional and Vocational Regulations
Division 20. Veterinary Medical Board

§ 2064. Approval of Schools Accredited by the American Veterinary Medical Association

All schools or degree programs accreditated by the American Veterinary Medical Association (AVMA) shall be deemed by the board to have met the minimum requirements of section 2065(a), (b), (d), and (e). Such schools and degree programs shall also be exempt from the initial inspection requirements of section 2065.7(a). Re-approval inspections shall be at the discretion of the board. All other requirements of section 2065, and all other sections applicable to schools or degree programs seeking board approval, continue to apply and must be demonstrated in the school's or degree program's application for board approval. Nothing in this section shall be construed to prohibit the board from disapproving or withdrawing approval from any school or degree program not complying with the requirements of this division or of any provision of the Veterinary Medicine Practice Act. Approval under this section shall automatically terminate upon loss of accreditation by the AVMA.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065. Minimum Requirements for Approved Schools or Degree Programs.

Schools or degree programs seeking approval from the board shall meet all of the following minimum requirements:
(a) The curriculum shall consist of:
(1) a minimum of 600 hours of classroom instruction,
(2) a minimum of 200 hours of clinical instruction, and
(3) an externship consisting of at least 200 hours.
(b) The curriculum shall cover applicable safety training in all coursework. Coursework shall include the following:
(1) Principles of anatomy and physiology,
(2) Biology and chemistry,
(3) Applied mathematics,
(4) Orientation to the vocation of veterinary technology,
(5) Ethics and jurisprudence in veterinary medicine including applicable regulatory requirements,
(6) Anesthetic nursing and monitoring including anesthetic evaluation, induction, and maintenance. It shall also include care and use of anesthetic and monitoring equipment,
(7) Animal husbandry, including restraint, species and breed identification, sex determination and sanitation,
(8) Animal nutrition and feeding,
(9) Client communication,
(10) Dental care of companion and laboratory animals including prophylaxis and extractions,
(11) Diseases and nursing management of companion, food, and laboratory animals including zoonoses,
(12) Emergency and critical care nursing,

(13) Laboratory procedures to include clinical biochemistry, cytology, hematology, immunology, basic microbiology, parasitology, and urine analysis testing,
(14) Imaging to include radiography, basic endoscopy, ultrasound principles, and radiation safety principles,
(15) Medical terminology,
(16) Medical office management including medical record keeping and drug control,
(17) Basic necropsy techniques including specimen collection and handling,
(18) Pharmacology, and
(19) Surgical nursing and assisting including instrumentation, suturing, bandaging and splinting.
(c) Each student shall be supervised during the externship or clinical rotation by a veterinarian or registered veterinary technician who is located at the site of the externship or clinical rotation. The school or degree program shall have a written agreement with the site that specifies the expectations and responsibility of the parties. A staff member of the school or degree program shall visit the site prior to beginning the externship or clinical rotation relationship and at least once annually following the initial inspection.
(d) The library facilities of the school or degree program must be adequate for the conducting of the educational program.
(e) The physical plant and equipment used for instruction in the academic teaching shall be adequate for the purposes intended.
(f)(1) The faculty shall include a California licensed veterinarian employed by the school or degree program as an advisor, administrator, or instructor. Instructors shall include, but need not be limited to a California registered veterinary technician. If there is any change in the faculty, the board must be immediately notified.
(2) Instructors shall be knowledgeable, current, skillful, and possess at least two years of experience in performing or teaching in the specialized area in which they are teaching. Each instructor shall have or currently be receiving training in current teaching methods. The school or degree program shall effectively evaluate the teaching ability of each instructor.
(3) The school or degree program shall have a director who meets the requirements of subdivision (f)(2) and who shall hold a current active California license as a veterinarian or registration as an RVT. The director shall have a minimum of three years experience as a veterinarian or RVT. This shall include one year of experience in teaching, administration, or clinical supervision or a combination thereof within the last five years. The director shall have completed or be receiving course work in administration.
(4) In the absence of a director, the school or degree program may appoint an interim director. The interim director shall meet the requirements of (f)(3), except that the interim director may have applied for, but not yet have received licensure or registration. The school or degree program shall not have an interim director for a period exceeding eighteen months.
(g) The number of students enrolled shall be at a ratio to the number of faculty and size of the facilities which is not detrimental to the quality of education. When animal patients are used as part of the curriculum the ratio shall be adequate to protect the health and safety of the animal patients and the students, taking into consideration the species of animal being treated.
(h) All students admitted shall possess a high school diploma or its equivalent.
(i) The school or degree program shall be part of an institution that is approved by the Department of Consumer Affairs, Bureau for Private Postsecondary Education, or its successor agency, or accredited by a regional or national accrediting agency recognized by the United States Department of Education.
(j) Every school or degree program shall be in compliance with the laws regulating the practice of veterinary medicine and the regulations adopted pursuant thereto.

(k) Any instruction covered under subsection (a)(3) shall be in a facility that is in compliance with registration requirements of Business and Professions Code section 4853.
(*l*) The schools or degree programs shall provide each prospective student, prior to enrollment, with literature which discloses the school's or degree program's pass rate for first time candidates and the state average pass rate for first time candidates on the board's registered veterinary technician examination during the two-year period immediately preceding the student's proposed enrollment and a description of the requirements for registration as a registered veterinary technician.
(m) The schools or degree programs shall provide each prospective veterinary technology student prior to enrollment written information regarding transferability of the units they receive in the courses that they take and shall post the information at all times in a conspicuous location at its facility so that there is ample opportunity for the veterinary technology students to read the information.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4830, 4841.5, 4843 and 4853, Business and Professions Code.

§ 2065.5. School or Degree Program Approval.

(a) A school or degree program seeking board approval of its registered veterinary technician curriculum and facilities shall submit an application to the board on a form provided by the board.
(b) When the application for approval or re-approval of a registered veterinary technician curriculum includes an onsite inspection by the board or its designee, the school or degree program shall pay for the board's actual costs associated with conducting the onsite inspection, including, but not limited to, the inspection team's travel, food and lodging expenses.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5, 4842.5 and 4843, Business and Professions Code.

§ 2065.6. School and Degree Program Approval Process

The following procedures shall be applicable to a school or degree program applying to the board for initial approval of its registered veterinary technician curriculum in accordance with section 2065 of these rules:
(a) The board shall conduct a qualitative review and assessment of the school's or degree program's registered veterinary technician curriculum through a comprehensive onsite review process, performed by an inspection team impaneled by the board for that purpose.
(b) After reviewing the inspection team's evaluation report and recommendations, the board shall take one of the following actions:
(1) Grant provisional approval for a period not to exceed two years. An additional two-year provisional approval may be granted by the board for good cause.
(2) Disapprove the application.
(c) For a school or degree program that does not have AVMA accreditation, but offers a registered veterinary technician curriculum in accordance with section 2065, the board shall not grant full approval until the curriculum has been in operation under provisional approval for at

least two years and the board has determined that the curriculum is in full compliance with the provisions of section 2065.
(d) For a school or degree program that has AVMA accreditation, if the board grants approval, it shall be full approval.
(e) For a school or degree program that has provisional or probationary AVMA accreditation, the board shall grant provisional approval on the same terms as all other schools or degree programs until such time as the AVMA grants full accreditation, at which time the board may grant the school or degree program full approval subject to compliance with section 2064.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.7. Inspections

(a) Where either provisional or full approval has been granted, the board shall conduct subsequent inspections every 4 years, notwithstanding other provisions of this section.
(b) The board may conduct an on-site inspection of a school or degree program which offers a registered veterinary technician curriculum in accordance with section 2065 where:
(1) It believes the school or degree program has substantially deviated from the standards for approval,
(2) For a period of two years the approved school's or degree program's yearly average pass rate on the registration examination falls below 10 percentage points of the state average pass rate for first time candidates for the registered veterinary technician examination.
(3) There has been change of director in charge of the curriculum for training registered veterinary technicians.
(c) Schools and degree programs accreditated by the American Veterinary Medical Association shall be exempt from the initial inspection. Inspections conducted for re-approval of such schools or degree programs shall be at the discretion of the board.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.8. Probation

(a) The board may place a school or degree program on probation for a prescribed period of time not to exceed 2 years, in the following circumstances:
(1) The board determines that an approved school or degree program is not maintaining the standards for approval required by the board.
(2) For a period of two years the approved school's or degree program's yearly average pass rate for the first time candidates who have taken the registration examination falls below 10 percentage points of the state average pass rate for first time candidates who have taken the registered veterinary technician examination during the same time period.
(3) The use of false or misleading advertising.
(4) Aiding or abetting in any acts that are in violation of any of the provisions of this division or any provision of the Veterinary Medicine Practice Act.

(b) During the period of probation, the school or degree program shall be subject to special monitoring. The conditions for probation may include the submission of periodic reports as prescribed by the board and special visits by authorized representatives of the board to determine progress toward total compliance.
(c) The board may extend the probationary period for good cause.
(d) The school or degree program shall notify in writing all current and prospective students and employees of the probationary status.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.8.1. Withdrawal of Approval

The board may withdraw its approval of any school or degree program in the following circumstances:
(a) The employment of fraud, misrepresentation, or deception in obtaining approval.
(b) If, at the end of a probationary period, the school or degree program has not eliminated the cause or causes for its probation to the satisfaction of the board.
(c) The board determines that the school or degree program has engaged in activities that are a danger to the health and safety of its students, staff, or animals.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.8.2. Procedures for Probation or Withdrawal of Approval

Prior to taking any action to place a school or degree program on probation or withdrawing of the board's approval, the board shall provide the school or degree program due notice and an opportunity to be heard.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.8.3. Director Notification

(a) Every approved school or degree program shall be required to notify the board in writing of the departure of the director or interim director within 15 working days, and shall notify the board in writing of the appointment of any director or interim director within 15 working days.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2065.9. Reporting

Every school or degree program shall be required to submit to the board within sixty (60) days after the close of the school's or degree program's fiscal year a current course catalog with a letter outlining the following:
(1) Any courses added/deleted or significantly changed from the previous year's curriculum;
(2) Any changes in faculty, administration, or governing body; and
(3) Any major change in the school's or degree program's facility.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2066. Out of State Schools.

(a) Candidates who have completed a course of study at a school or a degree program located outside of California and accredited by the AVMA shall be deemed to have completed the equivalent of a two-year curriculum in veterinary technology.
(b) Candidates seeking to apply to the board to take the exam in accordance with section 2010 and who have obtained their minimum educational requirements from a school or degree program located outside of California and not approved by the board shall demonstrate to the board, (1) that the education they have received is equivalent to educational requirements of section 2065(a) and (b), and, (2) that the school or degree program has been approved by a licensing body in the U.S. state, Canadian province or U.S. or Canadian territory. The burden to demonstrate educational equivalency is upon the candidate.

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

§ 2066.1 Unapproved In-State Schools

No candidate who has completed his or her course of study at a school or degree program located within the state that has not sought and been granted board approval shall be permitted to take either the national or state Veterinary Technician exams unless that candidate also meets the requirements of section 2068.5

Note: Authority cited: Section 4808, Business and Professions Code. Reference: Sections 4841.5 and 4843, Business and Professions Code.

Legislation

A. SB 361 (HILL) – ANTI-MICROBIAL STEWARDSHIP: EDUCATION AND POLICIES

CHAPTERED: 10/10/15 **STATUS:** Approved by Governor 10/10/15. Filed with Secretary of State 10/10/15.

BOARD POSITION: Support

Under the Veterinary Medicine Practice Act, the Veterinary Medical Board licenses veterinarians and regulates the practice of veterinary medicine. The act requires an applicant for a renewal license to complete 36 hours of continuing education in the preceding 2 years.

This bill would require a veterinarian who renews his or her license on or after January 1, 2018, to complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs, as defined, every 4 years as part of the continuing education requirement.

Existing law provides for the licensure and regulation of skilled nursing facilities by the State Department of Public Health. Under existing law, a violation of the provisions governing skilled nursing facilities constitutes a crime. Existing law also establishes the Hospital Infectious Disease Control Program, which requires the department and general acute care hospitals to implement various measures relating to the prevention of health care associated infection. The program requires, by July 1, 2015, that each general acute care hospital adopt and implement an antimicrobial stewardship policy, in accordance with guidelines established by the federal government and professional organizations, that includes a process to evaluate the judicious use of antibiotics, as specified.

This bill would require all skilled nursing facilities, as defined, by no later than January 1, 2017, to adopt and implement an antimicrobial stewardship policy that is consistent with the antimicrobial stewardship guidelines developed by the federal Centers for Disease Control and Prevention, the federal Centers for Medicare and Medicaid Services, or specified professional organizations.

By expanding the scope of an existing crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

B. AB 192 (ALLEN) – SPECIALIZED LICENSE PLATES

CHAPTERED: 10/5/15 **STATUS:** Approved by Governor 10/5/15. Filed with Secretary of State 10/5/15.

BOARD POSITION: Watch/No Position Taken

Existing law establishes a specialized license plate program and requires the Department of Motor Vehicles (DMV) to issue specialized license plates on behalf of a sponsoring state agency that meets certain requirements. Existing law requires that the DMV charge specified additional fees for the issuance, renewal, or transfer of specialized license plates, and requires the DMV to deposit the fees, less the DMV's costs, into the Specialized License Plate Fund. Existing law requires that moneys in the fund be allocated, upon appropriation by the Legislature, to each sponsoring agency in proportion to the amount that is attributable to the agency's specialized license plate program. Existing law authorizes the sponsoring state agency to use these moneys to fund projects and programs that promote the state agency's official policy, mission, or work.

The bill would require the DMV to deposit fees for the issuance, renewal, or transfer of the Pet Lover's specialized license plates, less the DMV's costs, into the Pet Lover's Fund, which the bill would establish in the Specialized License Plate Fund, for the deposit of revenue derived from these specialized license plates. The bill would require that these funds be allocated, upon appropriation by the Legislature, to the Veterinary Medical Board for disbursement by a nonprofit organization selected by the board to fund grants to providers of no-cost or low-cost animal sterilization services. The bill would require the board to determine eligibility requirements for the grants, establish the grant application process, and develop program specifics. The bill would authorize the board to contract with an entity, including a nonprofit organization, to provide advice, consultation, and administrative services for purposes of implementing and administering the grant program. The bill would require the board to provide oversight for the disbursal of grant funds under the grant program.

STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.
LEGAL AFFAIRS DIVISION
1625 N. Market Blvd., Suite S 309, Sacramento, CA 95834
P (916) 574-8220 F (916) 574-8623 | www.dca.ca.gov

MEMORANDUM

DATE	January 6, 2016
TO	Members, California Veterinary Board
FROM	**Kurt Heppler, Supervising Attorney** **Legal Affairs Division**
SUBJECT	**Assembly Bill 192; Implementation of the Pet Lover's Program**

This memo provides important information regarding the implementation of Assembly Bill (AB 192) [ch. 497, stats. 2015], which added section 5168 to the Vehicle Code (section 5168). AB 192 was enacted to provide an expenditure framework for the monies accrued in the Pet Lover's Fund (Fund) as a result funds generated by the purchase of spay-and-neuter specialized motor vehicle license plates from the Department of Motor Vehicles. At this time, the Fund contains more than $500,000 and the 7,500 license plate sales threshold has been reached.

As the provisions of section 5168 become operational January 1, 2016, and upon the appropriation of the monies in the Fund by the Legislature, the Veterinary Medical Board (VMB), as the sponsoring agency, is now responsible for the following obligations:

1) Allocating the accrued monies to a nonprofit organization for disbursement to spay and neuter facilities to fund grants to low or no cost providers of sterilization services as part of the Pet Lover's Program (Program).
2) Determining the eligibility requirements for the grants, establishing the process, and developing programing specifics.
3) Establishing oversight mechanisms for the funds disbursed.

AB 192 also contains two other crucial elements:

1) A cap on the costs associated with the Program, as follows:
   a. The nonprofit agency selected by VMB to disburse the Fund may not use more than five percent of the monies received into Fund for administrative costs.
   b. The annual administrative cost of the Program may not exceed 25 percent of the funds collected from the issuance of the Pat Lover's license plate.

2) A provision that the VMB may contract with an entity, including a nonprofit organization, to provide consultation, advice, and administrative services to the Board regarding this program. As these services would assist VMB with the administration of the Program, any contract costs would subject to the 25 percent cap.

Obligation Number 1 – Selection of the Nonprofit Agency

With respect to the disbursement of the funds to a non-profit entity, VMB simply cannot choose an entity without some sort of competitive selection process. As mentioned above, the maximum payment available to the entity to disburse the funds is five percent of the monies received. As there may be entities that could or would provide disbursement services for less than the cap, the VMB will have to use a competitive bid process to select the entity. VMB may want to establish criteria for an entity desiring to participate in the bidding process, and the established criteria would need to include the elements necessary to prevent any conflicts of interest. Additionally, VMB would want to bind this entity to a contract that includes, among other things, provisions to safeguard monies and report on its disbursement activity.

Consistent with provisions of section 156 of the Business and Professions Code and Department of Consumer Affairs (DCA) policy, VMB may wish to direct its staff to work with the DCA Contracts Unit to develop a solicitation document and administer the competitive bidding process. Please note that VMB members would not be evaluating the bids; rather, that function would be performed by DCA staff.

Obligation Number 2 – Program Process and Specifics

With respect to the grant process program specifics and eligibility requirements, it must be noted a considerable amount of work is necessary. In recognition of VMB's staff resource limitations but mindful of section 5168's cap on administrative costs, VMB may want to consider contracting out for the development of a 'cradle to grave' analysis of the processes necessary to implement the Program. Of course, any contract issued by the Department on behalf of VMB would necessarily be the product of a competitive bid process.

Alternatively, VMB may not wish to incur these administrative costs and maximize the funds available by having its staff, using existing examples of specialized licensed programs, develop guidelines for the Program. Such guidelines would include details such as the application form, application due date, duration and maximum amount of grant, periodic payment schedules, evaluation and reimbursement criteria, reporting requirements, and other items necessary for the administration of the Program. Once staff developed the guidelines, they would be brought before VMB for approval.

An option for VMB to consider is contracting for combination of the disbursement or administrative services. This option entails by having a single contractor, after a contract is executed, that will accept the grant proposals, evaluate them against the established guidelines and then prepare a recommendation for the VMB to consider at a duly-noticed meeting. In other words, the selected contractor would analyze and essentially rate the grant applications, and upon approval by VMB, disburse the funds to the applicant. Under this option, VMB would retain the authority to make the grant decision itself.

Obligation Number 3-Oversight

As to oversight, VMB needs to consider what type of audit capacity or capability is needed to ensure the proper level of accountability for all persons and entities associated with these funds. Please note that section 5168 does not specifically authorize VMB to contract out for oversight services, and, accordingly, VMB may elect to keep the performance of the oversight in-house by using its own staff or seeking the assistance of DCA auditors.

A substantial amount of oversight may be established in the guidelines. For example, the guidelines could require that any licensee who elects to participate in the Program shall make the records of the sterilization services readily available to VMB upon request. Additionally, the guidelines may require that the premises where the Program services are performed be open and available for inspection whenever an animal sterilization is performed. These same openness and transparency components may also be a requirement of the entity selected by VMB to provide administrative and disbursement services.

Pease contact me if you have any questions.

Assembly Bill No. 192

CHAPTER 497

An act to add Section 5168 to the Vehicle Code, relating to license plates.

[Approved by Governor October 5, 2015. Filed with
Secretary of State October 5, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 192, Travis Allen. Specialized license plates.

Existing law establishes a specialized license plate program and requires the Department of Motor Vehicles (DMV) to issue specialized license plates on behalf of a sponsoring state agency that meets certain requirements. Existing law requires that the DMV charge specified additional fees for the issuance, renewal, or transfer of specialized license plates, and requires the DMV to deposit the fees, less the DMV's costs, into the Specialized License Plate Fund. Existing law requires that moneys in the fund be allocated, upon appropriation by the Legislature, to each sponsoring agency in proportion to the amount that is attributable to the agency's specialized license plate program. Existing law authorizes the sponsoring state agency to use these moneys to fund projects and programs that promote the state agency's official policy, mission, or work.

The bill would require the DMV to deposit fees for the issuance, renewal, or transfer of the Pet Lover's specialized license plates, less the DMV's costs, into the Pet Lover's Fund, which the bill would establish in the Specialized License Plate Fund, for the deposit of revenue derived from these specialized license plates. The bill would require that these funds be allocated, upon appropriation by the Legislature, to the Veterinary Medical Board for disbursement by a nonprofit organization selected by the board to fund grants to providers of no-cost or low-cost animal sterilization services. The bill would require the board to determine eligibility requirements for the grants, establish the grant application process, and develop program specifics. The bill would authorize the board to contract with an entity, including a nonprofit organization, to provide advice, consultation, and administrative services for purposes of implementing and administering the grant program. The bill would require the board to provide oversight for the disbursal of grant funds under the grant program.

The people of the State of California do enact as follows:

SECTION 1. Section 5168 is added to the Vehicle Code, to read:

5168. (a) The fees specified in Section 5157 shall be imposed for the issuance, renewal, or transfer of the Pet Lover's specialized license plates.

Notwithstanding subdivision (c) of Section 5157, after deducting its administrative costs, the department shall deposit the revenue derived from the additional fees into the Pet Lover's Fund, which is hereby established in the Specialized License Plate Fund.

(b) Upon appropriation by the Legislature, the moneys in the Pet Lover's Fund shall be allocated to the Veterinary Medical Board. There shall not be an allocation to the board pursuant to subdivision (c) of Section 5157. The board shall allocate those funds to a nonprofit organization it selects for disbursal to qualifying spay and neuter facilities for the sole and exclusive purpose of funding grants to providers of no-cost or low-cost animal sterilization services.

(c) Annual administrative costs for the program shall not exceed 25 percent of the funds collected from the issuance of the Pet Lover's license plates, and may include marketing and other promotional activities associated with encouraging application for or renewal of Pet Lover's license plates.

(d) The nonprofit organization selected by the board shall not use more than 5 percent of the moneys received pursuant to this section for administrative costs.

(e) The board shall determine eligibility requirements for the grants, establish the grant application process, and develop program specifics. The board may contract with an entity, including a nonprofit organization, to provide advice, consultation, and administrative services for purposes of implementing and administering the grant program. The board shall provide oversight for the disbursal of grant funds under the grant program.

O

Senate Bill No. 361

CHAPTER 764

An act to amend Section 4846.5 of the Business and Professions Code, and to add Section 1275.4 to the Health and Safety Code, relating to public health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 10, 2015. Filed with Secretary of State October 10, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

SB 361, Hill. Antimicrobial stewardship: education and policies.

Under the Veterinary Medicine Practice Act, the Veterinary Medical Board licenses veterinarians and regulates the practice of veterinary medicine. The act requires an applicant for a renewal license to complete 36 hours of continuing education in the preceding 2 years.

This bill would require a veterinarian who renews his or her license on or after January 1, 2018, to complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs, as defined, every 4 years as part of the continuing education requirement.

Existing law provides for the licensure and regulation of skilled nursing facilities by the State Department of Public Health. Under existing law, a violation of the provisions governing skilled nursing facilities constitutes a crime. Existing law also establishes the Hospital Infectious Disease Control Program, which requires the department and general acute care hospitals to implement various measures relating to the prevention of health care associated infection. The program requires, by July 1, 2015, that each general acute care hospital adopt and implement an antimicrobial stewardship policy, in accordance with guidelines established by the federal government and professional organizations, that includes a process to evaluate the judicious use of antibiotics, as specified.

This bill would require all skilled nursing facilities, as defined, by no later than January 1, 2017, to adopt and implement an antimicrobial stewardship policy that is consistent with the antimicrobial stewardship guidelines developed by the federal Centers for Disease Control and Prevention, the federal Centers for Medicare and Medicaid Services, or specified professional organizations.

By expanding the scope of an existing crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

The people of the State of California do enact as follows:

SECTION 1. Section 4846.5 of the Business and Professions Code is amended to read:

4846.5. (a) Except as provided in this section, the board shall issue renewal licenses only to those applicants that have completed a minimum of 36 hours of continuing education in the preceding two years.

(b) (1) Notwithstanding any other law, continuing education hours shall be earned by attending courses relevant to veterinary medicine and sponsored or cosponsored by any of the following:

(A) American Veterinary Medical Association (AVMA) accredited veterinary medical colleges.

(B) Accredited colleges or universities offering programs relevant to veterinary medicine.

(C) The American Veterinary Medical Association.

(D) American Veterinary Medical Association recognized specialty or affiliated allied groups.

(E) American Veterinary Medical Association's affiliated state veterinary medical associations.

(F) Nonprofit annual conferences established in conjunction with state veterinary medical associations.

(G) Educational organizations affiliated with the American Veterinary Medical Association or its state affiliated veterinary medical associations.

(H) Local veterinary medical associations affiliated with the California Veterinary Medical Association.

(I) Federal, state, or local government agencies.

(J) Providers accredited by the Accreditation Council for Continuing Medical Education (ACCME) or approved by the American Medical Association (AMA), providers recognized by the American Dental Association Continuing Education Recognition Program (ADA CERP), and AMA or ADA affiliated state, local, and specialty organizations.

(2) Continuing education credits shall be granted to those veterinarians taking self-study courses, which may include, but are not limited to, reading journals, viewing video recordings, or listening to audio recordings. The taking of these courses shall be limited to no more than six hours biennially.

(3) The board may approve other continuing veterinary medical education providers not specified in paragraph (1).

(A) The board has the authority to recognize national continuing education approval bodies for the purpose of approving continuing education providers not specified in paragraph (1).

(B) Applicants seeking continuing education provider approval shall have the option of applying to the board or to a board-recognized national approval body.

(4) For good cause, the board may adopt an order specifying, on a prospective basis, that a provider of continuing veterinary medical education authorized pursuant to paragraph (1) or (3) is no longer an acceptable provider.

(5) Continuing education hours earned by attending courses sponsored or cosponsored by those entities listed in paragraph (1) between January 1, 2000, and January 1, 2001, shall be credited toward a veterinarian's continuing education requirement under this section.

(c) Every person renewing his or her license issued pursuant to Section 4846.4, or any person applying for relicensure or for reinstatement of his or her license to active status, shall submit proof of compliance with this section to the board certifying that he or she is in compliance with this section. Any false statement submitted pursuant to this section shall be a violation subject to Section 4831.

(d) This section shall not apply to a veterinarian's first license renewal. This section shall apply only to second and subsequent license renewals granted on or after January 1, 2002.

(e) The board shall have the right to audit the records of all applicants to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a period of four years and shall make these records available to the board for auditing purposes upon request. If the board, during this audit, questions whether any course reported by the veterinarian satisfies the continuing education requirement, the veterinarian shall provide information to the board concerning the content of the course; the name of its sponsor and cosponsor, if any; and specify the specific curricula that was of benefit to the veterinarian.

(f) A veterinarian desiring an inactive license or to restore an inactive license under Section 701 shall submit an application on a form provided by the board. In order to restore an inactive license to active status, the veterinarian shall have completed a minimum of 36 hours of continuing education within the last two years preceding application. The inactive license status of a veterinarian shall not deprive the board of its authority to institute or continue a disciplinary action against a licensee.

(g) Knowing misrepresentation of compliance with this article by a veterinarian constitutes unprofessional conduct and grounds for disciplinary action or for the issuance of a citation and the imposition of a civil penalty pursuant to Section 4883.

(h) The board, in its discretion, may exempt from the continuing education requirement any veterinarian who for reasons of health, military service, or undue hardship cannot meet those requirements. Applications for waivers shall be submitted on a form provided by the board.

(i) The administration of this section may be funded through professional license and continuing education provider fees. The fees related to the

administration of this section shall not exceed the costs of administering the corresponding provisions of this section.

(j) For those continuing education providers not listed in paragraph (1) of subdivision (b), the board or its recognized national approval agent shall establish criteria by which a provider of continuing education shall be approved. The board shall initially review and approve these criteria and may review the criteria as needed. The board or its recognized agent shall monitor, maintain, and manage related records and data. The board may impose an application fee, not to exceed two hundred dollars ($200) biennially, for continuing education providers not listed in paragraph (1) of subdivision (b).

(k) (1) On or after January 1, 2018, a licensed veterinarian who renews his or her license shall complete a minimum of one credit hour of continuing education on the judicious use of medically important antimicrobial drugs every four years as part of his or her continuing education requirements.

(2) For purposes of this subdivision, "medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

SEC. 2. Section 1275.4 is added to the Health and Safety Code, to read:

1275.4. (a) On or before January 1, 2017, each skilled nursing facility, as defined in subdivision (c) of Section 1250, shall adopt and implement an antimicrobial stewardship policy that is consistent with antimicrobial stewardship guidelines developed by the federal Centers for Disease Control and Prevention, the federal Centers for Medicare and Medicaid Services, the Society for Healthcare Epidemiology of America, or similar recognized professional organizations.

(b) All skilled nursing facilities, as defined in subdivision (c) of Section 1250, shall comply with this section. Failure to comply with the requirements of this section may subject the facility to the enforcement actions set forth in Section 1423.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect Californians from the burden and threats posed by the national security priority of antimicrobial-resistant infections, it is necessary that this act take effect immediately.

O

Multidisciplinary Committee Proposed Assignments

January 2016

EXISTING PRIORITIES – Currently being addressed by MDC

1) ***Animal Rehabilitation assigning task force – 5 specific content areas***

2) **Develop Language to Grant Authority for Veterinarians to Compound Drugs within FDA Guidelines**

   Met with Board of Pharmacy on Nov 12, 2015
   Language before MDC Jan 2016

3) **Evaluate Structure and Audit Enforcement Case Outcomes**
   Complaint Process/Audit Taskforce
   Subcommittee is performing in-house case audits - Report to the MDC Jan 2016.

4) **Develop minimum standards for alternate premises (large animal, equine mobile, public and private shelter medicine, ambulatory, etc.)**
   a) *CVMA Task Force held September 30, 2015*
   b) *Subcommittee on Shelter Medicine – Report to the MDC Jan 2016*
      a. *RVT protocols*
      b. *Minimum Standards*

5) **Review Business and Professions Code Section 4830(5) regarding veterinary student exemption, duties and supervision at a California veterinary university. *(Off –site surgery programs- should they be limited to 3rd/4th year students?)***

   Subcommittee drafting language – Before the MDC Jan 2016

FUTURE MDC PRIORITIES

6) **Pursue "extended duty" for Registered Veterinary Technicians.**

7) **Review standard of care for animal dentistry**

8) **Review 1st year licensure as a temporary license, working under the supervision of a currently licensed Veterinarian.**

§ 4830. Exemptions

Text

(a) This chapter does not apply to:

(1) Veterinarians while serving in any armed branch of the military service of the United States or the United States Department of Agriculture while actually engaged and employed in their official capacity.

~~(2) Regularly licensed veterinarians in actual consultation from other states.~~

(2~~3~~) Veterinarians holding a current, valid license in good standing in another state or country who provide assistance to a California licensed veterinarian and attend on a specific case. The California licensed veterinarian shall maintain a valid veterinarian-client-patient relationship. The veterinarian providing the assistance shall not establish a veterinarian-client-patient relationship with the client while attending the case or at a future time and shall not practice veterinary medicine, open an office, appoint a place to meet patients, communicate with clients who reside within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient who is located within this state.
~~Regularly licensed veterinarians actually called from other states to attend cases in this state, but who do not open an office or appoint a place to do business within this state.~~

(3) ***

(4) Veterinarians employed by the University of California while engaged in the performance of duties in connection with the College of Agriculture, the Agricultural Experiment Station, the School of Veterinary Medicine, or the agricultural extension work of the university or employed by the Western University of Health Sciences while engaged in the performance of duties in connection with the College of Veterinary Medicine or the agricultural extension work of the university.

(5) Students in the School of Veterinary Medicine of the University of California or the College of Veterinary Medicine of the Western University of Health Sciences who participate in diagnosis and treatment as part of their educational experience, including those in off-campus educational programs under the direct supervision of a licensed veterinarian in good standing, as defined in paragraph (1) of subdivision (b) of Section 4848, appointed by the University of California, Davis, or the Western University of Health Sciences.

(6) A veterinarian who is employed by the Meat and Poultry Inspection Branch of the California Department of Food and Agriculture while actually engaged and employed in his or her official capacity. A person exempt under this paragraph shall not otherwise engage in the practice of veterinary medicine unless he or she is issued a license by the board.

(7) Unlicensed personnel employed by the Department of Food and Agriculture or the United States Department of Agriculture when in the course of their duties they are directed by a veterinarian supervisor to conduct an examination, obtain biological specimens, apply biological tests, or administer medications or biological products as part of government disease or condition monitoring, investigation, control, or eradication activities.

(b) This section shall become operative on January 1, 2011.

History

Added Stats 2006 ch 823 § 2 (AB 2915), effective January 1, 2007, operative January 1, 2011.

***Need to exempt veterinarians called in per AB 316?

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Veterinary Medical Board
1747 N. Market Blvd., Ste. 230, Sacramento, CA 95834
Telephone: 916-515-5222 Fax: 916-928-6582 | www.vmb.ca.gov

MEMORANDUM

DATE	January 1, 2016
TO	MDC
FROM	Annemarie Del Mugnaio, Executive Officer DCA/Veterinary Medical Board
SUBJECT	**Compounded Medications and Veterinary Practice**

Background:

At its October 20, 2014 meeting, the MDC reviewed the issue of drug compounding by veterinarians for their animal patients. The issue, as raised by Board Counsel, was that there is no explicit grant of authority in the Veterinary Medicine Practice Act authorizing licensed veterinarians to compound drugs pursuant to federal law. Board Counsel advised that provisions for veterinarians to compound drugs for animal patients would need to be added to the veterinary medicine scope of practice. The MDC examined the lack of statutory guidance for veterinarians and ultimately recommended that the Board consider a legislative proposal to grant veterinarians the authority to compound drugs for their animal patients under the existing limitations of CFR Title 21 Part 530.13. The VMB agreed to pursue a statutory change, but ultimately referred the matter back to the MDC to work with the Board of Pharmacy and stakeholders on a statutory framework.

On November 12, 2015, an MDC Subcommittee of Dr. Klingborg and Dr. Sullivan joined me in a meeting with Virginia Herold, the Executive Officer of the Board of Pharmacy and Deputy Attorney General (DAG) Joshua Room to discuss a statutory proposal that would provide for limited drug compounding by veterinarians, and also address necessary compliance issues provided for in Pharmacy laws and regulations. At the meeting, the Subcommittee learned that the historical interpretation of CCR Section 1735.2 regarding restrictions on dispensing a 72-hour supply to a client/patient was not intended to be a dispensing restriction imposed on a veterinarian. Instead, the regulation defines a "reasonable quantity" of a compounded medication that may be furnished by a pharmacy to a veterinarian for in office use, or to dispense to their client/patient. Thus, the "reasonably quantity" is a formula used by pharmacies to supply prescribers and dispensers.

Shortly after the meeting, DAG Room prepared a draft proposal for review and consideration by the MDC (attached).

Issues:

Historically, the VMB has advised licensed veterinarians that it is only permissible to compound an oral or injectable medication if:

- There is no approved animal or human drug available that is labeled for, and in a concentration or form appropriate for, treating the condition diagnosed.

- *The compounding is performed by a licensed veterinarian within the scope of a professional practice.*
- Adequate measures are followed to ensure the safety and effectiveness of the compounded product.
- The quantity of compounding is commensurate with the established need of the identified patient.
- There is legitimate need for the drug when non-treatment would result in either suffering or death.

However, based on legal guidance, we understand that regulating drug compounding by veterinarians must be codified in statute.

The following issues must be considered in pursuing a legislative solution:

- FDA Guidance for Industry #230 Compounding Animal Drugs from Bulk Drug Substances
- The animal drugs that may or may not be available through Outsourcing Facilities & Compounding Pharmacies?
- Implementing regulations may be necessary to further address immediate use sterile injectable drugs

Attachments:

- Proposed Statutory Language – Business & Professions Code Sections 4825.1& 4826.3
- Proposed California Code of Regulations Title 16, Sections 1735-1735.8 & 1751 et seq. – Regulations Regarding Compounding
- Code of Federal Regulations Title 21, Part 530.13
- Summary of FDA Guidance #230 – AVMA
- AVMA Letter to FDA- Nov. 16, 2015 (Including attached Bulk Drug Nominations)
- UPS Comments to FDA Guidance

Action:

- Review draft statutory language as proposed and recommend action to the VMB.

Veterinary Compounding

Draft Statutory Proposal

SDAG Joshua A. Room – November 18, 2015

§ 4825.1. Definitions – ADD

(e) "Compounding," for the purposes of veterinary medicine, shall have the same meaning as that given in California Code of Regulations, title 16, section 1735, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and except that only a licensed veterinarian or a licensed RVT (following the written protocol of a licensed veterinarian) may perform compounding, and may not delegate to or supervise any part of the performance of compounding by any other person.

§ 4826.3. Veterinary Compounding

(a) Notwithstanding section 4051, a veterinarian RVT with a current and active license may compound a drug for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease of an animal, in a premises currently and actively registered with the board, only under the following conditions:

(1) Where there is no FDA-approved animal or human drug that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed;

(2) Where the compounded drug is not available from a compounding pharmacy, outsourcing facility, or other compounding supplier, in a dosage form and concentration to appropriately treat the disease, symptom, or condition for which the drug is being prescribed;

(3) Where the need and prescription for the compounded medication has arisen within an established veterinarian-client-patient relationship, as a means to treat a specific occurrence of a disease, symptom, or condition observed and diagnosed by the veterinarian in a specific animal which threatens the health of the animal or will cause suffering or death if left untreated;

(4) Where the quantity compounded does not exceed a quantity demonstrably needed to treat patients with which the veterinarian has a current veterinarian-client-patient relationship; and

(5) Except as specified in (c), where the compound is prepared only with commercially available FDA-approved animal or human drugs as active ingredients.

(b) A compounded veterinary drug may be prepared from an FDA-approved animal or human drug for extralabel use only when there is no approved animal or human drug that, when used as labeled or in an appropriate extralabel manner will, in the available dosage form and concentration, properly treat the

disease, symptom, or condition. Compounding from an approved human drug for use in food-producing animals is not permitted if an approved animal drug can be used for compounding.

(c) A compounded veterinary drug may be prepared from bulk drug substances only when:

(1) The drug is compounded and dispensed by the veterinarian to treat an individually identified animal patient under his or her care;

(2) The drug is not intended for use in food-producing animals;

(3) If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable marketed drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his or her patient;

(4) There are no FDA-approved animal or human drugs that can be used as labeled or in an appropriate extralabel manner to properly treat the disease, symptom, or condition for which the drug is being prescribed;

(5) All bulk drug substances used in compounding are manufactured by an establishment registered under 21 U.S.C. § 360 and are accompanied by a valid certificate of analysis;

(6) The drug is not sold or transferred by the veterinarian compounding the drug, except that the veterinarian shall be permitted to administer the drug to a patient under his or her care, or dispense it to the owner or caretaker of an animal under his or her care;

(7) Within fifteen (15) days of becoming aware of any product defect or serious adverse event associated with any drug compounded by the veterinarian from bulk drug substances, the veterinarian reports it to the FDA on Form FDA 1932a; and

(8) In addition to other requirements, the label of any veterinary drug compounded from bulk drug substances indicates the species of the intended animal patient, the name of the animal patient, and the name of the owner or caretaker of the patient.

(d) Each compounded veterinary drug preparation shall meet the labeling requirements of section 4076, and of California Code of Regulations, title 16, sections 1707.5 and 1735.4, except that every reference therein to “pharmacy” and “pharmacist” shall be replaced by “veterinary premises” and “veterinarian,” and any reference to “patient” shall be understood to refer to the animal patient. In addition, each label on a compounded veterinary drug preparation shall include withdrawal/holding times, if needed, and the disease, symptom, or condition for which the drug is being prescribed. Any compounded veterinary drug preparation that is intended to be sterile, including for injection, administration into the eye, or inhalation, shall in addition meet the labeling requirements of California Code of Regulations, title 16, section 1751.2, except that every reference therein to “pharmacy” and

"pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient.

(e) Any veterinarian and veterinary premises engaged in compounding shall meet the compounding requirements for pharmacies and pharmacists stated by the following sections and subdivisions of Article 4.5 of Title 16 of the California Code of Regulations, except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient:

(1) Section 1735.1;

(2) Section 1735.2, subdivisions (d), (e), (f), (g), (h), (i), (j), (k), and (l);

(3) Section 1735.3, except that only a licensed veterinarian or RVT may perform compounding, and may not delegate to or supervise any part of the performance of compounding by any other person.

(4) Section 1735.4;

(5) Section 1735.5;

(6) Section 1735.6;

(7) Section 1735.7; and

(8) Section 1735.8.

(f) Any veterinarian and veterinary premises engaged in sterile compounding shall meet the sterile compounding requirements for pharmacies and pharmacists stated by Article 7 of Title 16 of the California Code of Regulations (sections 1751 through 1751.8, inclusive), except that every reference therein to "pharmacy" and "pharmacist" shall be replaced by "veterinary premises" and "veterinarian," and any reference to "patient" shall be understood to refer to the animal patient. Section 1751.8 (e) allows a veterinarian or RVT to compound a "sterile IV product" outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for sterile compounding if the preparation is labeled "for immediate use only," and is used within one hour by the individual that has compounded the preparation.

(g) The California State Board of Pharmacy shall have authority with the Veterinary Medical Board to ensure compliance with this section, and shall have the right to inspect any veterinary premises engaged in compounding, along with or separate from the Veterinary Medical Board, to ensure compliance. The Veterinary Medical Board is specifically charged with enforcing this section with regard to its licensees.

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed language are shown by ~~double strike-through~~ for deleted language and double underline for added language. (The changes are also indicated in red font)

Changes made to the modified proposed language are shown by ~~double strike-through/bold underline~~ for deleted language and curved underline for added language. (The changes are also indicated in blue font)

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by ~~this~~ Article 4.5 (Section 1735 et seq.) apply

to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the ~~buffer area or~~ cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not ~~be begun~~ begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding~~ed~~ sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

~~(d) "Buffer area" means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials. The principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the~~

~~buffer area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.~~

~~(c)~~(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, ~~becomes~~ is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

~~(f)~~(e) "Cleanroom or clean area or buffer area" means a ~~physically separate~~ room or area ~~with walls and doors~~ with HEPA-filtered air that provides ~~at least an~~ ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a ~~A minimum differential~~ positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

~~(h)~~(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where ~~volatile~~ hazardous drugs are prepared, the exhaust air from the isolator ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be re-circulated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with

unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be re-circulated nor turbulent.

~~(i)~~(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35~~-6~~ degrees to 46~~-4~~ degrees F).

~~(j)~~(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

~~(k)~~(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(l)~~(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

~~(m)~~(l) "Daily" means occurring every day ~~that a~~ the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

~~(n)~~(m) "Displacement airflow method"~~:~~ means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the

ingredient, or for hazardous compounds.

~~(n)~~~~(o)~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient~~,~~ ~~except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit~~.

~~(a)~~~~(o)~~~~(p)~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(p)~~~~(q)~~(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

~~(q)~~~~(r)~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

~~(r)~~~~(s)~~(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

~~(b)~~~~(c)~~~~(t)~~(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions ~~after it is dispensed~~.

~~(t)~~~~(u)~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

~~(u)~~~~(v)~~(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby ~~that mimics~~ compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. ~~to demonstrate the competency of compounding personnel in aseptic techniques.~~ The media-fill test must mimic the most complex compounding procedures performed by the pharmacy ~~that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media-fill tests must be conducted on both the most routine and the most challenging compounding procedures performed~~.

~~(v)~~~~(w)~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

~~(w)~~~~(x)~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. ~~This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.~~ It does not include topical, sublingual, rectal or buccal routes of administration.

~~(x)~~~~(y)~~(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to ~~drug products~~ compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~(c)~~~~(y)~~~~(z)~~(y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range ~~may~~ shall be calculated and defined in the master formula.

~~(z)~~~~(aa)~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

~~(aa)~~~~(ab)~~(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

~~(ab)~~~~(ac)~~(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for ~~the exposure of critical sites when~~ compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic

containment isolators.

~~(ac)~~~~(ad)~~(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

~~(ad)~~~~(ae)~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

~~(d)~~~~(ae)~~~~(af)~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula ~~record~~ document.

~~(af)~~~~(ag)~~(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing ~~non-hazardous~~ of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows its meet~~ing~~ the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d) ~~(b)~~.

~~(e)~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~I~~Is ordered by the prescriber or the prescriber's agent ~~and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation,~~ using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for ~~either~~ office administration ~~or application to patients in the prescriber's office, or for distribution of not more than~~ ~~or~~ ~~furnishing of a 72-hour supply~~ ~~to the prescriber's patients, as estimated by the prescriber~~; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than ~~a 72-hour supply for human medical practices, or~~ a 120-hour

supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~the quantity provided for office use is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) ~~for~~ With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, ~~taken as a whole,~~ is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product~~ preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula ~~record~~ document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)~~(f) Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)~~(i) Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, ~~.~~ and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This "beyond use date" of the compounded drug product preparation~~ shall not exceed any of the following: ~~180 days from preparation or~~

(A) the shortest expiration date or beyond use date of any ~~component~~ ingredient in the compounded drug ~~product~~ preparation, ~~nor shall it exceed 180 days~~

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

~~from preparation~~

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be ~~using the same~~ identical ~~components~~ in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(i)~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(j)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the

pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

~~(k)~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy. ~~unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and~~

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy~~, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions~~.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.

(a) For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following: ~~The compounding document shall include the following:~~

(A) Name and Strength of the compounded drug preparation.

~~(2)~~(A)(B) The date the drug ~~product~~ preparation was compounded.

~~(3)~~(B)(C) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

~~(4)~~(C)(D) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)~~(D)(E) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)~~(E)(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(E)) are sterile ~~products~~ preparations compounded ~~on a one-time basis~~ in a single lot for administration within seventy-two (72) hours to a~~n in~~patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (~~35~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

~~(7)~~~~(F)~~(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product~~ preparation.

~~(8)~~~~(G)~~(H) The ~~expiration~~ beyond use date or beyond use date and time of the final compounded drug ~~product~~ preparation, expressed in the compounding ~~record~~ document in a standard date and time format.

~~(9)~~~~(H)~~(I) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA- registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products~~, and components~~ used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding ~~product~~ chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s)~~.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient. Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to a patient of the facility. To be treated as such, the "health care facility" must be licensed under Health and Safety Code section 1250.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a

statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration beyond use date and shall not be subject to minimum font size requirements.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain ~~a~~written policy~~y~~ies and procedures ~~manual~~ for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for

disciplinary action.

(b) The policy~~y~~ies and procedures ~~manual~~ shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures ~~manual~~ shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The policy~~y~~ies and procedures ~~manual~~ shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the~~ policy~~y~~ies or procedures ~~manual~~.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent ~~verification~~ information demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) ~~The p~~Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) ~~The p~~Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(~~4~~5) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.

(~~5~~6) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures ~~manual~~ by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures ~~manual~~ approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and

daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of ~~ed~~ compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded ~~in writing~~ in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-

contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of ~~12~~30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the [insert effective date upon adoption] amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation ~~that demonstrates~~ demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation ~~that~~ demonstrating that all personnel involved in compounding ~~was~~ are trained in all aspects of

policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the ~~sterile~~ compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Additionally, documentation demonstrating that staff have been trained on all policies and procedures shall be maintained.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled

strength, including the frequency of testing~~, analysis of compounded drug products preparations~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collated~~ maintained along with the compounding log ~~record document~~ and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy ~~or~~ and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~ preparations that is in a restricted location where traffic has no impact on the

performance of the PEC(s). The ~~buffer area or~~ cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

(1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)~~ (3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better ~~buffer area or~~ cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. ~~(A)~~ When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) ~~they~~ the sterile compounding area is ~~are~~ exempt from the room requirement listed in 1751(b)(3).

~~(7)~~ (4) There shall be a refrigerator and, ~~/or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; Sections 1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, any pharmacy engaged in any compounding of ~~for~~ sterile drug ~~products~~ preparations ~~compounded from one or more non-sterile~~ ~~ingredients~~, shall ~~make and~~ ~~keep~~ maintain the following records, which must be ~~must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile ~~product~~ drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable ~~volumetric~~ air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

~~(2)~~ ~~(5)~~(6) Documents indicating daily ~~recordation~~ documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

~~(3)~~ ~~(6)~~(7) Certification(s) of the sterile compounding environment(s).

~~(7)~~(8) Documents indicating daily documentation ~~recordation~~ of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

~~(4)~~ ~~(9)~~(9) Other facility quality control ~~logs~~ records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

~~(5)~~ ~~(9)~~(10) Logs or other documentation of ~~I~~inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

~~(6)~~ ~~(10)~~(11) Preparation records including the master formula document ~~work sheet~~, the preparation compounding log ~~document~~~~work sheet~~, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, ~~and~~ license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only

recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which~~ that compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the label~~s~~ for each such ~~those products~~ preparation:

(a) The ~~T~~telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile ~~injectable~~ drug ~~products~~ preparations ~~dispensed~~ administered ~~for~~ to inpatients ~~of a~~ within the hospital ~~pharmacy~~.

~~(b) Name (brand or generic) and concentration strength, volume, or weight of each active ingredients contained in the sterile injectable drug product preparation.~~

(~~c~~b) Instructions for storage, ~~and~~ handling, and administration.

(~~d~~c) All ~~cytotoxic~~ hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "~~Cytotoxic~~ Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling~~.~~ and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

~~(8)~~(9) Facility management including certification and maintenance of controlled environments and related equipment.

~~(9)~~(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

~~(10)~~(11) Hand hygiene and garbing.

~~(11)~~(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

~~(12)~~(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations. ~~Media-fill testing procedure~~.

~~(13)~~(14) Orientation, training, and competency evaluation of staff in all aspects of the

preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

~~(14)~~(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

~~(15)~~(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(16)~~(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(17)~~(18) Proper use of equipment and supplies.

~~(18)~~(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

~~(19)~~(20) Record keeping requirements.

~~(20)~~(21) Temperature monitoring in compounding and controlled storage areas.

~~(21)~~(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

~~(22)~~(23) Use of automated compounding devices (if applicable).

~~(23)~~(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products~~ preparations ~~shall maintain a written policyies and procedures manual for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action, that includes, i~~In addition to the elements required by section 1735.5, ~~written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds~~ drug preparations.

~~(2) Labeling of the sterile injectable product~~ compounded drug preparations ~~based on the~~

~~intended route of administration and recommended rate of administration.~~

~~(3) Proper use of E equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable drug products Hand hygiene and garbing.~~

~~(5) Procedures for handling cytotoxic agents Media-fill testing procedure.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(8) Compounded sterile drug preparation stability and beyond-use dating.~~

~~(9) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(10) Use of automated compounding devices (if applicable).~~

~~(11) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.~~

~~(12) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.~~

~~(13) Airflow considerations and pressure differential monitoring.~~

~~(14) Cleaning and maintenance of ISO environments and segregated compounding areas.~~

~~(15) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.~~

~~(16) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.~~

~~(17) Temperature monitoring in compounding and controlled storage areas.~~

~~(18) Facility management including certification and maintenance of controlled environments and related equipment.~~

~~(19) Action levels for colony forming units (CFUs) detected during viable surface testing, sampling, glove fingertip, and volumetric viable air sampling.~~

~~(b)(20) The determination and approval by a pharmacist of~~ The ingredients and the ~~compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c)(21)~~ ~~Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues.~~ ~~Procedures for handling, compounding and disposal of hazardous agents.~~ ~~The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(22) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(23) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.~~

(b) For lot compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula~~s~~ documents and compounding logs ~~documents work sheets~~.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ for compounding that includes, in addition to the elements required by section 1735.5, ~~and~~ 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen s~~S~~terilization methods ~~and shall include sterilization method suitability testing for each master formula document~~.

(2) End-product evaluation, quantitative, and qualitative testing.

(d)~~(1) All written p~~Policies and procedures ~~manuals and materials~~ shall be immediately available to all personnel involved in ~~these~~ compounding activities and to board inspectors.

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding

sterile ~~injectable products~~ drug preparations. ~~, and any~~ All personal involved must read all additions, revisions, and deletions to the written policies and procedures ~~must be communicated to all personnel involved in sterile compounding~~. ~~This~~ Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable~~ drug ~~product~~ preparation shall be compounded if it is known, or

reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable~~ drug ~~products~~ preparations.

(b) During the compounding of ~~preparation of~~ sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) ~~Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:~~ Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently ~~(at least every 30 minutes)~~, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or ~~B~~before ~~and after~~ each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) (e) Exterior workbench surfaces and other hard surfaces in the designated area, such as~~

~~walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.~~

~~(e)~~ (f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13~~1~~, Revised ~~January 31, 2012~~May 20, 2015). Certification records must be retained for at least 3 years. Unidirectional ~~C~~compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 ~~buffer area or~~ cleanroom if the isolator is certified to meet~~s~~ the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators ~~or compounding aseptic containment isolators~~ that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 ~~buffer area~~ cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the

California Code of Regulations.

(g) Pharmacies preparing ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented.The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-1~~3~~1, Revised ~~January 31, 2012~~May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur~~, complete with~~. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and ~~two layers of gloves with the outermost glove tested to meet~~ two pairs of sterile ASTM D6978-05 standard gloves. ~~Where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply.~~

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before

compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

~~(i)~~(j) Viable surface sampling shall be done at least ~~quarterly~~ every six months for all sterile-to-sterile compounding and ~~monthly~~ quarterly for all non-sterile-to-sterile compounding. ~~Volumetric~~ Viable air sampling shall be done by ~~impaction~~ volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and ~~volumetric~~ viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable s~~S~~urface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

~~(j)~~(k) The sterile compounding area ~~is~~in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-2~~3~~4 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times~~, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing is not required~~. For hazardous compounding double shoe covers are required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3)~~ (4) Compounding personnel shall not wear any wrist, ~~H~~hand, finger, ~~and~~ or ~~wrist~~ other visible ~~jewelry or piercing must be eliminated~~ jewelry, piercing, headphones, earbuds, or personal electronic device. ~~If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.~~

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ Sterile gloves that have been tested for

compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or ~~buffer area or~~ cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). ~~Exceptions are as listed in 1751.4(g).~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ **Sterile Compounding Consultation; Training of Sterile Compounding Staff**.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and

demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.

(e) Pharmacies that compound sterile drug ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures ~~using media-fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount or greater of volume transferred during the selected manipulations~~.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performs by the

individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media-fill~~

~~tests complete a validation process on technique before being allowed to prepare sterile injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media-fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media-fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media-fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented~~.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, ~~all compounding personnel~~ each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months

for personnel compounding products from non-sterile ingredients.

~~(c)~~ (e)(1) Batch-produced sterile ~~injectable~~ drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), ~~non-sterile-to-sterile batch drug preparations~~ shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogen~~,~~ per USP chapter 85 limits~~,~~ before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are ~~non-injectable~~ topical ophthalmic and inhalation preparation.

(~~1~~2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.~~

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation ~~the expiration date or beyond use date provided by the manufacturer for any component in the preparation~~, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify ~~a more~~ an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and

not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: ~~including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives.~~

~~For the purposes of this subdivision, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation,~~

~~transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.~~

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use"

preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 ~~buffer area or~~ cleanroom, with an ante-area. ~~(1)~~ Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times

when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policyies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an

inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container. (h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

CODE OF FEDERAL REGULATIONS:

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER E--ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 530 EXTRALABEL DRUG USE IN ANIMALS

Sec. 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.

(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:

(1) All relevant portions of this part have been complied with;

(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;

(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;

(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

(5) The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and

(6) All relevant State laws relating to the compounding of drugs for use in animals are followed.

(c) Guidance on the subject of compounding may be found in guidance documents issued by FDA.

FDA Proposed Guidance Document
Compounding Animal Drugs from Bulk Drug Substances
May 19, 2015

Overview

Current law does not permit compounding of animal drugs from bulk drug substances, but the Food and Drug Administration recognizes that there are limited circumstances when an animal drug compounded from bulk drug substances may be an appropriate treatment option. According to the FDA, a "bulk drug substance" applies to "any substance that is represented for use in a drug and that, when used in manufacturing, processing or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug."

On May 19, 2015, the FDA released a draft guidance document that proposes a new enforcement policy related to the compounding of veterinary preparations using bulk ingredients. This draft document, FDA's Guidance for Industry #230, "Compounding Animal Drugs from Bulk Drug Substances," outlines specific conditions under which the agency generally does not intend to take action against state-licensed pharmacies, veterinarians, and facilities registered as outsourcing facilities when drugs are compounded for animals from bulk drug substances.

GFI #230 will not become enforceable or official until a public comment period has closed and a final version is issued. Even then, it only represents the FDA's current thinking on this topic, which the agency will use as a baseline for determining whether to pursue enforcement action against undesirable compounding activities.

The veterinary profession and other stakeholders have 90 days to review and submit comments and questions to the FDA. The comment period for feedback on the overall guidance document is scheduled to close Aug. 17. The FDA is accepting nominations of bulk drug substances which can be used by outsourcing facilities through Nov. 16.

The AVMA has prepared the following summary for you, which contains key information on GFI #230. While the AVMA prepares to file formal comments on behalf of its members, we strongly encourage you to read through the draft guidance document and consider how its contents may affect your practice and how you care for your patients. Also, please review the questions at the end of this document and be sure to share your concerns and/or comments on those via e-mail with the AVMA or directly to the FDA.

By reading through GFI #230 and submitting your comments, you have an opportunity to shape how the FDA regulates compounding from bulk ingredients in the future. If you have

Deadlines:

Aug. 17, 2015: The comment period closes for feedback on the overall guidance document.

Nov. 16, 2015: The comment period closes for nominations of bulk drug substances which can be used by outsourcing facilities on FDA's proposed list.

Web Resources:

- FDA's draft Guidance for Industry #230, "Compounding Animal Drugs from Bulk Drug Substances"
- The Federal Register notice from May 19, 2015
- Information on how to nominate bulk ingredients to the 503B outsourcing facility "positive list" of animal drugs
- AVMA's policies on compounding

American Veterinary Medical Association Governmental Relations Division
1910 Sunderland Place, NW, Washington, DC 20036-1642 / Phone: 800.321.1473

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding In a State-Licensed Pharmacy

Pages 3-5 of the Proposed Guidance Document Policy III (A) (1-11)

Highlights

- Compounding must be done by or under the direct supervision of a pharmacist.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis (COA).
- All compounding must follow the standards of USP <795> for non-sterile preparations and USP <797> for sterile preparations.
- All product defects or serious adverse events associated with a bulk-compounded veterinary preparation must be reported on Form 1932a within 15 days to the FDA.
- The preparation label must include: the name of the animal patient, the name of the owner/caretaker, and the species of the animal.
- The compounded product may not be sold or transferred by any other entity—meaning that the product cannot be wholesaled. This does not prevent a pharmacy from dispensing an order related to a patient-specific prescription.
- No compounding from bulk ingredients is permitted for food-producing animals.
- **The prescription and/or documentation from the veterinarian must have the following statement**: "This patient is not a food-producing animal."
  - "Food-producing animals" are defined as all cattle, swine, chickens, turkeys, sheep, goats, and non-ornamental fish, regardless of whether the specific animal or food from the animal is intended to be introduced into the human or animal food chain (e.g. pet pot-bellied pigs, pet chicks).
  - The definition also includes any other animal which the veterinarian designates on the prescription as a food-producing animal regardless of species (e.g. rabbits, captive elk and deer).

No Office-Use Compounding Permitted

- Compounding with bulk ingredients must be patient-specific. Dispensing to the patient is permitted only after a valid prescription has been received by the pharmacy.

Compounding "Marketed" Drugs

- If an FDA-approved animal or human drug exists, the pharmacy may compound a preparation using bulk ingredients of the same active ingredient only if there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for the individual patient as determined by the veterinarian prescribing the compounded drug.

Documentation and Mandatory Statements

- The species of the animal being treated must be documented either on the prescription or other materials and be recorded by the pharmacist.
- If an FDA-approved animal or human drug with the same active ingredients exists and the pharmacist determines that the compound cannot be made using those ingredients, the pharmacist must document the reasoning for that (e.g., sterile injectable guafenisin for equine use cannot be made from an over-the-counter cough syrup).
- **On the prescription or other documentation, the following statement must be included by the veterinarian**: "There are no FDA-approved animal or human drugs that can be used as labeled or in an extra-label manner under section 512(a)(4) or (5) and 21 CFT part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed."
- If bulk ingredients are used to prepare a compound that contains the same active ingredient as an FDA-approved animal or human drug, it must be for a specific individual animal patient under the prescribing veterinarian's care. **The prescription or documentation must be accompanied by a statement from the veterinarian stating** that the compounded preparation "produces a clinical difference for the individually identified animal patient" with an explanation of what that difference is.

Overview of FDA's Proposed Guidance for Industry #230

Bulk Ingredient Compounding By a Licensed Veterinarian

Pages 5-6 of the Proposed Guidance Document Policy III (B) (1-9)

Highlights

- Compounding must be done by the veterinarian for an individual patient under his or her care.
- No compounding for food-producing animals by a veterinarian is permitted. (See the definition above for what constitutes a food-producing animal.)
- If an FDA-approved animal or human drug exists, the veterinarian may compound a preparation with the same active ingredient as the approved product using bulk ingredients *only if there is a change made that produces a clinical difference* for that individually identified animal patient under the veterinarian's care.
- Bulk ingredient compounding is not permitted if there is any FDA-approved animal or human drug that can be used as labeled or in an extra-label manner to appropriately treat the disease, symptom or condition.
- All veterinarians engaged in compounding must follow the standards of USP <795> for non-sterile preparations and USP <797> for sterile preparations.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis.
- All product defects or serious adverse events associated with a compounded veterinary preparation from a bulk ingredient must be reported on Form 1932a within 15 days to the FDA.
- The preparation label must include the name of the animal patient, the name of the owner/caretaker, and the species of the animal.
- The veterinarian may not sell or transfer any compound prepared using bulk ingredients (e.g., to another clinic or another veterinarian). The veterinarian is permitted to use those compounds for administration to the individual animal patient or dispensing to that animal patient's owner or caretaker.

Bulk Ingredient Compounding By a 503B Outsourcing Facility

Pages 6-8 of the Proposed Guidance Document Policy III (C) (1-10)

Highlights

- Outsourcing facilities registered with the FDA are permitted to compound and distribute non-patient-specific veterinary preparations (i.e., office stock), but only using bulk drug substances which will appear on Appendix A of the guidance.
- Compounding must be done by or under the direct supervision of a pharmacist.
- Any bulk ingredient used to compound must come from an FDA-registered manufacturer and have a valid certificate of analysis.
- All compounding (sterile and non-sterile) conducted by a 503B outsourcing facility must comply with cGMP standards that the FDA is developing specifically for outsourcing.
- All product defects or serious adverse events associated with a bulk ingredient-compounded veterinary preparation must be reported on Form 1932a within 15 days to the FDA.
- No bulk ingredient-based compounding for food producing animals is permitted. **The prescription, order or other documentation from the veterinarian must have the following statement**: "This drug will not be dispensed for or administered to food-producing animals." (See for the definition above for what constitutes a food-producing animal.)
- The compounded product may not be sold or transferred by any other entity—meaning that the product cannot be wholesaled. This does not prevent an outsourcing facility from filling an order from a veterinarian (i.e., office stock) for administration of the product to a patient in his or her care.
- All drugs compounded for animals must be reported by a 503B outsourcing facility on its biannual report to the FDA. It must list: the active ingredients; bulk ingredient source; assigned National Drug Code (NDC), where available; strength per unit; dosage form; route of administration; package description; and the quantity of units produced. The report must clearly designate which products were

intended for animal use.

- **All orders from veterinarians, including prescriptions, must include a statement** confirming that the product is to be used in a manner and on a species that complies with the list of permitted bulk ingredient uses under Appendix A.

Positive List

Because Section 503B of the Drug Quality and Security Act of 2013 restricts the "what" and "when" of using a bulk ingredient by an outsourcing facility, the FDA is proposing a new process for nominating bulk substances that may be used by an outsourcing facility in compounding drugs for use in animals.

- The FDA issued a request for nominations of bulk ingredients at the same time the draft guidance document was released. The deadline for nominations is **Nov. 16, 2015**.
- Nominated bulk ingredients for animal compounding by 503B outsourcing facilities will need to provide information that shows:
  - No marketed, conditionally approved or index-listed animal drug is available to treat the specific condition.
  - No marketed, approved or human drug exists that could be used to treat the condition.
  - The drug cannot be compounded using an approved animal or human-finished manufactured drug product.
  - Use of a bulk ingredient compound is needed to prevent animal death or suffering.
  - No significant safety concerns exist that are associated with using a bulk ingredient for compounding.
- The FDA will review the nominated bulk list on a rolling basis and periodically update Appendix A. The actual frequency of the review and update timeline is not specified in the guidance document.

Labeling Requirements

- The labeling of animal drugs compounded using bulk ingredients by outsourcing facilities must include:
  - Active ingredients, inactive ingredients, dosage form, strength, flavoring (if any), directions for use, quantity/volume, lot/batch number, date of compounding, Beyond-Use-Date, name of veterinarian who ordered or prescribed the drug, address and phone number of the outsourcing facility.
- A clear statement that says, "Not for resale."
- A statement, "For use in [species, condition, and limitations]."
- The statement, "Compounded by [name of 503B outsourcing facility]."
- The statement, "Adverse events associated with this compounded drug should be reported to the FDA on Form FDA1932a."
- If the drug is being dispensed based upon the receipt of patient specific prescription, the name of the animal, the animal owner/caretaker's name, and the species must be included.

Overview of FDA's Proposed Guidance for Industry #230

Specific Veterinary-Related Questions Posed in the Guidance Notice

The FDA specifically seeks comments from the public on a number of questions, including the following:

- Should the final guidance address the issue of FDA-approved animal and human drugs that are in shortage or are otherwise unavailable? If so:
  - How should these situations be addressed in the final guidance?
  - How should the final guidance define "shortage" and "unavailable?"
  - What criteria should the FDA use to determine if an approved animal drug is in shortage or otherwise unavailable?
- Should licensed veterinarians be able to sell or transfer an animal drug compounded from bulk drug substances by a state-licensed pharmacy or an outsourcing facility to owners or caretakers of animals under the veterinarian's care?
- Is additional guidance needed to address the compounding of animal drugs from approved animal or human drugs under sections 512(a)(4) or (a)(5) of the FFDCA and 21 CFR Part 530?
- Is additional guidance needed to address the compounding of animal drugs from bulk drug substances for food-producing animals?
- Do United States Pharmacopeia and National Formulary (USP–NF) chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians?
- How should the FDA apply the condition to identify an individual patient when it is not possible to identify an individual animal (e.g., koi in a koi pond)?
- Should facilities registered as "outsourcing facilities" be able to compound animal drugs from bulk drug substances that do not appear on Appendix A for an individually identified animal patient under conditions similar to those applicable to state-licensed pharmacies?
- The FDA is proposing that licensed pharmacies and veterinarians report any product defect or serious adverse event within 15 days of becoming aware of the product defect or serious adverse event.
  - How many licensed veterinarians compound animal drugs from bulk drug substances and would potentially be reporting product defects and serious adverse events to the FDA?
  - Are veterinarians reporting the same or similar information to any state regulatory agency?
  - If so, how many reports on average does each veterinarian submit each year?
  - How should the FDA define the terms "product defect" and "serious adverse event"?
- Can the FDA achieve the same objective of identifying and tracing the source of injuries or disease associated with an animal drug compounded from bulk substance through means other than product defect and serious adverse event reporting and if so, what other means?
- Is additional guidance needed to address the repackaging of drugs for animal use?
  - How widespread is the practice of repackaging drugs for animal use?
  - What types of drugs are repackaged for animal use, and why are they repackaged?
  - Have problems been identified with repackaged drugs for animal use?

AVMA
Our Passion. Our Profession.

November 16, 2015

Dr. Neal Bataller
Center for Veterinary Medicine
Director, Division of Surveillance
FDA Center for Veterinary Medicine
7519 Standish Pl
Rockville, MD 20852

Re: Docket No. FDA-2015-N-1196 - List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Request for Nominations

Dear Dr. Bataller:

The American Veterinary Medical Association recognizes that the List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals [Docket No. FDA-2015-N-1196] proposes that outsourcing facilities compound animal drugs only from bulk drug substances that will be listed in Appendix A of the final guidance, either pursuant to a veterinarian's order or pursuant to a patient-specific prescription. We understand that when a facility registered as an outsourcing facility under section 503B of the Federal Food, Drug, & Cosmetic Act uses the listed bulk drug substances to make the specified drug products pursuant to an order from a licensed veterinarian without a prescription for an individually identified animal, the FDA does not intend to take action under sections 512(a), 501(a)(5) (21 U.S.C. 351(a)(5)), 502(f), and 501(a)(2)(B) as long as such compounding is done in accordance with any associated conditions described in GFI #230.

We continue to have reservations related to creation of a "list" of bulk drug substances, even considering that the Appendix A list is focused upon in-office use, which is a subset of wider needs to compound from bulk drug substances. In lieu of a list, the AVMA continues to believe that there are three circumstances wherein compounding from bulk drug substances may be medically necessary in nonfood animals and should be allowable within the confines of a Veterinarian-Client-Patient Relationship, specifically when:

- the approved product is not commercially available,
- the needed compounded preparation cannot be made from the approved product, or
- there is no approved product from which to compound the needed preparation.

We have a number of concerns related to the use of a list of bulk drug substances that can be used to create compounded preparations for in-office emergent needs:

- In species including, but not limited to zoo animals, laboratory animals, exotic pets, wildlife, aquaria animals, and nonfood aquacultural animals, the use of compounded preparations is unquestionably

necessary. Although significant time and resources went into the development of our nominations, the bibliographies required for each submission are lacking because of the sometimes limited numbers of studies showing safety and efficacy of the needed dosage forms across the various species and conditions seen by veterinarians. Many of the compounding needs in these species are due to requirements to limit stress in the animals, promote worker safety, and diminish the need for lethal methods of wildlife and zoo immobilization in a dangerous public setting. For example, a zoo and wildlife veterinarian's use of a consistently produced compounded immobilization preparation to dart an escaped animal is more desirable in the eyes of the public than the use of a firearm, even if the substance used to prepare the medication has been subject to only limited research studies illustrating safety and efficacy.

- How will the list be maintained in an up-to-date, clinically relevant way? We contend that the FDA should provide for an immediate, nimble mechanism to consider and allow for changes to the list. Patients in need of emergency care cannot afford to wait for a response to a citizen's petition each time a new need arises. To preserve the FDA's drug approval process, we ask that the FDA also ensure the immediate removal of a bulk drug substance when it is no longer necessary.
- The FDA's request for information on "safety concerns" of nominated bulk drug substances is difficult, if not impossible, to fulfill. Any substance can be toxic in certain scenarios (e.g., used at a toxic dose or used in a patient with an idiosyncratic response). Substances that have known, serious safety concerns in the target species have not been included in our nominations.
- We understand the FDA seeks to mirror veterinary compounding enforcement to that of human compounding. However, veterinary bulk drug substance nominations are required to illustrate needs above and beyond those required for human compounding. Specifically, veterinary compounding nominations must illustrate why immediate treatment with the compounded preparation is necessary to avoid animal suffering or death. Why is there this discrepancy? Any delay in treatment of an animal's medical condition inherently endangers animal health and welfare. We again contend that the FDA should instead use the AVMA's three circumstances for compounding from bulk drug substances, as bulleted above.

Despite our reservations related to the feasibility of a list of bulk drug substances for outsourcing facilities to prepare compounded preparations for in-office use, we are submitting nominations for the list on behalf of our members. We wish to help ensure the list is fitting with the needs of our patients as much as possible; see our attachment.

Extensive consideration was given to preparations that are compounded from bulk drug substances and needed for in-office use for emergent and urgent situations. Our list of nominations is based on existing availability of FDA-approved drug products. As we have stressed in previous communications, backorders and shortages of FDA-approved drug products make access to compounded preparations even more important. Some of these medications are needed for in-office use. How will the FDA address access to these substances during the short- and long-term breaks in availability? If the FDA mirrors the human framework by allowing outsourcing facilities to compound using substances on a shortage list, will outsourcing facilities be able to respond appropriately and in a timely fashion during these periods? As stated in our letter dated August 14, 2015, we appreciate that the use of outsourcing facilities in the preparation of office stock is intended to increase safety of compounded preparations, yet we caution that use of outsourcing facilities might have the unintended consequence that some preparations of critical importance to animal health may no longer be available because of economic or other business considerations. We contend that before any list is finalized, the FDA must engage in further discussions

with the pharmacy, veterinary, and drug manufacturing communities to determine how the Agency will address this issue.

Additionally, we recognize that food-animal compounding is not permissible within the draft Guidance For Industry #230 nor its Appendix A. We reiterate our previous request that the FDA develop a separate guidance document specific to compounding from bulk drug substances in food animals and limited to euthanasia, depopulation, and poison antidote preparations.

The AVMA, founded in 1863, is one of the oldest and largest veterinary medical organizations in the world, with more than 86,500 member veterinarians worldwide engaged in a wide variety of professional activities and dedicated to the art and science of veterinary medicine. Thank you for your time and consideration of our comments and nominations. For questions or concerns regarding the AVMA's request, please contact Dr. Lynne White-Shim at (800) 248-2862 ext. 6784 or at lwhite@avma.org and Dr. Ashley Morgan at (202) 289-3210 or at amorgan@avma.org.

Respectfully,

W. Ron DeHaven, DVM, MBA
Executive Vice President and CEO

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Amlodipine	**3,5-Pyridinedicarboxylic acid, 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-, 3-ethyl 5-methyl ester, (±)-, monobenzenesulfonate. 3-Ethyl 5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(o-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulfonate**	**1J444QC288**	USP	Neat	yes	Yes Amlodipine Oral Suspension	Gel	12.5 mg/ml	Transdermal	Feline treatment of systemic hypertension	Helms SR. Treatment of Feline Hypertension With Transdermal Amlodipine: A Pilot Study. J Amer Anim Hospital Assoc. 2007; 43:149-156.	oral dosing can be very difficult in cats
Apomorphine	**4H-Dibenzo[de,g]quinoline-10,11-diol, 5,6,6a,7-tetrahydro-6-methyl-, hydrochloride, hemihydrate, (R)-; 6a-Aporphine-10,11-diol hydrochloride hemihydrate**	**N21FAR7B4S**	USP	Neat	Yes	No	Solution	3.125-6.25 mg/ml	solution for subconjunctival administration	Canine, induction of emesis	Khan etal. Effectiveness and adverse effects of the use of apomorphine and 3% hydrogen peroxide solution to induce emesis in dogs. *J Am Vet Med Assoc* 2012;241:1179-1184.	no FDA approved injectable, capsule or powder available
Budesonide	**Pregna-1,4-diene-3,20-dione, 16,17-[1R-butylidenebis(oxy)]-11,21-dihydroxy and pregna-1,4-diene-3,20-dione,16,17-[1S-butylidenebis(oxy)]-11,21-dihydroxy; (RS)-11,16,17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with butyraldehyde**	**Q3OKS62Q6X**	USP	Neat	Yes	No	1 mg/cat	1 mg/cat	Oral capsule/tab and oral suspension,	Feline, IBD	Plumb's Veterinary Handbook, 8th Ed, 2015	No veterinary approved product, Human product is too large for most cats (FDA product 3 mg capsule - most cats need 0.5 - 2 mg)
Chloramphenicol	**Acetamide, 2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-, [R-(R*,R*)]-D-threo-()-2,2-Dichloro-N-[-hydroxy--(hydroxymethyl)-p-nitrophenethyl]acetamide**	**66974FR9Q1**	USP	Neat	Yes	No	Ophthalmic ointment or solution	1% (both solution and ointment)	Conjunctival	Equine	Limited data due to recent unavailability of commercial preparations	No opthalmic ointment or solutions available as approved product

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Amlodipine	Buoncompagni S, Bowles MH. Treatment of systemic hypertension associated with kidney disease in the dog and cat. Tierarztl Prax Ausg K Kleintiere Heimtiere 2014;42(3):194-201. Jepson RE, Syme HM, Elliott J. Plasma renin activity and aldosterone concentrations in hypertensive cats with and without azotemia and in response to treatment with amlodipine besylate. J Vet Intern Med. 2014 Jan-Feb;28(1):144-53. doi: 10.1111/jvim.12240. Epub 2013 Nov 13. Trepanier LA. Pharmacologic management of feline hyperthyroidism. Vet Clin North Am Small Anim Pract. 2007 Jul;37(4):775-88, vii. Helms SR. Treatment of feline hypertension with transdermal amlodipine: a pilot study. J Am Anim Hosp Assoc. 2007 May-Jun;43(3):149-56. Mathur S, Syme H, Brown CA, Elliot J, Moore PA, Newell MA, Munday JS, Cartier LM, Sheldon SE, Brown SA. Effects of the calcium channel antagonist amlodipine in cats with surgically induced hypertensive renal insufficiency. Am J Vet Res. 2002 Jun;63(6):833-9. Elliott J, Barber PJ, Syme HM, Rawlings JM, Markwell PJ. Feline hypertension: clinical findings and response to antihypertensive treatment in 30 cases. J Small Anim Pract. 2001 Mar;42(3):122-9. Snyder PS, Sadek D, Jones GL. Effect of amlodipine on echocardiographic variables in cats with systemic hypertension. J Vet Intern Med. 2001 Jan-Feb;15(1):52-6. Snyder PS. Amlodipine: a randomized, blinded clinical trial in 9 cats with systemic hypertension. J Vet Intern Med. 1998 May-Jun;12(3):157-62. Henik RA, Snyder PS, Volk LM. Treatment of systemic hypertension in cats with amlodipine besylate. J Am Anim Hosp Assoc. 1997 May-Jun;33(3):226-34.	The binders and excipients in amlodipine tablets occupy more space that the typical 0.1ml volume of dose that is applied. If bulk API is used then a 0.625mg dose can easily be solubilized into 0.1ml TD dose.	Less stress to patients	Emergency treatment of systemic hypertension	No known minimal safety risk to cats and horses
Apomorphine	Plumb's Veterinary Handbook, 8th Ed, 2015	There is no approved formulation for apomorphine available, Human injectable is no longer marketed.	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency emesis induction	Described in Plumb's Veterinary Handbook, 8th Ed, 2015
Budesonide	Plumb's Veterinary Handbook, 8th Ed, 2015	enteric coated beads prevent compounding, Plumb's Veterinary Handbook, 8th Ed, 2015	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency treatment of acute inflammatory gastrointestinal conditions	Known Safety information described in Plumb's Veterinary Handbook, 8th Ed, 2015
Chloramphenicol	Must be compounded, no human or animal preparation available. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268. Matthews AG. Ophthalmic antimicrobial therapy in the horse. Equine Vet Ed, 2009; 36(5): 271-280. Brooks D, Kzallberg M, Utter M, et al. Survival Methods for the Equine Practitioner in Equine Ophthalmology. AAEP Proceedings 2007; 53:374-396.	No approved ointments, solutions or sterile injectable products on the market for ophthalmic use.	No approved product available for ophthalmic use. Urgent need for emergency antimicrobial ophthalmic use in the horse. Extensive number of references citing rationale and history of past use in the horses. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268. Brooks D, Kzallberg M, Utter M, et al. Survival Methods for the Equine Practitioner in Equine Ophthalmology. AAEP Proceedings 2007; 53:374-396. Matthews AG. Ophthalmic antimicrobial therapy in the horse. Equine Vet Ed, 2009; 36(5): 271-280.	Emergency antibiotic treatment	No known minimal safety risk to horses

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Cisapride	**Benzamide, 4-amino-5-chloro-N-[1-[3-(4-fluorophenoxy)propyl]-3-methoxy-4-piperidinyl]-2-methoxy-, cis- cis-4-Amino-5-chloro-N-[1-[3-(p-fluorophenoxy)propyl]-3-methoxy-4-piperidyl]-o-anisamide**	**UVL329170W**	USP	Neat	Yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Oral suspension, IV solution. See available data in Veterinary Clinical Drug Information Monograph	See available data in Veterinary Clinical Drug Information Monograph	oral capsule/tab and oral suspension, GI motility disorders	Feline	USP Clinical Drug Information Monograph, Plumb's Veterinary Handbook, 8th Ed, 2015, Can Vet Jv.36(2); 1995 Feb, Equine Veterinary Education Volume 3, Issue 3, pages 143–145, September 1991 Volume 3, Issue 3, pages 138–142, September 1991 Volume 21, Issue S7, pages 52–55, June 1989	no FDA product available
Dexamethasone	**Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11,16)-. 9-Fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione**	**7S5I7G3JQL**	USP	Neat	yes	Yes - Veterinary Clinical Drug Information Monograph (available on AAVPT.org)	Powder	Packets of 10 mg	Oral	Equine	Detailed info on USP Clinical Drug Monograph. Willis-Goulet HS, Schmidt, BA, Nicklin CF, et al. Comparison of serum dexamethasone	Azium product off the market; dex injetable available but not useable
Dipyrone	**sodium;[(1,5-dimethyl-3-oxo-2-phenylpyrazol-4-yl)-methylamino]methanesulfonate**	VSU62Z74ON	USP	Neat	yes	No	Injectable solution	250-500 mg/dog	Subcutaneous	Canine	Shimada SG, Otterness IG, Stitt JT. A study of the mechanism of action of the mild analgesic dipyrone. Agents Actions 1994; 41: 188–192. Jasiecka A, Maslanka T, Jaroszewski JJ. Pharmacological characteristics of metamizole. Polish J Vet Sci 2014; 17:207-214. Imagawa VH, Fantoni DT, Tatarunas AC, Mastrocinque S, Almeida TF, Ferreira F, Posso IP. The use of different doses of metamizole for post-operative analgesia in dogs. Vet Anaesth Analg. 2011 Jul;38(4):385-93.	Shar Pei Fever

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Cisapride	Must be compounded, no human or animal drug available. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data. Boothe DM. Digestive drugs. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 672-744.	Must be compounded, no human or animal drug available.	Must be compounded, no human or animal drug available. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data	Emergency treatment of GI motility disorders: constipation, esophagitis, megacolon, Esophogeal reflux during surgery, Ileus in horses	Appears to be safe at recommended doses, QT issues seen in humans, not been reported in dogs or cats. See USP Clinical Drug Information Monograph for complete review of efficacy/safety data
Dexamethasone	See response in Column Q	Approved oral product no longer available	Approved oral product is no longer available.	Emergency treatment of histaminergic reactions	Detailed info on USP Clinical Drug Monograph. Willis-Goulet HS, Schmidt, BA, Nicklin CF, et al.
Dipyrone	Boothe DM. Antiinflammatory drugs. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 1045-1118. Rivas AL, et al. A primary immunodeficiency syndrome in Shar-Pei dogs. Clin Immunol Immunopathol. Mar;74(3):243-51. 1995. Zhang Y, Wang X, Baranov SV, et al. Dipyrone inhibits neuronal cell death and diminishes hypoxic/ischemic brain injury. Neurosurgery 2011; 69:942–956.	Shar Pei Fever	No approved product available. Urgent need in some Shar Pei patients.	Emergency treatment of Shar Pei Fever	No known minimal safety risk to dogs

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Doxycycline	**2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, [4S-(4,4a,5,5a,6,12a)]-, monohydrate; 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate**	**N12000U13O**	USP	Neat	yes	Yes (Vet Compounding Monograph for oral Suspension)	Reformulated capsule, pill, solution	Equine: 10 mg/kg	Oral	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015	inappropriate mg strength for equine use
Gabapentin	**Cyclohexaneacetic acid, 1-(aminomethyl)-; 1-(Aminomethyl)cyclohexaneacetic acid**	**6CW7F3G59X**	USP	Neat	yes	No	Oral suspension, capsules	100 mg/ml	Oral	Feline	Plumb's Veterinary Handbook, 8th Ed, 2015. Muller G. Compounded gabapentin suspension for lower back pain in an older cat: a case report. Int J Pharm Compd. 2010;14(3):215-7.	Smallest FDA product too high mg for most feline patients
Idoxuridine	**Uridine, 2¢-deoxy-5-iodo-; 2¢-Deoxy-5-iodouridine**	**LGP81V5245**	USP	Neat	yes	No	Ophthalmic ointment or solution	0.1%.	Ophthalmic	Feline	Maggs, DJ. Update on pathogenesis, diagnosis and treatment of feline herpesvirus type 1. Clin Techniques Small Anim Practice. 2005; 20:94-101.	Human product is only injectable; no ophthalmic producst on market
Itraconazole	**3H-1,2,4-Triazol-3-one, 4-[4-[4-[[2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-2,4-dihydro-2-(1-methylpropyl)-; (±)-1-sec-Butyl-4-[p-[4-[p-[[(2R*,4S*)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]-D2-1,2,4-triazolin-5-one**	**304NUG5GF4**	USP	Neat	yes	No	Ophthalmic ointment or solution	1%	Ophthalmic	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015. Ball MA, Rebhun WC, Trepanier L. Corneal concentrations and preliminary toxicological evaluation of an itraconazole/dimethyl sulphoxide ophthalmic	No approved products; for ophthalmic indiction is okay; would not reference any oral at all
Metronidazole benzoate	**2-(2-Methyl-5-nitroimidazol-1-yl)ethyl benzoate**	**A355C835XC**	USP	Neat	yes	Yes Metronidazole Benzoate Compounded Oral Suspension	oral suspension, tabs or capsules	80 mg/ml	oral	Canine, feline	Plumb's Veterinary Handbook, 8th Ed, 2015; Davidson, G. To benzoate or not to benzoate: Cats are the question. Int J Pharm Compounding 2001; 5: 89-90. Scorza AV, Lappin MR. Metronidazole for the treatment of feline giardiasis. J feline Med Surg 2004; 6: 157-160.	FDA tab (250) mg too high mg to split accurately for many cats that require 30-40 mg; benzoate liquid lacks bitter metallic taste of HCl salt

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Doxycycline	Davis JL, Papich MG. Antimicrobial therapy. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 514-584.	Question for Gigi: Do you think that there are enough approved strengths to compound for cats adequately instead of using bulk?	USP Compounding Monograph	Emergency antibiotic treatment	Plumb's Veterinary Handbook, 8th Ed, 2015
Gabapentin	Boothe DM. Anticonvulsants and other neurologic therapies in small animals. In: Small animal clinical pharmacology and therapeutics. 2nd ed. Saint Louis: Elsevier, 2011; 932-991. KuKanich B. Outpatient oral analgesics in dogs and cats beyond nonsteroidal antiinflammatory drugs: an evidence-based approach. Vet Clin North Am Small Anim Pract. 2013; 43(5):1109-1125.	Compounding by emptying approved capsules is inaccurate. Commercially available soutions contain xylitol, which presents safety concerns for dogs. Compounding with the bulk allows for more precise and safe dosing.	Nahata (1999) Development of two stable oral suspensions for gabapentin. Pediatric Neurol 20 (3): 195-7	emergency control of severe neuropathic pain in cats	Plumb's Veterinary Handbook, 8th Ed, 2015
Idoxuridine	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118.	Human product has been discontinued	Human product has been discontinued	Emergency treatment of viral keratitis	No known minimal safety risk to cats and horses
Itraconazole	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118. i. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268.	No approved opthalmic products	J Vet Pharmacol Ther. 1997 Apr;20(2):100-4.	Emergency treatment of fungal keratomycosis	No known minimal safety risk to horses
Metronidazole benzoate	Willard MD. Feline inflammatory bowel disease: a review. J Feline Med Surg. 1999 Sep; 1(3):155-64.	HCl product is very bitter and cannot be taste masked, benzoate salt is more palatble	Described in Plumb's Veterinary Handbook, 8th Ed, 2015	Emergency treatment of acute infectious disease	Plumb's Veterinary Handbook, 8th Ed, 2015

	Chemical grade	UNII	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format	Recognition in Pharmacopeias	Presence of USP monograph?	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)
Miconazole nitrate	**1H-Imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-, mononitrate; 1-[2,4-Dichloro--[(2,4-dichlorobenzyl)oxy]phenethyl]imidazole mononitrate**	**VW4H1CYW1K**	USP	Neat	yes	No	Miconazole in solution, Miconazole in petroleum	1%, 2%	Ophthalmic	Equine	Plumb's Veterinary Handbook, 8th Ed, 2015	Ophthalmic solution not commercially available; commercially available ones not suitable for the eye
Potassium bromide	**Potassium bromide**	**OSD78555ZM**	USP	Neat	yes	Yes (Vet Compounding Monograph for Oral Solution)	solution, capsules	250 mg/ml	oral	canine, equine	Plumb's Veterinary Handbook, 8th Ed, 2015	Not available any other way than the compounded formulation or a manufactured unapproved drug
		OSD78555ZM										

	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rationale and history of past use	Why immediate treatment is needed	Safety concerns
Miconazole nitrate	Plummer CE, Colitz CMH, Kuonen V. Ocular infections. In: Equine Infectious Diseases. 2nd ed. Saint Louis: Elsevier, 2014; 109-118. i. Labelle A. Therapy of the Eye. In: C Cole, B Bentz, L Maxwell, eds. Equine Pharmacology: Wiley Blackwell, 2015: 254-268.i.	**Solution:** Miconazole in solution is administered onto the corneal surface via a subpalpebral lavage tube. There is no approved drug available in solution format. **Ointment**: A majority of horses will not tolerate eyedrop instillation of liquids without a lavage tube; they require an ointment for topical therapy.	Ophthalmic solution not commercially available; commercially available ones not suitable for the eye	Emergency treatment of fungal keratomycosis	No known minimal safety risk to horses
Potassium bromide	March PA, Podell M, Sams RA. Pharmacokinetics and toxicity of bromide following high-dose oral potassium bromide administration in healthy Beagles. J Vet Pharmacol Therap 2002; 25:425-432. Podell M, Fenner WR. Bromide therapy in refractory canine idiopathic epilepsy. J Vet Int Med 2003; 7: 318-327. Schwartz-Porsche D, U. Jurgens. Wirksamkeit von Bromid bei den therapieresistenten Epilepsien des Hundes. Tierarztl Prax 1991; 19:395-401. Baird-Heinz, HE, Van Schoick AL, Pelsor FR, et al. A systematic review of the safety of potassium bromide in dogs. J Am Vet Med Assoc 2012; 240:705-715.Pharmacokinetics and toxicity of bromide following high-dose oral potassium bromide administration in healthy Beagles. J Vet Pharmacol Therap 2002; 25:425-432. Podell M, Fenner WR. Bromide therapy in refractory canine idiopathic epilepsy. J Vet Int Med 2003; 7: 318-327. Schwartz-Porsche D, U. Jurgens. Wirksamkeit von Bromid bei den therapieresistenten Epilepsien des Hundes. Tierarztl Prax 1991; 19:395-401. Trepanier LA, Babish JGwell PJ. Feline hypertension: clinical findings and response to antihypertensive treatment in 30 cases. J Small Anim Pract. 2001 Mar;42(3):12	No approved product available	USP Compounding Monograph	Emergency control of seizures	Plumb's Veterinary Handbook, 8th Ed, 2015

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ACTH	Acth (4-11); Cosyntropin, Corticotropin 4-11; AC1L4XVG; Acth 4-11; AR-1J3349; AM006795; (2S)-6-amino-2-[[2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-[[(2S)-2-amino-4-methylsulfanylbutanoyl]amino]-4-carboxybutanoyl]amino]-3-(4H-imidazol-4-yl)propanoyl]amino]-3-phenylpropanoyl]amino]-5-(diaminomethylideneamino)pentanoyl]amino]-3-(1H-indol-3-yl)propanoyl]amino]acetyl]amino]hexanoic acid	Corticotropin	J48AU3I790	USP (synthetic cosyntropin)	USP	neat	USP	Gel	As specified by clinician	Topical or oral	Zoo animals (sea otters) NB: this could apply to any species needing this treatment; and increasing endocrine evaluations could present this situation as a future need	see below	frequently unavailable	see below	not typical product at this time	gel - reported by front line clinicians as effecive use for species	Addisonian crises	None known	
Albuterol	Salbutamol; Albuterol; Proventil; 18559-94-9; Sultanol; Aerolin; 4-[2-(tert-butylamino)-1-hydroxyethyl]-2-(hydroxymethyl)phenol	Albuterol	021SEF3731	USP	USP	neat	USP	Solution	As specified by clinician	Inhalant or oral	Zoo animals any exotic species which presented with need of brochodilation; in particular, this product is used in nebulizing solutions with mucolytics and or antibiotics - such as for chelonians with upper respiratory disease	Mader Reptile Medicine and Surgery; Carpenter Formulary	variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline	see below	specific concentration formulation would be needed from bulk drug	solution - personal use of the product for clinical cases in nebulization	to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies when exotic species require nebulization, marked respiratory impact often is present which is a life-threatening concern; this product woudl permit a clinician to intervene and provide deeper penetration into the respiratory tree of other therapeutic agents specific to treat the issue presented.	None known	

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Atipamezole	Atipamezole; 104054-27-5; Antisedan; MPV-1248; Atipamezol [Spanish]; Atipamezolum [Latin]; 5-(2-ethyl-1,3-dihydroinden-2-yl)-1H-imidazole	Atipamezole	03N9U5JAF6	ACS	neat	No	no information	Sterile Injectable	25 mg/ml	parenteral - IV, SC, IM	any and all exotic species (such as captive and free ranging mammals, birds, reptiles and elasmobranchs) for which alpha-2 agonist anesthesia is utilized; which is considered standard of care within the zoo and wildlife community for balance anesthetic efforts, reduced quantities of more potent anesthetics, and improved quality of anesthetic episodes	Throughout JZWM, Fowler, and West, repeated documentation of the use and efficacy of the alpha-2 agonist for which this product reverses the effects - older generation of reversals are not as effective or potentially as concentrated for delivery by projectile when supplementaiton is needed.	Variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	approved formulation too dilute to use in large hoofstock	explained in other blocks	more concentrated solution is needed, so cannot use FDA-approved drug	None known	
Azaperone	Azaperone; Fluoperidol; Stresnil; Suicalm; 1649-18-9; Azaperon; 1-(4-fluorophenyl)-4-(4-pyridin-2-ylpiperazin-1-yl)butan-1-one	Azaperone	19BV78AK7W	USP	USP	neat	USP	Solution	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals, birds and reptiles and elasmobranchs	throughout JZWM, Fowler, and West, repeated documentation of the use of this product for tranquilization especially in transport situations of hoofstock and charismatic megavertebrates and acclimination of anxious species. Previously held NADA.	variable concentration of this product maximizes the flexiblity of its application throughout the exotic animal discipline	see below	Not available	explained in other blocks	tranquilization	None known	

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Buprenorphine	Buprenorphine; Buprenex; Temgesic; Subutex; Buprenorfina; Buprenorphinum;	Buprenorphine	40D3SCR4GZ	USP	USP	neat	USP	Sterile Injectable	3 mg/ml and slow release	parenteral - IV, SC, IM - generally and IM for slow release; has been used orally	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; thorughout JZWM, West, Fowler, and AAZV proceedings, this product has been idenified as useful and beneficial to multitudes of species. Article Citation: Christine M. Molter, Lorraine Barbosa, Shawn Johnson, Heather K. Knych, Sathya K. Chinnadurai, and Raymund F. Wack (2015) PHARMACOKINETICS OF A SINGLE SUBCUTANEOUS DOSE OF SUSTAINED RELEASE BUPRENORPHINE IN NORTHERN ELEPHANT SEALS (MIROUNGA ANGUSTIROSTRIS). Journal of Zoo and Wildlife Medicine: March 2015, Vol. 46, No. 1, pp. 52-61.	More concentrated solution is critical to release dart and administration volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentration formulation would be needed from bulk drug	pain management, improved animal welfare	analgesic; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies and in treatment situations, reduced handling needs by higher concentrations with smaller volumes.	None known	

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Butorphanol	Butorphanol; Butorfanol; Beforal; Moradol; Butorphanol tartrate; Levo-BC-2627;	Butorphanol	QV897JC36D	USP	USP	neat	USP	Sterile Injectable	30 and 50 mg/ml	parenteral - IV, SC, IM	Captive and free ranging mammals and birds	exceptional analgesia and part of balanced anesthetic plans; thorughout JZWM, West, Fowler, and AAZV proceedings, this product has been idenified as useful and beneficial to multitudes of species. Michele Miller, Peter Buss, Jenny Joubert, Nomkhosi Mathebula, Marius Kruger, Laura Martin, Markus Hofmeyr, and Francisco Olea-Popelka (2013) USE OF BUTORPHANOL DURING IMMOBILIZATION OF FREE-RANGING WHITE RHINOCEROS (CERATOTHERIUM SIMUM). Journal of Zoo and Wildlife Medicine: March 2013, Vol. 44, No. 1, pp. 55-61.	More concentrated solution is critical to release dart and administration volume for a variety of patients. Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	specific concentration formulation would be needed from bulk drug	Combined with potent alpha 2 for immobilization	sedation; to alleviate potentially serious captive and free-ranging wild animal health and welfare, or public safety, problems or emergencies; and in treatment situations, for analgesia, reduced handling needs by higher concentrations with smaller volumes, or less dart impact.	None known	

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Calcium edetate	EDTA; Ethylenediaminetetraacetic acid; Edetic acid; 60-00-4; Edathamil; Endrate; 2-[2-[bis(carboxymethyl)amino]ethyl-(carboxymethyl)amino]acetic acid	Calcium EDTA	9G34HU7RV0	USP	USP	neat	USP	Solution	As specified by clinician	parenteral - IV or IM	Zoo animals (raptors)- any zoo species with heavy metal poisoning - esp lead; but particularly - galliforms, raptors, penguins; additionally, wildlife rehabilitation raptors (esp concern California condors); water birds (such as loons); cranes.	Of note, publications are available in JZWM on lead intoxication in sea ducks as wildlife concern; galliforms in zoo setting (Bronx Zoo); penguins from personal experience and proceedings documentation AAZV; California condor medicine in Fowler ZAWAM and AAZV proceedings cite lead intoxication as one of primary medical concerns in free-ranging/released condors; cranes also listed in Fowler as species of major concern.	cost prohibitive human formulation that has true acquisition potential issues when emergency arises for this treatment as it is preferentially provided for humans; concentration of product can produce painful injection concerns	see below	specific concentration formulation would be needed from bulk drug	necessary product that is currently used in formulation available but needed for more species specific flexiblity in compounded form	emergency intoxications need rapid response; high profile endangered species release program	None known	
Carfentanil	methyl 4- (1-oxopropyl) phenylaminol-1-(2 phenylethyl)-4-piperidinecarboxylate-2 hydroxy-1, 2, 3-propanetricarboxylate (1:1).	Wildnil	LA9DTA2L8F	ACS	ACS	Carfentanil citrate 4.46 mg (equivalent to 3 mg Carfentanil), sodium chloride 8 mg, methyl paraben 1.8 mg, propyl paraben 0.2 mg in water for injection.	no information	Sterile Injectable	3 mg/ml	Intramuscular	Captive and free ranging mammals, birds and elasmobranchs	Common in current text books	not available	see below	not available	In published literature	anesthesia	None known	

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Cisapride	(±)-*cis* -4-amino-5-chloro-*N* -(1-[3-(4-fluorophenoxy)propyl]-3-methoxypiperidin-4-yl)-2-methoxybenzamide		UVL329170W	no information	no information	no information	no information	Suspension	Variable 1-10 mg/ml based on size of species	Oral	Zoo species: GI motility disorders	see below	Not currently commerciall y available	see below	No available FDA approved drug	Literature supports its effectiveness	Gastrointestinal motility disorders can result in death	None known	
Clotrimazole	Clotrimazole; Lotrimin; Canesten; Mycelex; Empecid; Mycosporin. 1-[(2-chlorophenyl)-diphenylmethyl]imidazole	Clotrimazole	G07GZ97H65	USP	USP	neat; 10 mg/ml in propylene glycol	USP	Nebulization	10 mg/ml	Inhalant	Zoo animals	see below	Formulation for nebulization not commerciall y available	see below	Appropriate formulation not commercially availabe.	In published literature	Birds will die quickly from respiratory aspergillosis	None known	
Dexmedetomidine	DEXMEDETOMIDINE; Dexmedetomidina; Dexmedetomidinum; MPV 1440; 113775-47-6; CHEMBL778; 5-[(1S)-1-(2,3-dimethylphenyl)ethyl]-1H-imidazole	Dexmedetomidine	67VB76HONO	USP	USP	Neat	USP	not available	not available	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	not available	None known	
Diazepam	Diazepam; Valium; Ansiolisina; Diazemuls; Apaurin; Faustan; 7-chloro-1-methyl-5-phenyl-3H-1,4-benzodiazepin-2-one	Diazepam	Q3JTX2Q7TU	USP	USP	neat	USP	not available	10 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	see below	see below	not available	not available	tranquilization	None known	
Enrofloxacin	Enrofloxacin; Baytril; 93106-60-6; Enrofloxacine; CFPQ; Bay-Vp-2674;1-cyclopropyl-7-(4-ethylpiperazin-1-yl)-6-fluoro-4-oxoquinoline-3-carboxylic acid	Enrofloxacin	3DX3XEK1BN	USP	USP	neat	USP	Suspension	Variable; greater than 200 mg/ml	Oral	Zoo animals; treatment of bacterial infections. Once daily dosing is advantageous.	see below	Concentrated formualtion facilitates delivery of feasible	see below	High concentration formulations not commerci	Routinely used by zoo clinicians	Delayed treatment of bacterial diseases can result in death.	None known	
Etorphine	6,14-Ethenomorphinan-7-methanol, 4,5-epoxy-3-hydroxy-6-methoxy-ά,17-dimethyl-ά-propyl-, (5ά,7á-(R))- hydrochloride.	M99	8CBE01N748	ACS	ACS	Etorphine Hcl, citric acid, propylene glycol and WFI		Sterile Injectable	10 mg/ml and 1 mg/ml	Intramuscular	Captive and free ranging mammals and reptiles	Common in current text books	not available	see below	not available	Common in published literature	anesthesia	None known	
Famcyclovir	Famciclovir; Famvir; 104227-87-4; Famciclovirum; BRL-42810; Oravir; [2-(acetyloxymethyl)-4-(2-aminopurin-9-yl)butyl] acetate	Famciclovir	QIC03ANI02	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Fentanyl	N-(1-(2-phenylethyl)-4-piperidinyl)-N-phenylpropanamide	Duragesic,Sublimase 50 mcg/ml	UF599785JZ	USP	USP	neat	Yes	Sterile Injectable	not available	not available	Captive and free ranging mammals	see below	not available	see below	not available	not available	not available	None known	

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Fluphenazine	FLUPHENAZINE; Triflumethazine; Fluorophenazine; Fluorfenazine; Fluorphenazine; Siqualine; 2-[4-[3-[2-(trifluoromethyl)phenothiazin-10-yl]propyl]piperazin-1-yl]ethanol	Fluphenazine	S79426A41Z	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Guaifenesin	Glycerol guaiacolate; Guaiacol glyceryl ether; 93-14-1;	Guaifenesin	495W7451VQ	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below		see below	not available	not available	not available	None known	
Haloperidol	Haloperidol; Haldol; Eukystol; Serenace; Aloperidin; Aloperidol;4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	Haloperidol	J6292F8L3D	USP	USP	neat	USP	Sterile Injectable	20 mg/ml	Intramuscular	Captive and free ranging mammals	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term tranquilization	None known	
Hyaluronidase	Hyaluronidase/; Apaziquone/; Cetuximab/; Desloratadine/; Prucalopride/; Rosuvastatin/; 6-(3,3-dimethyl-2-methylideneindol-1-yl)hexanoic acid;hydrobromide	Hyaluronidase	8KOG53Z5EM	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Isoxsuprine	Isoxsuprine; Vasodilian; Dilavase; Vasosurpine; 395-28-8; Isoxsuprine [INN:BAN]; 4-[1-hydroxy-2-(1-phenoxypropan-2-ylamino)propyl]phenol	Isoxsuprine	R15UI3245N	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	

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Itraconazole	Itraconazole; Sporanox; Oriconazole; Itraconazolum; Itraconazol; Itrizole (TN); 2-butan-2-yl-4-[4-[4-[4-[[(2R,4S)-2-(2,4-dichlorophenyl)-2-(1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]piperazin-1-yl]phenyl]-1,2,4-triazol-3-one	Itraconazole	304NUG5GF4	USP	USP	neat	USP	not available	40 mg capsules	not available	zoo birds, primarily penguins (aspergillosis)	see below	not available	see below	API is not bioavailable in penguins	not available	not available	None known	
Ketamine	Ketamine; Ketaject; Ketalar; DI-Ketamine; Ketanest; CI 581 base; 2-(2-chlorophenyl)-2-(methylamino)cyclohexan-1-one	Ketamine	690G0D6V8H	USP	USP	neat	USP	not available	200 mg/ml	not available	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	not available	see below	not available	not available	anesthesia	None known	
Large-volume parenteral fluids	not available	not available	not available	not available	not available	not available	not available	Sterile injectable	not available	not available	Zoo animals	see below	not available	not available	not available	not available	not available	None known	
Leuprolide acetate	Leuprolide acetate; Leuprorelin acetate; Enantone; Abbott-43818; CHEBI:63597; TAP-144;acetic acid;(2S)-N-[(2S)-1-[[(2S)-1-[[(2S)-1-[[(2S)-1-[[(2R)-1-[[(2S)-1-[[(2S)-5-(diaminomethylideneamino)-1-[(2S)-2-(ethylcarbamoyl)pyrrolidin-1-yl]-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-4-methyl-1-oxopentan-2-yl]amino]-3-(4-hydroxyphenyl)-1-oxopropan-2-yl]amino]-3-hydroxy-1-oxopropan-2-yl]amino]-3-(1H-indol-3-yl)-1-oxopropan-2-yl]amino]-3-(1H-imidazol-5-yl)-1-oxopropan-2-yl]-5-oxopyrrolidine-2-carboxamide	Leuprolide acetate	37JNS02E7V	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	human product might/might not be right	not available	not available	None known	

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Medetomidine	-4-[1-(2,3-dimethylphenyl) ethyl] -1H-imidazole monohydrochloride.	Domitor 1 mg/ml	MR15E85MQM	ACS	ACS	neat	not available	Sterile Injectable	10, 20, and 40 mg/ml	Intramuscular	Captive and free ranging mammals, birds, reptiles, fish and elasmobranchs	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	Too dilute	not available	sedation/anesthesia, animal welfare, public safety	None known	
Melengestrol acetate	MELENGESTROL ACETATE; 2919-66-6; UNII-4W5HDS3936; CHEBI:34831; 17-Hydroxy-6-methyl-16-methylenepregna-4,6-diene-3,20-dione acetate; NSC-70968; [(8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-16-methylidene-3-oxo-1,2,8,9,11,12,14,15-octahydrocyclopenta[a]phenanthren-17-yl] acetate	Melegestrol acetate	4W5HDS3936	ACS	ACS	neat	not available	Sterile implant or feed additive	Variable based on individual weight	SQ or in feed	Contraception for primates, carnivores, hoofstock species	see below	There is no approved formulation	see below	There is no approved formulation	Common contraceptive in use in the zoo community for 25 + years	Population management	None known	
Meloxicam	Meloxicam; Mobic; 71125-38-7; Metacam; Movalis; Meloxicamum; 4-hydroxy-2-methyl-N-(5-methyl-1,3-thiazol-2-yl)-1,1-dioxo-1$l^{6},2-benzothiazine-3-carboxamide	Meloxicam	VG2QF83CGL	USP	USP	neat	USP	not available	2 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	comes as 5 mg/ml solution	not available	analgesic	None known	
Midazolam	Midazolam; Versed; Dormicum; Midazolamum; 59467-70-8; Midazolamum [INN-Latin]; 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine	Midazolam	R60L0SM5BC	USP	USP	Neat	USP	not available	20 mg/ml	not available	Captive and free ranging mammals, birds, reptiles	see below	not available	see below	not available	not available	tranquilization	None known	

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Nalbuphine	–)-17-(cyclobutylmethyl)- 4,5α-epoxymorphinan- 3,6α,14-triol hydrochloride	Nubain (human) 10 mg/ml	L2T84IQI2K	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	Intramuscular	Captive and free ranging mammals	Published use combined with Med and Azaperone in Bears and Cervids	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	not available	not available	long term sedation, animal welfare and public safety	None known	
Naloxone	Naloxone; L-Naloxone; Narcan; N-Allylnoroxymorphone; Naloxona; Naloxonum; (4R,4aS,7aR,12bS)-4a,9-dihydroxy-3-prop-2-enyl-2,4,5,6,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7-one	Naloxone	36B82AMQ7N	USP	USP	neat	usp	not available	10 mg/ml	not available	Wildlife	see below		see below			human reversal for narcotic exposure	None known	
Naltrexone	17-(cyclopropylmethyl)-4,5-epoxy-3,14 dihydroxy-morphinan-6-one hydrochloride.	Revia 50 mg tablet for human use	5S6W795CQM	USP	USP	neat	USP	Sterile Injectable	50 mg/ml	not available	Captive and free ranging mammals, birds and elasmobranchs	Previously a FDA approved product	Currently not commerciall y available	see below	Revia is an oral tablet	Previously an approved NADA	reversal of narcotics	None known	
Ponazuril	Toltrazuril sulfone; Ponazuril; 69004-04-2; UNII-JPW84AS66U; NCGC00182044-01; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione; 1-methyl-3-[3-methyl-4-[4-(trifluoromethylsulfonyl)phenoxy]phenyl]-1,3,5-triazinane-2,4,6-trione	Ponazuril	JPW84AS66U	ACS	ACS	neat	?	Solution or suspension	Variable based on species	not available	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Coccidiosis, Atoxoplasmosis, Toxoplasmosis	see below	Paste formulation not ammendable for oral suspensions or for treatment of groups of birds in the water	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	

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Praziquantel	Praziquantel; Biltricide; 55268-74-1; Droncit; Cesol; Pyquiton; 2-(cyclohexanecarbonyl)-3,6,7,11b-tetrahydro-1H-pyrazino[2,1-a]isoquinolin-4-one	Praziquantel	6490C9U457	USP	USP	neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available	not available	not available	None known	
Primaquine	PRIMAQUINE; Neo-Quipenyl; Primachin; 90-34-6; 8-(4-Amino-1-methylbutylamino)-6-methoxyquinoline; Primaquin; 4-N-(6-methoxyquinolin-8-yl)pentane-1,4-diamine	Primaquine	MVR3634GX1	USP	USP	neat	USP	Suspension	Variable based on species	Oral	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Coccidiosis, Atoxoplasmosis, Toxoplasmosis	see below	Inability to accurately get concentrations needed for the treatment of small patients	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	
Pyrimethamine	Pyrimethamine; 58-14-0; Daraprim; Chloridine; Ethylpyrimidine; Chloridin;	Pyrimethamine	Z3614QOX8W	USP	USP	Neat	USP	Suspension	Variable based on species	Oral	Zoo species suscpetible to protozoal diseases such as Sarcocystis, Malaria, Atoxoplasmosis, Toxoplasmosis	see below	Inability to accurately get concentrations needed for the treatment of small patients	see below	not available	not available	Protozoal diseases left untreated will result in death	None known	

	Chemical name	Common name	UNII Code	Chemical grade	Description of the strength, quality, stability, and purity of the ingredient	Ingredient format(s)	Recognition in Pharmacopeias	Final compounded formulation dosage form(s)	Final compounded formation strength(s)	Final compounded formulation route(s) of administration	Species and condition(s)	Bibliographies on safety and efficacy data	Why necessary (why approved drug is not suitable for patients)	Literature review to determine whether FDA-approved animal or human drugs that could be prescribed as an extra-label use	Explanation supported by scientific data of why drug cannot be compounded from approved drug	Final compounded formulation clinical rational and history of past use	Why immediate treatment is needed	Safety concerns	
Pyrimethamine-Trimethoprim sulfa	not available	not available	not available	not available	not available	not available	not available	Suspension	480mg/ml	parenteral - IM or SC	generally zoo species but also could apply to pet exotics	repeated mention in Carpenter's formularies; JZWM in clinical settings	frequently unavailable	currently off market	not available	parenteral suspension	broad-spectrum antibiotic use which needs administration at time of sedation while other diagnostics are ongoing; in particular, it is a front line treatment for amoebic meningoencephalitis in great ape/non-human primate species which would need administration for more rapid onset to therapeutic drug concentrations rather than oral; additionally, many ill animals will not consume medications until after infection was considered more controlled; product needs to be available on shelf for immediate use.	None known	
Terbinafine	Terbinafine; 91161-71-6; Lamisil; Lamasil; SF-86-327; Lamisil Tablet;(E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine	Terbinafine	G7RIW8S0XP	USP	USP	Neat	USP	not available	not available	not available	Zoo animals	see below	not available	see below	not available		not available	None known	
Thiafentanil	4-methoxycarbonyl-4(*N*-phenyl-methoxyacetamido)-1-[2'-(2"-thienyl)ethyl]-piperidinium oxalate	Thianil (under review as a MUMS Indexed drug)	no information	no information	no information	no information	no information	Sterile Injectable	10 mg/ml	Intramuscular	Captive and free ranging mammals	see below	Currently not commerciall y available	see below	not available	Field results superior to other potent opiates (Carfentanil and Etorphine)	anesthesia	None known	

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Tolazoline hydrochloride (concentrated)	1H-imidazole,4,5-dihydro-2-(phenylmethyl)-monohydrochlroide	CHH9H12AQ3	USP	USP	Neat	USP	no information	sterile injectable	200 mg/ml	IM, IV, SC	aptive and free ranging mammals	see below	Concentrated form to antagonize concentrated xylazine hydrochloride	see below	approved formulation too dilute to use in large hoofstock		anesthetic antagonist	None known	
MS-222 or Tricaine methanesulfonate	Tricaine methanesulfonate	Finquel, MS222, Tricaine-S	no information	no information	no information	no information	no information	no information	aqueous	no information	Bath	Aquatic animals (large fish such as sharks)	see below	Used as an aqueous anesthetic and aqutic animal euthanasia solution; concentrated form for large aquatic animals (e.g., sharks)	see below	approved formulation too dilute to use in large hoofstock		sedation, anesthesia	None known	
Trimethoprim sulfadiazine paste	not available	not available	no information	no information	no information	no information	no information	no information	oral paste	400 mg/ml	Oral	Zoo animals (e.g., large ungulates)	see below	FDA-approved product requently backordered from manufacturer	see below	approved formulation too dilute to use in large hoofstock		antibiotic for large ungulates	None known	

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Vitamin K1 (phytonadione)	Phytomenadione; Konakion; Phytonadione; Phylloquinone; Phytylmenadione; Aquamephyton; 2-methyl-3-[(E)-3,7,11,15-tetramethylhexadec-2-enyl]naphthalene-1,4-dione	Phytonadione	S5Z3U87QHF	USP	USP	neat	USP	injectable	not available	SC, IV, Oral	Large zoo animals	see below	Concentrated form for larger animals; used for coagulopathies, rodenticide toxicities, newborn hemorrhagic disease,	see below	approved formulation too dilute to use in large hoofstock		coagulopathies, rodenticide toxicities, newborn hemorrhagic disease	None known	
Voriconazole	Voriconazole; Vfend; 137234-62-9; UK-109496; UK 109496; Voriconazol; (2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1,2,4-triazol-1-yl)butan-2-ol	Voriconazole	JFU09I87TR	USP	USP	Neat	USP	oral suspension	300 mg/ml	Oral	Zoo animals, exotic pets, aquaria, wildlife	see below	Concentrated formulations for treating fungal infections in a variety of species	see below	approved formulation too dilute to use in large hoofstock		antifungal	None known	
Xylazine (concentrated)	2- (2,6-dimethylphenylamino) -4H-5,6-dihydro-1,3-thiazine hydrochloride	Cervizine	2KFG9TP5V8	USP	USP	neat	USP	sterile injectable	300 and 450 mg/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Injection volume necessary for effect is not possible by dart delivery or hand injection in many species.	see below	approved formulation too dilute to use in large hoofstock		sedation	None known	

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Yohimbine (concentrated)	Yohimban-16-carboxylic acid, 17-hydroxy-, methyl ester, hydrochloride	Antagonil	not available	no information	no information	no information	no information	sterile injectable	10 mg/ml, 30 ml/ml	IM, IV, SC	Captive and free ranging mammals, birds, reptiles	see below	Concentrated form to antagonize concentrated xylazine hydrochloride	see below	approved formulation too dilute to use in large hoofstock		anesthetic antagonist	None known	
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November 16, 2015

Submitted electronically to http://www.regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Subject: USP's Comments on Compounding Animal Drugs from Bulk Drug Substances; Draft Guidance for Industry, Docket No. FDA-2015-D-1176

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on the "Compounding Animal Drugs from Bulk Drug Substances Draft Guidance for Industry" (Draft Guidance). USP's standards for animal drugs support access to customized therapies designed for animal patients. We appreciate FDA's efforts in continuing to support standards for animal health, including recognizing the critical role of USP's compounding chapters. We look forward to working with FDA and other stakeholders on these important issues.

Similar to existing statutory and FDA requirements governing traditional compounding of human drug preparations, the Draft Guidance stipulates that licensed pharmacies and licensed veterinarians comply with *USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations*, and meet other conditions, if they want to compound animal drugs from bulk substances and be aligned with FDA's enforcement policy set forth in the Draft Guidance. USP fully supports this stipulation.

Related to FDA's intent to handle traditional animal compounding in this manner, the Agency has specifically requested comments on whether *United States Pharmacopeia and National Formulary (USP-NF) General Chapters <795> and <797> provide suitable standards for animal drugs compounded by veterinarians, and if not, what standards of safety, purity, and quality should apply to animal drugs compounded by veterinarians.* **USP fully supports full compliance with both <795> and <797> when compounding extemporaneous preparations for animal patients as suitable standards.**

I. USP Position

USP standards provide compounders with guidance on applying good compounding practices for extemporaneously compounded preparations. USP General Chapters <795> and <797> provide practice and quality standards for compounding preparations for human and animal patients. General Chapter <795> also provides specific information on compounding for animal patients. USP continues to encourage regulators to adopt USP General Chapters to help ensure the quality and benefit of compounded preparations for all patients. **USP's public standards on compounding protect animal patients—an important commitment to USP—and we are prepared to help ensure the utilization of General Chapters <795> and <797> as well as consider additional animal compounding-specific standards by working closely with FDA, States, practitioners, pharmacists, veterinarians, and other stakeholders.**

USP–U.S.
12601 Twinbrook Parkway
Rockville, MD 20852–1790, USA
+1-301-881-0666

USP–Switzerland
Basel

USP–India
Hyderabad

USP–China
Shanghai

USP–Brazil
São Paulo

USP–Ghana
Accra

USP–Ethiopia
Addis Ababa

USP–Indonesia
Jakarta

II. USP's Standards-Setting Role

USP is a scientific nonprofit organization that sets public standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP develops its standards through Expert Committees, consisting of leading scientific expert volunteers, which are the ultimate decision-making bodies that approve USP standards, including monographs and general chapters. Consistent with our commitment to provide public standards, USP is advancing its animal health standards, including those devoted to veterinary drug products, whether in the form of a manufactured product or compounded preparation.

Animal-specific standards for drug substances and manufactured products are the responsibility of one of USP's six Chemical Medicines (CHM) Expert Committees, with support from two liaisons from the FDA Center for Veterinary Medicine (CVM). USP's compounding standards are developed through USP's Compounding Expert Committee, whose work is supported by eight FDA liaisons (including two from CVM) and two liaisons from the Centers for Disease Control (CDC). USP has been active in setting standards for animal drugs for many years including supporting the public's access to customized drug therapy for animal patients. For animal drug compounding, similar to human compounding, three types of standards add value by assuring quality for compounders, regulators, and animal patients:

1. Monographs for drug articles

   Under the Federal Food, Drug, and Cosmetic Act, USP monographs for drug articles are legally enforceable by FDA. Monographs for drug articles include standards of identity, quality, purity, strength, packaging and labeling and are applicable to both human drugs and animal drugs. There are more than 190 veterinary-specific monographs for FDA approved drug substances and drug products.

2. Veterinary-specific compounded preparation monographs

   There are currently more than 10 veterinary-specific compounded preparation monographs providing standardized formulas and beyond-use dates.

3. General Chapters

   General Chapters may serve as introductory overviews of test or of analytical methods or provide more specific techniques or detailed procedures. In the case of <795> and <797>, they provide practice standards such as those for personnel and environments to ensure quality compounded preparations.

   By way of information, General Chapters (in addition to <795> and <797>) relevant to Animal Drugs include:

   - General Chapter <1151> *Pharmaceutical Dosage Forms* discusses general principles related to the manufacture or compounding of drug products, or dosage forms, commonly used to administer the drug substance (active pharmaceutical

ingredient, API) including general descriptions and definitions for these dosage forms.

- General Chapter <1152> Animal Drugs for Use in Animal Feeds provides important information and general principles involved in the manufacture, packaging, and labeling of animal drugs and drug products intended to be delivered in animal feeds.

We appreciate FDA's work in this area and look forward to continued collaboration with the Agency and other stakeholders.

Thank you for your consideration of this matter. For more information please feel free to contact Morgan Puderbaugh, Scientific Liaison, Science-Chemical Medicines, at (301) 998-6833 or mxp@usp.org; or Rick Schnatz, Pharm. D., Senior Manager, HQS and Compounding, Science-Healthcare Quality Standards, at (301) 816-8526 or rxs@usp.org.

Sincerely,

Jaap Venema, Ph.D.
Executive Vice President and Chief Science Officer

VMB Agenda Item #10 – Board Chair Report

HAND CARRY

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS *v.* FEDERAL TRADE COMMISSION

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 13–534. Argued October 14, 2014—Decided February 25, 2015

North Carolina's Dental Practice Act (Act) provides that the North Carolina State Board of Dental Examiners (Board) is "the agency of the State for the regulation of the practice of dentistry." The Board's principal duty is to create, administer, and enforce a licensing system for dentists; and six of its eight members must be licensed, practicing dentists.

The Act does not specify that teeth whitening is "the practice of dentistry." Nonetheless, after dentists complained to the Board that nondentists were charging lower prices for such services than dentists did, the Board issued at least 47 official cease-and-desist letters to nondentist teeth whitening service providers and product manufacturers, often warning that the unlicensed practice of dentistry is a crime. This and other related Board actions led nondentists to cease offering teeth whitening services in North Carolina.

The Federal Trade Commission (FTC) filed an administrative complaint, alleging that the Board's concerted action to exclude nondentists from the market for teeth whitening services in North Carolina constituted an anticompetitive and unfair method of competition under the Federal Trade Commission Act. An Administrative Law Judge (ALJ) denied the Board's motion to dismiss on the ground of state-action immunity. The FTC sustained that ruling, reasoning that even if the Board had acted pursuant to a clearly articulated state policy to displace competition, the Board must be actively supervised by the State to claim immunity, which it was not. After a hearing on the merits, the ALJ determined that the Board had unreasonably restrained trade in violation of antitrust law. The FTC again sustained the ALJ, and the Fourth Circuit affirmed the FTC in

all respects.

Held: Because a controlling number of the Board's decisionmakers are active market participants in the occupation the Board regulates, the Board can invoke state-action antitrust immunity only if it was subject to active supervision by the State, and here that requirement is not met. Pp. 5–18.

(a) Federal antitrust law is a central safeguard for the Nation's free market structures. However, requiring States to conform to the mandates of the Sherman Act at the expense of other values a State may deem fundamental would impose an impermissible burden on the States' power to regulate. Therefore, beginning with *Parker* v. *Brown*, 317 U. S. 341, this Court interpreted the antitrust laws to confer immunity on the anticompetitive conduct of States acting in their sovereign capacity. Pp. 5–6.

(b) The Board's actions are not cloaked with *Parker* immunity. A nonsovereign actor controlled by active market participants—such as the Board—enjoys *Parker* immunity only if "'the challenged restraint . . . [is] clearly articulated and affirmatively expressed as state policy,' and . . . 'the policy . . . [is] actively supervised by the State.'" *FTC* v. *Phoebe Putney Health System, Inc.*, 568 U. S. ___, ___ (quoting *California Retail Liquor Dealers Assn.* v. *Midcal Aluminum, Inc.*, 445 U. S. 97, 105). Here, the Board did not receive active supervision of its anticompetitive conduct. Pp. 6–17.

(1) An entity may not invoke *Parker* immunity unless its actions are an exercise of the State's sovereign power. See *Columbia* v. *Omni Outdoor Advertising, Inc.*, 499 U. S. 365, 374. Thus, where a State delegates control over a market to a nonsovereign actor the Sherman Act confers immunity only if the State accepts political accountability for the anticompetitive conduct it permits and controls. Limits on state-action immunity are most essential when a State seeks to delegate its regulatory power to active market participants, for dual allegiances are not always apparent to an actor and prohibitions against anticompetitive self-regulation by active market participants are an axiom of federal antitrust policy. Accordingly, *Parker* immunity requires that the anticompetitive conduct of nonsovereign actors, especially those authorized by the State to regulate their own profession, result from procedures that suffice to make it the State's own. *Midcal*'s two-part test provides a proper analytical framework to resolve the ultimate question whether an anticompetitive policy is indeed the policy of a State. The first requirement—clear articulation—rarely will achieve that goal by itself, for entities purporting to act under state authority might diverge from the State's considered definition of the public good and engage in private self-dealing. The second *Midcal* requirement—active supervision—seeks to avoid this

harm by requiring the State to review and approve interstitial policies made by the entity claiming immunity. Pp. 6–10.

(2) There are instances in which an actor can be excused from *Midcal*'s active supervision requirement. Municipalities, which are electorally accountable, have general regulatory powers, and have no private price-fixing agenda, are subject exclusively to the clear articulation requirement. See *Hallie* v. *Eau Claire*, 471 U. S. 34, 35. That *Hallie* excused municipalities from *Midcal*'s supervision rule for these reasons, however, all but confirms the rule's applicability to actors controlled by active market participants. Further, in light of *Omni*'s holding that an otherwise immune entity will not lose immunity based on ad hoc and *ex post* questioning of its motives for making particular decisions, 499 U. S., at 374, it is all the more necessary to ensure the conditions for granting immunity are met in the first place, see *FTC* v. *Ticor Title Ins. Co.*, 504 U. S. 621, 633, and *Phoebe Putney, supra,* at ___. The clear lesson of precedent is that *Midcal*'s active supervision test is an essential prerequisite of *Parker* immunity for any nonsovereign entity—public or private—controlled by active market participants. Pp. 10–12.

(3) The Board's argument that entities designated by the States as agencies are exempt from *Midcal*'s second requirement cannot be reconciled with the Court's repeated conclusion that the need for supervision turns not on the formal designation given by States to regulators but on the risk that active market participants will pursue private interests in restraining trade. State agencies controlled by active market participants pose the very risk of self-dealing *Midcal*'s supervision requirement was created to address. See *Goldfarb* v. *Virginia State Bar*, 421 U. S. 773, 791. This conclusion does not question the good faith of state officers but rather is an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals. While *Hallie* stated "it is likely that active state supervision would also not be required" for agencies, 471 U. S., at 46, n. 10, the entity there was more like prototypical state agencies, not specialized boards dominated by active market participants. The latter are similar to private trade associations vested by States with regulatory authority, which must satisfy *Midcal*'s active supervision standard. 445 U. S., at 105–106. The similarities between agencies controlled by active market participants and such associations are not eliminated simply because the former are given a formal designation by the State, vested with a measure of government power, and required to follow some procedural rules. See *Hallie, supra,* at 39. When a State empowers a group of active market participants to decide who can participate in its market, and on what terms, the need for supervision is manifest. Thus,

the Court holds today that a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity. Pp. 12–14.

(4) The State argues that allowing this FTC order to stand will discourage dedicated citizens from serving on state agencies that regulate their own occupation. But this holding is not inconsistent with the idea that those who pursue a calling must embrace ethical standards that derive from a duty separate from the dictates of the State. Further, this case does not offer occasion to address the question whether agency officials, including board members, may, under some circumstances, enjoy immunity from damages liability. Of course, States may provide for the defense and indemnification of agency members in the event of litigation, and they can also ensure *Parker* immunity is available by adopting clear policies to displace competition and providing active supervision. Arguments against the wisdom of applying the antitrust laws to professional regulation absent compliance with the prerequisites for invoking *Parker* immunity must be rejected, see *Patrick* v. *Burget*, 486 U. S. 94, 105–106, particularly in light of the risks licensing boards dominated by market participants may pose to the free market. Pp. 14–16.

(5) The Board does not contend in this Court that its anticompetitive conduct was actively supervised by the State or that it should receive *Parker* immunity on that basis. The Act delegates control over the practice of dentistry to the Board, but says nothing about teeth whitening. In acting to expel the dentists' competitors from the market, the Board relied on cease-and-desist letters threatening criminal liability, instead of other powers at its disposal that would have invoked oversight by a politically accountable official. Whether or not the Board exceeded its powers under North Carolina law, there is no evidence of any decision by the State to initiate or concur with the Board's actions against the nondentists. P. 17.

(c) Here, where there are no specific supervisory systems to be reviewed, it suffices to note that the inquiry regarding active supervision is flexible and context-dependent. The question is whether the State's review mechanisms provide "realistic assurance" that a nonsovereign actor's anticompetitive conduct "promotes state policy, rather than merely the party's individual interests." *Patrick*, 486 U. S., 100–101. The Court has identified only a few constant requirements of active supervision: The supervisor must review the substance of the anticompetitive decision, see *id.*, at 102–103; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy, see *ibid.*; and the "mere potential for state

Syllabus

supervision is not an adequate substitute for a decision by the State," *Ticor*, *supra*, at 638. Further, the state supervisor may not itself be an active market participant. In general, however, the adequacy of supervision otherwise will depend on all the circumstances of a case. Pp. 17–18.

717 F. 3d 359, affirmed.

KENNEDY, J., delivered the opinion of the Court, in which ROBERTS, C. J., and GINSBURG, BREYER, SOTOMAYOR, and KAGAN, JJ., joined. ALITO, J., filed a dissenting opinion, in which SCALIA and THOMAS, JJ., joined.

SUPREME COURT OF THE UNITED STATES

No. 13–534

NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS, PETITIONER *v.* FEDERAL TRADE COMMISSION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[February 25, 2015]

JUSTICE KENNEDY delivered the opinion of the Court.

This case arises from an antitrust challenge to the actions of a state regulatory board. A majority of the board's members are engaged in the active practice of the profession it regulates. The question is whether the board's actions are protected from Sherman Act regulation under the doctrine of state-action antitrust immunity, as defined and applied in this Court's decisions beginning with *Parker* v. *Brown*, 317 U. S. 341 (1943).

I

A

In its Dental Practice Act (Act), North Carolina has declared the practice of dentistry to be a matter of public concern requiring regulation. N. C. Gen. Stat. Ann. §90–22(a) (2013). Under the Act, the North Carolina State Board of Dental Examiners (Board) is "the agency of the State for the regulation of the practice of dentistry." §90–22(b).

The Board's principal duty is to create, administer, and enforce a licensing system for dentists. See §§90–29 to

90–41. To perform that function it has broad authority over licensees. See §90–41. The Board's authority with respect to unlicensed persons, however, is more restricted: like "any resident citizen," the Board may file suit to "perpetually enjoin any person from . . . unlawfully practicing dentistry." §90–40.1.

The Act provides that six of the Board's eight members must be licensed dentists engaged in the active practice of dentistry. §90–22. They are elected by other licensed dentists in North Carolina, who cast their ballots in elections conducted by the Board. *Ibid.* The seventh member must be a licensed and practicing dental hygienist, and he or she is elected by other licensed hygienists. *Ibid.* The final member is referred to by the Act as a "consumer" and is appointed by the Governor. *Ibid.* All members serve 3-year terms, and no person may serve more than two consecutive terms. *Ibid.* The Act does not create any mechanism for the removal of an elected member of the Board by a public official. See *ibid.*

Board members swear an oath of office, §138A–22(a), and the Board must comply with the State's Administrative Procedure Act, §150B–1 *et seq.*, Public Records Act, §132–1 *et seq.*, and open-meetings law, §143–318.9 *et seq.* The Board may promulgate rules and regulations governing the practice of dentistry within the State, provided those mandates are not inconsistent with the Act and are approved by the North Carolina Rules Review Commission, whose members are appointed by the state legislature. See §§90–48, 143B–30.1, 150B–21.9(a).

B

In the 1990's, dentists in North Carolina started whitening teeth. Many of those who did so, including 8 of the Board's 10 members during the period at issue in this case, earned substantial fees for that service. By 2003, nondentists arrived on the scene. They charged lower

prices for their services than the dentists did. Dentists soon began to complain to the Board about their new competitors. Few complaints warned of possible harm to consumers. Most expressed a principal concern with the low prices charged by nondentists.

Responding to these filings, the Board opened an investigation into nondentist teeth whitening. A dentist member was placed in charge of the inquiry. Neither the Board's hygienist member nor its consumer member participated in this undertaking. The Board's chief operations officer remarked that the Board was "going forth to do battle" with nondentists. App. to Pet. for Cert. 103a. The Board's concern did not result in a formal rule or regulation reviewable by the independent Rules Review Commission, even though the Act does not, by its terms, specify that teeth whitening is "the practice of dentistry."

Starting in 2006, the Board issued at least 47 cease-and-desist letters on its official letterhead to nondentist teeth whitening service providers and product manufacturers. Many of those letters directed the recipient to cease "all activity constituting the practice of dentistry"; warned that the unlicensed practice of dentistry is a crime; and strongly implied (or expressly stated) that teeth whitening constitutes "the practice of dentistry." App. 13, 15. In early 2007, the Board persuaded the North Carolina Board of Cosmetic Art Examiners to warn cosmetologists against providing teeth whitening services. Later that year, the Board sent letters to mall operators, stating that kiosk teeth whiteners were violating the Dental Practice Act and advising that the malls consider expelling violators from their premises.

These actions had the intended result. Nondentists ceased offering teeth whitening services in North Carolina.

C

In 2010, the Federal Trade Commission (FTC) filed an

administrative complaint charging the Board with violating §5 of the Federal Trade Commission Act, 38 Stat. 719, as amended, 15 U. S. C. §45. The FTC alleged that the Board's concerted action to exclude nondentists from the market for teeth whitening services in North Carolina constituted an anticompetitive and unfair method of competition. The Board moved to dismiss, alleging state-action immunity. An Administrative Law Judge (ALJ) denied the motion. On appeal, the FTC sustained the ALJ's ruling. It reasoned that, even assuming the Board had acted pursuant to a clearly articulated state policy to displace competition, the Board is a "public/private hybrid" that must be actively supervised by the State to claim immunity. App. to Pet. for Cert. 49a. The FTC further concluded the Board could not make that showing.

Following other proceedings not relevant here, the ALJ conducted a hearing on the merits and determined the Board had unreasonably restrained trade in violation of antitrust law. On appeal, the FTC again sustained the ALJ. The FTC rejected the Board's public safety justification, noting, *inter alia*, "a wealth of evidence . . . suggesting that non-dentist provided teeth whitening is a safe cosmetic procedure." *Id.*, at 123a.

The FTC ordered the Board to stop sending the cease-and-desist letters or other communications that stated nondentists may not offer teeth whitening services and products. It further ordered the Board to issue notices to all earlier recipients of the Board's cease-and-desist orders advising them of the Board's proper sphere of authority and saying, among other options, that the notice recipients had a right to seek declaratory rulings in state court.

On petition for review, the Court of Appeals for the Fourth Circuit affirmed the FTC in all respects. 717 F. 3d 359, 370 (2013). This Court granted certiorari. 571 U. S. ___ (2014).

II

Federal antitrust law is a central safeguard for the Nation's free market structures. In this regard it is "as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms." *United States* v. *Topco Associates, Inc.*, 405 U. S. 596, 610 (1972). The antitrust laws declare a considered and decisive prohibition by the Federal Government of cartels, price fixing, and other combinations or practices that undermine the free market.

The Sherman Act, 26 Stat. 209, as amended, 15 U. S. C. §1 *et seq.*, serves to promote robust competition, which in turn empowers the States and provides their citizens with opportunities to pursue their own and the public's welfare. See *FTC* v. *Ticor Title Ins. Co.*, 504 U. S. 621, 632 (1992). The States, however, when acting in their respective realm, need not adhere in all contexts to a model of unfettered competition. While "the States regulate their economies in many ways not inconsistent with the antitrust laws," *id.*, at 635–636, in some spheres they impose restrictions on occupations, confer exclusive or shared rights to dominate a market, or otherwise limit competition to achieve public objectives. If every duly enacted state law or policy were required to conform to the mandates of the Sherman Act, thus promoting competition at the expense of other values a State may deem fundamental, federal antitrust law would impose an impermissible burden on the States' power to regulate. See *Exxon Corp.* v. *Governor of Maryland*, 437 U. S. 117, 133 (1978); see also Easterbrook, Antitrust and the Economics of Federalism, 26 J. Law & Econ. 23, 24 (1983).

For these reasons, the Court in *Parker* v. *Brown* interpreted the antitrust laws to confer immunity on anticompetitive conduct by the States when acting in their sovereign capacity. See 317 U. S., at 350–351. That ruling

recognized Congress' purpose to respect the federal balance and to "embody in the Sherman Act the federalism principle that the States possess a significant measure of sovereignty under our Constitution." *Community Communications Co.* v. *Boulder*, 455 U. S. 40, 53 (1982). Since 1943, the Court has reaffirmed the importance of *Parker*'s central holding. See, *e.g.*, *Ticor*, *supra*, at 632–637; *Hoover* v. *Ronwin*, 466 U. S. 558, 568 (1984); *Lafayette* v. *Louisiana Power & Light Co.*, 435 U. S. 389, 394–400 (1978).

III

In this case the Board argues its members were invested by North Carolina with the power of the State and that, as a result, the Board's actions are cloaked with *Parker* immunity. This argument fails, however. A nonsovereign actor controlled by active market participants—such as the Board—enjoys *Parker* immunity only if it satisfies two requirements: "first that 'the challenged restraint . . . be one clearly articulated and affirmatively expressed as state policy,' and second that 'the policy . . . be actively supervised by the State.'" *FTC* v. *Phoebe Putney Health System, Inc.*, 568 U. S. ___, ___ (2013) (slip op., at 7) (quoting *California Retail Liquor Dealers Assn.* v. *Midcal Aluminum, Inc.*, 445 U. S. 97, 105 (1980)). The parties have assumed that the clear articulation requirement is satisfied, and we do the same. While North Carolina prohibits the unauthorized practice of dentistry, however, its Act is silent on whether that broad prohibition covers teeth whitening. Here, the Board did not receive active supervision by the State when it interpreted the Act as addressing teeth whitening and when it enforced that policy by issuing cease-and-desist letters to nondentist teeth whiteners.

A

Although state-action immunity exists to avoid conflicts

between state sovereignty and the Nation's commitment to a policy of robust competition, *Parker* immunity is not unbounded. "[G]iven the fundamental national values of free enterprise and economic competition that are embodied in the federal antitrust laws, 'state action immunity is disfavored, much as are repeals by implication.'" *Phoebe Putney*, *supra*, at ___ (slip op., at 7) (quoting *Ticor*, *supra*, at 636).

An entity may not invoke *Parker* immunity unless the actions in question are an exercise of the State's sovereign power. See *Columbia* v. *Omni Outdoor Advertising, Inc.*, 499 U. S. 365, 374 (1991). State legislation and "decision[s] of a state supreme court, acting legislatively rather than judicially," will satisfy this standard, and "*ipso facto* are exempt from the operation of the antitrust laws" because they are an undoubted exercise of state sovereign authority. *Hoover*, *supra*, at 567–568.

But while the Sherman Act confers immunity on the States' own anticompetitive policies out of respect for federalism, it does not always confer immunity where, as here, a State delegates control over a market to a nonsovereign actor. See *Parker*, *supra*, at 351 ("[A] state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful"). For purposes of *Parker*, a nonsovereign actor is one whose conduct does not automatically qualify as that of the sovereign State itself. See *Hoover*, *supra*, at 567–568. State agencies are not simply by their governmental character sovereign actors for purposes of state-action immunity. See *Goldfarb* v. *Virginia State Bar*, 421 U. S. 773, 791 (1975) ("The fact that the State Bar is a state agency for some limited purposes does not create an antitrust shield that allows it to foster anticompetitive practices for the benefit of its members"). Immunity for state agencies, therefore, requires more than a mere facade of state involvement, for it is necessary in light of

Parker's rationale to ensure the States accept political accountability for anticompetitive conduct they permit and control. See *Ticor*, 504 U. S., at 636.

Limits on state-action immunity are most essential when the State seeks to delegate its regulatory power to active market participants, for established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor. In consequence, active market participants cannot be allowed to regulate their own markets free from antitrust accountability. See *Midcal*, *supra*, at 106 ("The national policy in favor of competition cannot be thwarted by casting [a] gauzy cloak of state involvement over what is essentially a private price-fixing arrangement"). Indeed, prohibitions against anticompetitive self-regulation by active market participants are an axiom of federal antitrust policy. See, *e.g.*, *Allied Tube & Conduit Corp.* v. *Indian Head, Inc.*, 486 U. S. 492, 501 (1988); *Hoover*, *supra*, at 584 (Stevens, J., dissenting) ("The risk that private regulation of market entry, prices, or output may be designed to confer monopoly profits on members of an industry at the expense of the consuming public has been the central concern of . . . our antitrust jurisprudence"); see also Elhauge, The Scope of Antitrust Process, 104 Harv. L. Rev. 667, 672 (1991). So it follows that, under *Parker* and the Supremacy Clause, the States' greater power to attain an end does not include the lesser power to negate the congressional judgment embodied in the Sherman Act through unsupervised delegations to active market participants. See Garland, Antitrust and State Action: Economic Efficiency and the Political Process, 96 Yale L. J. 486, 500 (1986).

Parker immunity requires that the anticompetitive conduct of nonsovereign actors, especially those authorized by the State to regulate their own profession, result from procedures that suffice to make it the State's own.

See *Goldfarb, supra*, at 790; see also 1A P. Areeda & H. Hovencamp, Antitrust Law ¶226, p. 180 (4th ed. 2013) (Areeda & Hovencamp). The question is not whether the challenged conduct is efficient, well-functioning, or wise. See *Ticor, supra*, at 634–635. Rather, it is "whether anticompetitive conduct engaged in by [nonsovereign actors] should be deemed state action and thus shielded from the antitrust laws." *Patrick* v. *Burget*, 486 U. S. 94, 100 (1988).

To answer this question, the Court applies the two-part test set forth in *California Retail Liquor Dealers Assn.* v. *Midcal Aluminum, Inc.*, 445 U. S. 97, a case arising from California's delegation of price-fixing authority to wine merchants. Under *Midcal*, "[a] state law or regulatory scheme cannot be the basis for antitrust immunity unless, first, the State has articulated a clear policy to allow the anticompetitive conduct, and second, the State provides active supervision of [the] anticompetitive conduct." *Ticor, supra*, at 631 (citing *Midcal, supra*, at 105).

Midcal's clear articulation requirement is satisfied "where the displacement of competition [is] the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature. In that scenario, the State must have foreseen and implicitly endorsed the anticompetitive effects as consistent with its policy goals." *Phoebe Putney*, 568 U. S., at ___ (slip op., at 11). The active supervision requirement demands, *inter alia*, "that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy." *Patrick, supra*, U. S., at 101.

The two requirements set forth in *Midcal* provide a proper analytical framework to resolve the ultimate question whether an anticompetitive policy is indeed the policy of a State. The first requirement—clear articulation—rarely will achieve that goal by itself, for a policy may

satisfy this test yet still be defined at so high a level of generality as to leave open critical questions about how and to what extent the market should be regulated. See *Ticor*, *supra*, at 636–637. Entities purporting to act under state authority might diverge from the State's considered definition of the public good. The resulting asymmetry between a state policy and its implementation can invite private self-dealing. The second *Midcal* requirement—active supervision—seeks to avoid this harm by requiring the State to review and approve interstitial policies made by the entity claiming immunity.

Midcal's supervision rule "stems from the recognition that '[w]here a private party is engaging in anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interests of the State.'" *Patrick*, *supra*, at 100. Concern about the private incentives of active market participants animates *Midcal*'s supervision mandate, which demands "realistic assurance that a private party's anticompetitive conduct promotes state policy, rather than merely the party's individual interests." *Patrick*, *supra*, at 101.

B

In determining whether anticompetitive policies and conduct are indeed the action of a State in its sovereign capacity, there are instances in which an actor can be excused from *Midcal*'s active supervision requirement. In *Hallie* v. *Eau Claire*, 471 U. S. 34, 45 (1985), the Court held municipalities are subject exclusively to *Midcal*'s "'clear articulation'" requirement. That rule, the Court observed, is consistent with the objective of ensuring that the policy at issue be one enacted by the State itself. *Hallie* explained that "[w]here the actor is a municipality, there is little or no danger that it is involved in a private price-fixing arrangement. The only real danger is that it will seek to further purely parochial public interests at the

expense of more overriding state goals." 471 U. S., at 47. *Hallie* further observed that municipalities are electorally accountable and lack the kind of private incentives characteristic of active participants in the market. See *id.*, at 45, n. 9. Critically, the municipality in *Hallie* exercised a wide range of governmental powers across different economic spheres, substantially reducing the risk that it would pursue private interests while regulating any single field. See *ibid.* That *Hallie* excused municipalities from *Midcal*'s supervision rule for these reasons all but confirms the rule's applicability to actors controlled by active market participants, who ordinarily have none of the features justifying the narrow exception *Hallie* identified. See 471 U. S., at 45.

Following *Goldfarb*, *Midcal*, and *Hallie*, which clarified the conditions under which *Parker* immunity attaches to the conduct of a nonsovereign actor, the Court in *Columbia* v. *Omni Outdoor Advertising, Inc.*, 499 U. S. 365, addressed whether an otherwise immune entity could lose immunity for conspiring with private parties. In *Omni*, an aspiring billboard merchant argued that the city of Columbia, South Carolina, had violated the Sherman Act—and forfeited its *Parker* immunity—by anticompetitively conspiring with an established local company in passing an ordinance restricting new billboard construction. 499 U. S., at 367–368. The Court disagreed, holding there is no "conspiracy exception" to *Parker*. *Omni, supra*, at 374.

Omni, like the cases before it, recognized the importance of drawing a line "relevant to the purposes of the Sherman Act and of *Parker*: prohibiting the restriction of competition for private gain but permitting the restriction of competition in the public interest." 499 U. S., at 378. In the context of a municipal actor which, as in *Hallie*, exercised substantial governmental powers, *Omni* rejected a conspiracy exception for "corruption" as vague and unworkable, since "virtually all regulation benefits some

segments of the society and harms others" and may in that sense be seen as "'corrupt.'" 499 U. S., at 377. *Omni* also rejected subjective tests for corruption that would force a "deconstruction of the governmental process and probing of the official 'intent' that we have consistently sought to avoid." *Ibid.* Thus, whereas the cases preceding it addressed the preconditions of *Parker* immunity and engaged in an objective, *ex ante* inquiry into nonsovereign actors' structure and incentives, *Omni* made clear that recipients of immunity will not lose it on the basis of ad hoc and *ex post* questioning of their motives for making particular decisions.

Omni's holding makes it all the more necessary to ensure the conditions for granting immunity are met in the first place. The Court's two state-action immunity cases decided after *Omni* reinforce this point. In *Ticor* the Court affirmed that *Midcal*'s limits on delegation must ensure that "[a]ctual state involvement, not deference to private price-fixing arrangements under the general auspices of state law, is the precondition for immunity from federal law." 504 U. S., at 633. And in *Phoebe Putney* the Court observed that *Midcal*'s active supervision requirement, in particular, is an essential condition of state-action immunity when a nonsovereign actor has "an incentive to pursue [its] own self-interest under the guise of implementing state policies." 568 U. S., at ___ (slip op., at 8) (quoting *Hallie*, *supra*, at 46–47). The lesson is clear: *Midcal*'s active supervision test is an essential prerequisite of *Parker* immunity for any nonsovereign entity—public or private—controlled by active market participants.

C

The Board argues entities designated by the States as agencies are exempt from *Midcal*'s second requirement. That premise, however, cannot be reconciled with the Court's repeated conclusion that the need for supervision

turns not on the formal designation given by States to regulators but on the risk that active market participants will pursue private interests in restraining trade.

State agencies controlled by active market participants, who possess singularly strong private interests, pose the very risk of self-dealing *Midcal*'s supervision requirement was created to address. See Areeda & Hovencamp ¶227, at 226. This conclusion does not question the good faith of state officers but rather is an assessment of the structural risk of market participants' confusing their own interests with the State's policy goals. See *Patrick*, 486 U. S., at 100–101.

The Court applied this reasoning to a state agency in *Goldfarb*. There the Court denied immunity to a state agency (the Virginia State Bar) controlled by market participants (lawyers) because the agency had "joined in what is essentially a private anticompetitive activity" for "the benefit of its members." 421 U. S., at 791, 792. This emphasis on the Bar's private interests explains why *Goldfarb*, though it predates *Midcal*, considered the lack of supervision by the Virginia Supreme Court to be a principal reason for denying immunity. See 421 U. S., at 791; see also *Hoover*, 466 U. S., at 569 (emphasizing lack of active supervision in *Goldfarb*); *Bates* v. *State Bar of Ariz.*, 433 U. S. 350, 361–362 (1977) (granting the Arizona Bar state-action immunity partly because its "rules are subject to pointed re-examination by the policymaker").

While *Hallie* stated "it is likely that active state supervision would also not be required" for agencies, 471 U. S., at 46, n. 10, the entity there, as was later the case in *Omni*, was an electorally accountable municipality with general regulatory powers and no private price-fixing agenda. In that and other respects the municipality was more like prototypical state agencies, not specialized boards dominated by active market participants. In important regards, agencies controlled by market partici-

pants are more similar to private trade associations vested by States with regulatory authority than to the agencies *Hallie* considered. And as the Court observed three years after *Hallie*, "[t]here is no doubt that the members of such associations often have economic incentives to restrain competition and that the product standards set by such associations have a serious potential for anticompetitive harm." *Allied Tube*, 486 U. S., at 500. For that reason, those associations must satisfy *Midcal*'s active supervision standard. See *Midcal*, 445 U. S., at 105–106.

The similarities between agencies controlled by active market participants and private trade associations are not eliminated simply because the former are given a formal designation by the State, vested with a measure of government power, and required to follow some procedural rules. See *Hallie*, *supra*, at 39 (rejecting "purely formalistic" analysis). *Parker* immunity does not derive from nomenclature alone. When a State empowers a group of active market participants to decide who can participate in its market, and on what terms, the need for supervision is manifest. See Areeda & Hovencamp ¶227, at 226. The Court holds today that a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity.

D

The State argues that allowing this FTC order to stand will discourage dedicated citizens from serving on state agencies that regulate their own occupation. If this were so—and, for reasons to be noted, it need not be so—there would be some cause for concern. The States have a sovereign interest in structuring their governments, see *Gregory* v. *Ashcroft*, 501 U. S. 452, 460 (1991), and may conclude there are substantial benefits to staffing their

agencies with experts in complex and technical subjects, see *Southern Motor Carriers Rate Conference, Inc.* v. *United States*, 471 U. S. 48, 64 (1985). There is, moreover, a long tradition of citizens esteemed by their professional colleagues devoting time, energy, and talent to enhancing the dignity of their calling.

Adherence to the idea that those who pursue a calling must embrace ethical standards that derive from a duty separate from the dictates of the State reaches back at least to the Hippocratic Oath. See generally S. Miles, The Hippocratic Oath and the Ethics of Medicine (2004). In the United States, there is a strong tradition of professional self-regulation, particularly with respect to the development of ethical rules. See generally R. Rotunda & J. Dzienkowski, Legal Ethics: The Lawyer's Deskbook on Professional Responsibility (2014); R. Baker, Before Bioethics: A History of American Medical Ethics From the Colonial Period to the Bioethics Revolution (2013). Dentists are no exception. The American Dental Association, for example, in an exercise of "the privilege and obligation of self-government," has "call[ed] upon dentists to follow high ethical standards," including "honesty, compassion, kindness, integrity, fairness and charity." American Dental Association, Principles of Ethics and Code of Professional Conduct 3–4 (2012). State laws and institutions are sustained by this tradition when they draw upon the expertise and commitment of professionals.

Today's holding is not inconsistent with that idea. The Board argues, however, that the potential for money damages will discourage members of regulated occupations from participating in state government. Cf. *Filarsky* v. *Delia*, 566 U. S. ___, ___ (2012) (slip op., at 12) (warning in the context of civil rights suits that the "the most talented candidates will decline public engagements if they do not receive the same immunity enjoyed by their public employee counterparts"). But this case, which does not

present a claim for money damages, does not offer occasion to address the question whether agency officials, including board members, may, under some circumstances, enjoy immunity from damages liability. See *Goldfarb*, 421 U. S., at 792, n. 22; see also Brief for Respondent 56. And, of course, the States may provide for the defense and indemnification of agency members in the event of litigation.

States, furthermore, can ensure *Parker* immunity is available to agencies by adopting clear policies to displace competition; and, if agencies controlled by active market participants interpret or enforce those policies, the States may provide active supervision. Precedent confirms this principle. The Court has rejected the argument that it would be unwise to apply the antitrust laws to professional regulation absent compliance with the prerequisites for invoking *Parker* immunity:

> "[Respondents] contend that effective peer review is essential to the provision of quality medical care and that any threat of antitrust liability will prevent physicians from participating openly and actively in peer-review proceedings. This argument, however, essentially challenges the wisdom of applying the antitrust laws to the sphere of medical care, and as such is properly directed to the legislative branch. To the extent that Congress has declined to exempt medical peer review from the reach of the antitrust laws, peer review is immune from antitrust scrutiny only if the State effectively has made this conduct its own." *Patrick*, 486 U. S. at 105–106 (footnote omitted).

The reasoning of *Patrick* v. *Burget* applies to this case with full force, particularly in light of the risks licensing boards dominated by market participants may pose to the free market. See generally Edlin & Haw, Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny? 162 U. Pa. L. Rev. 1093 (2014).

E

The Board does not contend in this Court that its anticompetitive conduct was actively supervised by the State or that it should receive *Parker* immunity on that basis.

By statute, North Carolina delegates control over the practice of dentistry to the Board. The Act, however, says nothing about teeth whitening, a practice that did not exist when it was passed. After receiving complaints from other dentists about the nondentists' cheaper services, the Board's dentist members—some of whom offered whitening services—acted to expel the dentists' competitors from the market. In so doing the Board relied upon cease-and-desist letters threatening criminal liability, rather than any of the powers at its disposal that would invoke oversight by a politically accountable official. With no active supervision by the State, North Carolina officials may well have been unaware that the Board had decided teeth whitening constitutes "the practice of dentistry" and sought to prohibit those who competed against dentists from participating in the teeth whitening market. Whether or not the Board exceeded its powers under North Carolina law, cf. *Omni*, 499 U. S., at 371–372, there is no evidence here of any decision by the State to initiate or concur with the Board's actions against the nondentists.

IV

The Board does not claim that the State exercised active, or indeed any, supervision over its conduct regarding nondentist teeth whiteners; and, as a result, no specific supervisory systems can be reviewed here. It suffices to note that the inquiry regarding active supervision is flexible and context-dependent. Active supervision need not entail day-to-day involvement in an agency's operations or micromanagement of its every decision. Rather, the question is whether the State's review mechanisms provide "realistic assurance" that a nonsovereign actor's anticom-

petitive conduct "promotes state policy, rather than merely the party's individual interests." *Patrick*, *supra,* at 100–101; see also *Ticor*, 504 U. S., at 639–640.

The Court has identified only a few constant requirements of active supervision: The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it, see *Patrick*, 486 U. S., at 102–103; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy, see *ibid.*; and the "mere potential for state supervision is not an adequate substitute for a decision by the State," *Ticor*, *supra*, at 638. Further, the state supervisor may not itself be an active market participant. In general, however, the adequacy of supervision otherwise will depend on all the circumstances of a case.

* * *

The Sherman Act protects competition while also respecting federalism. It does not authorize the States to abandon markets to the unsupervised control of active market participants, whether trade associations or hybrid agencies. If a State wants to rely on active market participants as regulators, it must provide active supervision if state-action immunity under *Parker* is to be invoked.

The judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 13–534

NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS, PETITIONER *v.* FEDERAL TRADE COMMISSION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[February 25, 2015]

JUSTICE ALITO, with whom JUSTICE SCALIA and JUSTICE THOMAS join, dissenting.

The Court's decision in this case is based on a serious misunderstanding of the doctrine of state-action antitrust immunity that this Court recognized more than 60 years ago in *Parker* v. *Brown*, 317 U. S. 341 (1943). In *Parker*, the Court held that the Sherman Act does not prevent the States from continuing their age-old practice of enacting measures, such as licensing requirements, that are designed to protect the public health and welfare. *Id.*, at 352. The case now before us involves precisely this type of state regulation—North Carolina's laws governing the practice of dentistry, which are administered by the North Carolina Board of Dental Examiners (Board).

Today, however, the Court takes the unprecedented step of holding that *Parker* does not apply to the North Carolina Board because the Board is not structured in a way that merits a good-government seal of approval; that is, it is made up of practicing dentists who have a financial incentive to use the licensing laws to further the financial interests of the State's dentists. There is nothing new about the structure of the North Carolina Board. When the States first created medical and dental boards, well before the Sherman Act was enacted, they began to staff

them in this way.[1] Nor is there anything new about the suspicion that the North Carolina Board—in attempting to prevent persons other than dentists from performing teeth-whitening procedures—was serving the interests of dentists and not the public. Professional and occupational licensing requirements have often been used in such a way.[2] But that is not what *Parker* immunity is about. Indeed, the very state program involved in that case was unquestionably designed to benefit the regulated entities, California raisin growers.

The question before us is not whether such programs serve the public interest. The question, instead, is whether this case is controlled by *Parker*, and the answer to that question is clear. Under *Parker*, the Sherman Act (and the Federal Trade Commission Act, see *FTC* v. *Ticor Title Ins. Co.*, 504 U. S. 621, 635 (1992)) do not apply to state agencies; the North Carolina Board of Dental Examiners is a state agency; and that is the end of the matter. By straying from this simple path, the Court has not only distorted *Parker*; it has headed into a morass. Determining whether a state agency is structured in a way that militates against regulatory capture is no easy task, and there is reason to fear that today's decision will spawn confusion. The Court has veered off course, and therefore I cannot go along.

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[1] S. White, History of Oral and Dental Science in America 197–214 (1876) (detailing earliest American regulations of the practice of dentistry).

[2] See, *e.g.*, R. Shrylock, Medical Licensing in America 29 (1967) (Shrylock) (detailing the deterioration of licensing regimes in the mid-19th century, in part out of concerns about restraints on trade); Gellhorn, The Abuse of Occupational Licensing, 44 U. Chi. L. Rev. 6 (1976); Shepard, Licensing Restrictions and the Cost of Dental Care, 21 J. Law & Econ. 187 (1978).

I

In order to understand the nature of *Parker* state-action immunity, it is helpful to recall the constitutional landscape in 1890 when the Sherman Act was enacted. At that time, this Court and Congress had an understanding of the scope of federal and state power that is very different from our understanding today. The States were understood to possess the exclusive authority to regulate "their purely internal affairs." *Leisy* v. *Hardin*, 135 U. S. 100, 122 (1890). In exercising their police power in this area, the States had long enacted measures, such as price controls and licensing requirements, that had the effect of restraining trade.[3]

The Sherman Act was enacted pursuant to Congress' power to regulate interstate commerce, and in passing the Act, Congress wanted to exercise that power "to the utmost extent." *United States* v. *South-Eastern Underwriters Assn.*, 322 U. S. 533, 558 (1944). But in 1890, the understanding of the commerce power was far more limited than it is today. See, *e.g.*, *Kidd* v. *Pearson*, 128 U. S. 1, 17–18 (1888). As a result, the Act did not pose a threat to traditional state regulatory activity.

By 1943, when *Parker* was decided, however, the situation had changed dramatically. This Court had held that the commerce power permitted Congress to regulate even local activity if it "exerts a substantial economic effect on interstate commerce." *Wickard* v. *Filburn*, 317 U. S. 111, 125 (1942). This meant that Congress could regulate many of the matters that had once been thought to fall exclusively within the jurisdiction of the States. The new interpretation of the commerce power brought about an expansion of the reach of the Sherman Act. See *Hospital*

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[3] See Handler, The Current Attack on the *Parker* v. *Brown* State Action Doctrine, 76 Colum. L. Rev. 1, 4–6 (1976) (collecting cases).

Building Co. v. *Trustees of Rex Hospital*, 425 U. S. 738, 743, n. 2 (1976) ("[D]ecisions by this Court have permitted the reach of the Sherman Act to expand along with expanding notions of congressional power"). And the expanded reach of the Sherman Act raised an important question. The Sherman Act does not expressly exempt States from its scope. Does that mean that the Act applies to the States and that it potentially outlaws many traditional state regulatory measures? The Court confronted that question in *Parker*.

In *Parker*, a raisin producer challenged the California Agricultural Prorate Act, an agricultural price support program. The California Act authorized the creation of an Agricultural Prorate Advisory Commission (Commission) to establish marketing plans for certain agricultural commodities within the State. 317 U. S., at 346–347. Raisins were among the regulated commodities, and so the Commission established a marketing program that governed many aspects of raisin sales, including the quality and quantity of raisins sold, the timing of sales, and the price at which raisins were sold. *Id.*, at 347–348. The *Parker* Court assumed that this program would have violated "the Sherman Act if it were organized and made effective solely by virtue of a contract, combination or conspiracy of private persons," and the Court also assumed that Congress could have prohibited a State from creating a program like California's if it had chosen to do so. *Id.*, at 350. Nevertheless, the Court concluded that the California program did not violate the Sherman Act because the Act did not circumscribe state regulatory power. *Id.*, at 351.

The Court's holding in *Parker* was not based on either the language of the Sherman Act or anything in the legislative history affirmatively showing that the Act was not meant to apply to the States. Instead, the Court reasoned that "[i]n a dual system of government in which, under the Constitution, the states are sovereign, save only as Con-

gress may constitutionally subtract from their authority, an unexpressed purpose to nullify a state's control over its officers and agents is not lightly to be attributed to Congress." 317 U. S., at 351. For the Congress that enacted the Sherman Act in 1890, it would have been a truly radical and almost certainly futile step to attempt to prevent the States from exercising their traditional regulatory authority, and the *Parker* Court refused to assume that the Act was meant to have such an effect.

When the basis for the *Parker* state-action doctrine is understood, the Court's error in this case is plain. In 1890, the regulation of the practice of medicine and dentistry was regarded as falling squarely within the States' sovereign police power. By that time, many States had established medical and dental boards, often staffed by doctors or dentists,[4] and had given those boards the authority to confer and revoke licenses.[5] This was quintessential police power legislation, and although state laws were often challenged during that era under the doctrine of substantive due process, the licensing of medical professionals easily survived such assaults. Just one year before the enactment of the Sherman Act, in *Dent* v. *West Virginia*, 129 U. S. 114, 128 (1889), this Court rejected such a challenge to a state law requiring all physicians to obtain a certificate from the state board of health attesting to their qualifications. And in *Hawker* v. *New York*, 170 U. S. 189, 192 (1898), the Court reiterated that a law

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[4] Shrylock 54–55; D. Johnson and H. Chaudry, Medical Licensing and Discipline in America 23–24 (2012).

[5] In *Hawker* v. *New York*, 170 U. S. 189 (1898), the Court cited state laws authorizing such boards to refuse or revoke medical licenses. *Id.*, at 191–193, n. 1. See also *Douglas* v. *Noble*, 261 U. S. 165, 166 (1923) ("In 1893 the legislature of Washington provided that only licensed persons should practice dentistry" and "vested the authority to license in a board of examiners, consisting of five practicing dentists").

specifying the qualifications to practice medicine was clearly a proper exercise of the police power. Thus, the North Carolina statutes establishing and specifying the powers of the State Board of Dental Examiners represent precisely the kind of state regulation that the *Parker* exemption was meant to immunize.

II

As noted above, the only question in this case is whether the North Carolina Board of Dental Examiners is really a state agency, and the answer to that question is clearly yes.

- The North Carolina Legislature determined that the practice of dentistry "affect[s] the public health, safety and welfare" of North Carolina's citizens and that therefore the profession should be "subject to regulation and control in the public interest" in order to ensure "that only qualified persons be permitted to practice dentistry in the State." N. C. Gen. Stat. Ann. §90–22(a) (2013).
- To further that end, the legislature created the North Carolina State Board of Dental Examiners "as the agency of the State for the regulation of the practice of dentistry in th[e] State." §90–22(b).
- The legislature specified the membership of the Board. §90–22(c). It defined the "practice of dentistry," §90–29(b), and it set out standards for licensing practitioners, §90–30. The legislature also set out standards under which the Board can initiate disciplinary proceedings against licensees who engage in certain improper acts. §90–41(a).
- The legislature empowered the Board to "maintain an action in the name of the State of North Carolina to perpetually enjoin any person from . . . unlawfully practicing dentistry." §90–40.1(a). It authorized the Board to conduct investigations and to hire legal

counsel, and the legislature made any "notice or statement of charges against any licensee" a public record under state law. §§ 90–41(d)–(g).

- The legislature empowered the Board "to enact rules and regulations governing the practice of dentistry within the State," consistent with relevant statutes. §90–48. It has required that any such rules be included in the Board's annual report, which the Board must file with the North Carolina secretary of state, the state attorney general, and the legislature's Joint Regulatory Reform Committee. §93B–2. And if the Board fails to file the required report, state law demands that it be automatically suspended until it does so. *Ibid.*

As this regulatory regime demonstrates, North Carolina's Board of Dental Examiners is unmistakably a state agency created by the state legislature to serve a prescribed regulatory purpose and to do so using the State's power in cooperation with other arms of state government.

The Board is not a private or "nonsovereign" entity that the State of North Carolina has attempted to immunize from federal antitrust scrutiny. *Parker* made it clear that a State may not "'give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful.'" *Ante,* at 7 (quoting *Parker,* 317 U. S., at 351). When the *Parker* Court disapproved of any such attempt, it cited *Northern Securities Co.* v. *United States*, 193 U. S. 197 (1904), to show what it had in mind. In that case, the Court held that a State's act of chartering a corporation did not shield the corporation's monopolizing activities from federal antitrust law. *Id.*, at 344–345. Nothing similar is involved here. North Carolina did not authorize a private entity to enter into an anticompetitive arrangement; rather, North Carolina *created a state agency* and gave that agency the power to regulate a particular subject affecting public health and

safety.

Nothing in *Parker* supports the type of inquiry that the Court now prescribes. The Court crafts a test under which state agencies that are "controlled by active market participants," *ante*, at 12, must demonstrate active state supervision in order to be immune from federal antitrust law. The Court thus treats these state agencies like private entities. But in *Parker*, the Court did not examine the structure of the California program to determine if it had been captured by private interests. If the Court had done so, the case would certainly have come out differently, because California conditioned its regulatory measures on the participation and approval of market actors in the relevant industry.

Establishing a prorate marketing plan under California's law first required the petition of at least 10 producers of the particular commodity. *Parker*, 317 U. S., at 346. If the Commission then agreed that a marketing plan was warranted, the Commission would "select a program committee *from among nominees chosen by the qualified producers.*" *Ibid.* (emphasis added). That committee would then formulate the proration marketing program, which the Commission could modify or approve. But even after Commission approval, the program became law (and then, automatically) only if it gained the approval of 65 percent of the relevant producers, representing at least 51 percent of the acreage of the regulated crop. *Id.*, at 347. This scheme gave decisive power to market participants. But despite these aspects of the California program, *Parker* held that California was acting as a "sovereign" when it "adopt[ed] and enforc[ed] the prorate program." *Id.*, at 352. This reasoning is irreconcilable with the Court's today.

III

The Court goes astray because it forgets the origin of the

Parker doctrine and is misdirected by subsequent cases that extended that doctrine (in certain circumstances) to private entities. The Court requires the North Carolina Board to satisfy the two-part test set out in *California Retail Liquor Dealers Assn.* v. *Midcal Aluminum, Inc.*, 445 U. S. 97 (1980), but the party claiming *Parker* immunity in that case was not a state agency but a private trade association. Such an entity is entitled to *Parker* immunity, *Midcal* held, only if the anticompetitive conduct at issue was both "'clearly articulated'" and "'actively supervised by the State itself.'" 445 U. S., at 105. Those requirements are needed where a State authorizes private parties to engage in anticompetitive conduct. They serve to identify those situations in which conduct *by private parties* can be regarded as the conduct of a State. But when the conduct in question is the conduct of a state agency, no such inquiry is required.

This case falls into the latter category, and therefore *Midcal* is inapposite. The North Carolina Board is not a private trade association. It is a state agency, created and empowered by the State to regulate an industry affecting public health. It would not exist if the State had not created it. And for purposes of *Parker*, its membership is irrelevant; what matters is that it is part of the government of the sovereign State of North Carolina.

Our decision in *Hallie* v. *Eau Claire*, 471 U. S. 34 (1985), which involved Sherman Act claims against a municipality, not a State agency, is similarly inapplicable. In *Hallie,* the plaintiff argued that the two-pronged *Midcal* test should be applied, but the Court disagreed. The Court acknowledged that municipalities "are not themselves sovereign." 471 U. S., at 38. But recognizing that a municipality is "an arm of the State," *id.*, at 45, the Court held that a municipality should be required to satisfy only the first prong of the *Midcal* test (requiring a clearly articulated state policy), 471 U. S., at 46. That municipalities

are not sovereign was critical to our analysis in *Hallie*, and thus that decision has no application in a case, like this one, involving a state agency.

Here, however, the Court not only disregards the North Carolina Board's status as a full-fledged state agency; it treats the Board less favorably than a municipality. This is puzzling. States are sovereign, *Northern Ins. Co. of N. Y.* v. *Chatham County*, 547 U. S. 189, 193 (2006), and California's sovereignty provided the foundation for the decision in *Parker, supra,* at 352. Municipalities are not sovereign. *Jinks* v. *Richland County*, 538 U. S. 456, 466 (2003). And for this reason, federal law often treats municipalities differently from States. Compare *Will* v. *Michigan Dept. of State Police*, 491 U. S. 58, 71 (1989) ("[N]either a State nor its officials acting it their official capacities are 'persons' under [42 U. S. C.] §1983"), with *Monell* v. *City Dept. of Social Servs., New York*, 436 U. S. 658, 694 (1978) (municipalities liable under §1983 where "execution of a government's policy or custom . . . inflicts the injury").

The Court recognizes that municipalities, although not sovereign, nevertheless benefit from a more lenient standard for state-action immunity than private entities. Yet under the Court's approach, the North Carolina Board of Dental Examiners, a full-fledged state agency, is treated like a private actor and must demonstrate that the State actively supervises its actions.

The Court's analysis seems to be predicated on an assessment of the varying degrees to which a municipality and a state agency like the North Carolina Board are likely to be captured by private interests. But until today, *Parker* immunity was never conditioned on the proper use of state regulatory authority. On the contrary, in *Columbia* v. *Omni Outdoor Advertising, Inc.*, 499 U. S. 365 (1991), we refused to recognize an exception to *Parker* for cases in which it was shown that the defendants had

engaged in a conspiracy or corruption or had acted in a way that was not in the public interest. *Id.*, at 374. The Sherman Act, we said, is not an anticorruption or good-government statute. 499 U. S., at 398. We were unwilling in *Omni* to rewrite *Parker* in order to reach the allegedly abusive behavior of city officials. 499 U. S., at 374–379. But that is essentially what the Court has done here.

III

Not only is the Court's decision inconsistent with the underlying theory of *Parker*; it will create practical problems and is likely to have far-reaching effects on the States' regulation of professions. As previously noted, state medical and dental boards have been staffed by practitioners since they were first created, and there are obvious advantages to this approach. It is reasonable for States to decide that the individuals best able to regulate technical professions are practitioners with expertise in those very professions. Staffing the State Board of Dental Examiners with certified public accountants would certainly lessen the risk of actions that place the well-being of dentists over those of the public, but this would also compromise the State's interest in sensibly regulating a technical profession in which lay people have little expertise.

As a result of today's decision, States may find it necessary to change the composition of medical, dental, and other boards, but it is not clear what sort of changes are needed to satisfy the test that the Court now adopts. The Court faults the structure of the North Carolina Board because "active market participants" constitute "a controlling number of [the] decisionmakers," *ante,* at 14, but this test raises many questions.

What is a "controlling number"? Is it a majority? And if so, why does the Court eschew that term? Or does the Court mean to leave open the possibility that something less than a majority might suffice in particular circum-

stances? Suppose that active market participants constitute a voting bloc that is generally able to get its way? How about an obstructionist minority or an agency chair empowered to set the agenda or veto regulations?

Who is an "active market participant"? If Board members withdraw from practice during a short term of service but typically return to practice when their terms end, does that mean that they are not active market participants during their period of service?

What is the scope of the market in which a member may not participate while serving on the board? Must the market be relevant to the particular regulation being challenged or merely to the jurisdiction of the entire agency? Would the result in the present case be different if a majority of the Board members, though practicing dentists, did not provide teeth whitening services? What if they were orthodontists, periodontists, and the like? And how much participation makes a person "active" in the market?

The answers to these questions are not obvious, but the States must predict the answers in order to make informed choices about how to constitute their agencies.

I suppose that all this will be worked out by the lower courts and the Federal Trade Commission (FTC), but the Court's approach raises a more fundamental question, and that is why the Court's inquiry should stop with an examination of the structure of a state licensing board. When the Court asks whether market participants control the North Carolina Board, the Court in essence is asking whether this regulatory body has been captured by the entities that it is supposed to regulate. Regulatory capture can occur in many ways.[6] So why ask only whether

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[6] See, *e.g.*, R. Noll, Reforming Regulation 40–43, 46 (1971); J. Wilson, The Politics of Regulation 357–394 (1980). Indeed, it has even been

the members of a board are active market participants? The answer may be that determining when regulatory capture has occurred is no simple task. That answer provides a reason for relieving courts from the obligation to make such determinations at all. It does not explain why it is appropriate for the Court to adopt the rather crude test for capture that constitutes the holding of today's decision.

IV

The Court has created a new standard for distinguishing between private and state actors for purposes of federal antitrust immunity. This new standard is not true to the *Parker* doctrine; it diminishes our traditional respect for federalism and state sovereignty; and it will be difficult to apply. I therefore respectfully dissent.

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charged that the FTC, which brought this case, has been captured by entities over which it has jurisdiction. See E. Cox, "The Nader Report" on the Federal Trade Commission vii–xiv (1969); Posner, Federal Trade Commission, Chi. L. Rev. 47, 82–84 (1969).

LEGISLATIVE COUNSEL BUREAU

A TRADITION OF TRUSTED LEGAL SERVICE TO THE CALIFORNIA LEGISLATURE

LEGISLATIVE COUNSEL BUREAU
925 L STREET
SACRAMENTO, CALIFORNIA 95814
TELEPHONE (916) 341-8000
FACSIMILE (916) 341-8020
INTERNET WWW.LEGISLATIVECOUNSEL.CA.GOV

July 15, 2015

Honorable Jerry Hill
Room 5035, State Capitol

ANTITRUST LIABILITY: STATE-ACTION IMMUNITY - #1509722

Dear Senator Hill:

The Sherman Act[1] prohibits anticompetitive conduct including monopolies and agreements in restraint of trade, but states are immune from Sherman Act liability in certain circumstances. In *North Carolina State Bd. of Dental Examiners v. F.T.C.* (2015) 574 U.S. __ [135 S.Ct. 1101, 1110] (hereafter *North Carolina*), the United States Supreme Court held that the State of North Carolina's dental board, which was controlled by active market participants, was not immune from liability under the Sherman Act with respect to its anticompetitive actions because the board was not actively supervised by the state. You have asked us to describe the effect of this holding on the legal standard used by courts to determine when a state agency or board will be granted immunity from liability under the Sherman Act.

1. The Sherman Act

The Sherman Act prohibits agreements in restraint of trade and monopolies, as provided in sections 1 and 2 of the act. Section 1 of the Sherman Act prohibits contracts, combinations, or conspiracies in restraint of trade or commerce, or, in other words, the anticompetitive conduct of a combination of firms. Section 2 of the Sherman Act prohibits monopolies, attempts to monopolize, and combinations or conspiracies to monopolize, or, in other words, the anticompetitive conduct of either a single firm or a combination of firms. Not every combination in restraint of trade is unlawful under the Sherman Act. (*People v. Santa Clara Val. Bowling Proprietors' Ass'n* (1965) 238 Cal.App.2d 225, 233.) Rather, the act proscribes only those restraints that are unreasonable. (*Ibid.*)

[1] 15 U.S.C. §§ 1-7; hereafter the Sherman Act. All further section references are to title 15 of the United States Code.

2. History of state-action immunity prior to the ruling in *North Carolina*

In order to determine the impact of the *North Carolina* decision on the legal standards for state-action immunity, we must first examine United States Supreme Court jurisprudence applying state-action immunity leading up to *North Carolina*.

In *Parker v. Brown* (1943) 317 U.S. 341, 350-351 (hereafter *Parker*), the Supreme Court first addressed the issue of whether the Sherman Act applies to states and concluded that "nothing in the language of the Sherman Act or in its history ... suggests that its purpose was to restrain a state or its officers or agents from activities directed by its legislature." *Parker* involved a suit that challenged a California statute as violating the Sherman Act. The statute in that case established a program for the marketing of agricultural commodities produced in the state by restricting competition among growers and maintaining prices. (*Id.* at p. 346.) The program restricted the trade of raisins by authorizing the establishment of a commission with the authority to approve a petition of raisin producers for the establishment of a prorate marketing plan for raisins. (*Ibid.*) If the commission approved the program and 65 percent of specified raisin producers approved the program, then the program was instituted. (*Id.* at pp. 346-347.) In concluding that the Sherman Act did not prohibit the California program, the court held that state actions are immune from liability under the Sherman Act. (*Id.* at p. 352.) The court reasoned that the California program constituted state action because of the following:

> "It is the state which has created the machinery for establishing the prorate program. Although the organization of a prorate zone is proposed by producers, and a prorate program, approved by the Commission, must also be approved by referendum of producers, *it is the state, acting through the Commission, which adopts the program* and which enforces it with penal sanctions, *in the execution of a governmental policy.* The prerequisite approval of the program upon referendum by a prescribed number of producers is not the imposition by them of their will upon the minority by force of agreement or combination which the Sherman Act prohibits. The state itself exercises its legislative authority in making the regulation and in prescribing the conditions of its application." (*Ibid.*; emphasis added.)

Although the court held that the California program was entitled to state-action immunity, the court limited the application of state-action immunity by cautioning that "a state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful." (*Id.* at p. 351.)

Thus, the holding in *Parker* established that a state entity is immune from Sherman Act liability where it is executing a governmental policy. Following *Parker*, the United States Supreme Court decided a series of cases that developed the application of state-action immunity by examining the nature and extent of state involvement necessary for an action to be considered state action.

In *Goldfarb v. Virginia State Bar* (1975) 421 U.S. 773, 775 (hereafter *Goldfarb*), the United States Supreme Court determined that a minimum fee schedule for lawyers published

by a county bar association and enforced by the Virginia State Bar violated the Sherman Act. In reaching this conclusion, the court ruled that the anticompetitive activity of establishing a minimum fee schedule was not state action because "it cannot fairly be said that the State of Virginia through its Supreme Court Rules required the anticompetitive activities." (*Id.* at p. 790.) Furthermore, the court stated as follows:

> "The fact that the State Bar is a state agency for some limited purposes does not create an antitrust shield that allows it to foster anticompetitive practices for the benefit of its members. [Citation.] The State Bar, by providing that deviation from County Bar minimum fees may lead to disciplinary action, has voluntarily joined in what is essentially a private anticompetitive activity, and in that posture cannot claim it is beyond the reach of the Sherman Act. [Citation.]" (*Id.* at pp. 791-792; fns. omitted.)

Thus, the holding in *Goldfarb* clarified that actions by a purported state agency are, nevertheless, subject to the prohibitions of the Sherman Act where those actions in essence constitute private anticompetitive activity.

However, in *Bates v. State Bar of Arizona* (1977) 433 U.S. 350, 362-363 (hereafter *Bates*), the United States Supreme Court held that the Arizona Supreme Court's imposition and enforcement of a disciplinary rule that restricted advertising did not violate the Sherman Act because the action qualified as exempt state action under *Parker, supra*. The court reached this conclusion after finding that the "disciplinary rules reflect a clear articulation of the State's policy with regard to professional behavior. Moreover, as the instant case shows, the rules are subject to pointed re-examination by the policymaker the Arizona Supreme Court in enforcement proceedings." (*Bates, supra,* at p. 362.) The court deemed "it significant that the state policy is so clearly and affirmatively expressed and that the State's supervision is so active." (*Ibid.*) Thus, *Bates* clarified that it is relevant to a grant of state-action immunity whether the anticompetitive actions represent a clear articulation of the state's policy and are subject to a pointed re-examination by the state Supreme Court.

In *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.* (1980) 445 U.S. 97, 99 (hereafter *Midcal*), the United States Supreme Court examined a California statute that required all wine producers, wholesalers, and rectifiers to file fair trade contracts or price schedules with the state, and prohibited wine merchants from selling wine to a retailer at a price other than a price set in such an effective price schedule or fair trade contract. Under the statute, California had no direct control over, and did not review the reasonableness of, the prices set by wine dealers. (*Id.* at p. 100.) In determining whether the state's involvement in the above program was sufficient to establish antitrust immunity under *Parker, supra,* the court examined its preceding decisions and held that two standards must be met for state-action immunity to apply: "First, the challenged restraint must be 'one clearly articulated and affirmatively expressed as state policy'; second, the policy must be 'actively supervised' by the State itself." (*Midcal, supra,* at p. 105, citing *City of Lafayette, La. v. Louisiana Power & Light Co.* (1978) 435 U.S. 389, 410 (hereafter *City of Lafayette*).) Ultimately, the court in *Midcal* found that the California program failed to meet the second requirement for state-action immunity because the state "neither establishes prices nor reviews the

reasonableness of the price schedule; nor does it regulate the terms of fair trade contracts. The State does not monitor market conditions or engage in any 'pointed reexamination' of the program. [Fn. omitted.]" (*Midcal, supra,* at pp. 105-106.) In sum, the court in *Midcal* expressly imposed two requirements for state-action immunity to apply: (1) a clearly articulated and affirmatively expressed state policy, and (2) active supervision of that policy by the state.

Subsequently, in *Hoover v. Ronwin* (1984) 466 U.S. 558 (hereafter *Hoover*), the United States Supreme Court examined whether state-action immunity applied to a committee appointed by the Arizona Supreme Court to administer the state bar examination. The court reiterated *Midcal's* two-part test and stated that when "the conduct at issue is in fact that of the state legislature or supreme court, we need not address the issues of 'clear articulation' and 'active supervision.'" (*Hoover, supra,* at p. 569.) However, the court articulated that when the conduct is that of a "nonsovereign state representative," it must be pursuant to a "'clearly articulated and affirmatively expressed state policy' to replace competition with regulation," and the degree of state supervision is also "relevant to the inquiry." (*Ibid.*) Applying these standards, the court held that the actions of the committee were entitled to state-action immunity because the Arizona Supreme Court "retained strict supervisory powers and ultimate full authority over [the committee's] actions." (*Id.* at p. 572.) In the court's view, the Arizona Supreme Court retained sufficient supervision and authority over the committee by specifying the subjects to be tested on the bar exam and the general qualifications required for bar applicants, approving the committee's grading formula, and, most significantly, making the final decision to grant or deny admission to the bar and providing individualized review of bar examinations when requested. (*Id.* at pp. 572-573.) In sum, *Hoover* confirmed that a "nonsovereign state representative" is entitled to state-action immunity when its actions meet *Midcal's* clear articulation requirement and emphasized that the degree of state supervision is also "relevant to the inquiry."

The court in *Town of Hallie v. City of Eau Claire* (1985) 471 U.S. 34, 44-46 (hereafter *Town of Hallie*) addressed the application of the state immunity doctrine with respect to municipalities. Distinguishing municipal actors from state actors, the court applied only the first *Midcal* requirement. Thus, the court held that municipalities are immune from Sherman Act liability when acting pursuant to a clearly articulated and affirmatively expressed state policy to displace competition, but need not show active state supervision to maintain their state-action exemption. (*Town of Hallie, supra,* at pp. 40 & 46.) In deciding to apply only the first *Midcal* requirement, the court distinguished municipalities from both the state and private parties, explaining that municipalities "are not beyond the reach of antitrust laws by virtue of their status because they are not themselves sovereign." (*Town of Hallie, supra,* at p. 38.) In making this distinction, the court emphasized that municipalities differ from private parties because there is a real danger that private parties will act to further their own interests over the interests of the state. The court reasoned that with municipalities there is "little or no danger" of this occurring. (*Id.* at p. 47.) In sum, the ruling in *Town of Hallie* stands for the proposition that, to be entitled to state-action immunity, municipalities need only meet the first *Midcal* requirement of acting pursuant to a clearly articulated and affirmatively expressed state policy to displace competition.

The United States Supreme Court examined whether state-action immunity applied to protect private physicians with respect to their anticompetitive conduct on a hospital's peer-review committee that the hospital was under a statutory obligation to establish and review in *Patrick v. Burget* (1988) 486 U.S. 94, 102 (hereafter *Patrick*). The court determined that both *Midcal* requirements must be satisfied for the anticompetitive actions of private parties to be deemed state action and shielded from antitrust laws. (*Patrick, supra,* at p. 100.) After finding that the actions of the peer review committees did not meet the active supervision prong, the court declined to consider the clear articulation requirement and held that state-action immunity did not apply. (*Ibid.*) In discussing active supervision, the court stated that the requirement "stems from the recognition that '[w]here a private party is engaging in anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the governmental interests of the State.' [Citation.]" (*Ibid.*) Therefore, the court determined that there was a danger that the private physicians on a hospital peer review committee were furthering their own private interests because the state did not have the ability to review the committee's decisions regarding hospital privileges to determine whether those decisions comported with state regulatory policy and correct abuses. (*Id.* at pp. 101-102.) In other words, according to the court in *Patrick*, both *Midcal* requirements apply to the anticompetitive actions of private parties because of the real danger that private parties will act to further their own interests.

In *City of Columbia v. Omni Outdoor Advertising, Inc.* (1991) 499 U.S. 365, 368-369 (hereafter *City of Columbia*), a private billboard company argued that the city's billboard ordinances were the result of an anticompetitive conspiracy between city officials and a private local billboard company, whereby the city colluded with the local billboard company to pass local ordinances intended to restrict competition from out-of-town companies. The United States Supreme Court rejected the argument that a conspiracy exception exists for *Parker's* state-action exemption "'where politicians or political entities are involved as conspirators' with private actors in the restraint of trade." (*City of Columbia, supra,* at p. 374.) In reaching this conclusion, the court cautioned that "[t]his does not mean, of course, that the States may exempt *private* action from the scope of the Sherman Act; we in no way qualify the well-established principal that 'a state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring their action is unlawful.'" (*Id.* at p. 379, citing *Parker, supra,* 317 U.S. at p. 351; emphasis in original.) Additionally, the court stated that "with the possible market participant exception, *any* action that qualifies as state action is *'ipso facto* ... exempt from the operation of the antitrust laws.'" (*Id.* at p. 379, citing *Hoover, supra,* 466 U.S. at p. 568; emphasis in original.) Therefore, in *City of Columbia* the Supreme Court left open a "possible" exception from state-action immunity in instances where the state is acting as a market participant.

Next, the United States Supreme Court in *F.T.C. v. Ticor Title Ins. Co.* (1992) 504 U.S. 621, 632 (hereafter *Ticor*) considered whether the mere existence of a state regulatory program for setting insurance rates, if staffed, funded, and empowered by law, satisfied the active supervision requirement in *Midcal.* The court concluded that the regulatory program did not meet the active supervision requirement because "The mere potential for state supervision is not an adequate substitute for a decision by the State." (*Ticor, supra,* at p. 638.)

The court explained that "[w]here prices or rates are set as an initial matter by private parties, subject only to a veto if the State chooses to exercise it, the party claiming the immunity must show that state officials have undertaken the necessary steps to determine the specifics of the price-fixing or ratesetting scheme." (*Ibid.*)[2] Accordingly, the holding in *Ticor* emphasized that the mere potential for state supervision by itself is not adequate for a finding of active state supervision.

Recently, in *F.T.C. v. Phoebe Putney Health System, Inc.* (2013) 568 U.S. __ [133 S.Ct. 1003] (hereafter *Phoebe Putney*), the United States Supreme Court addressed the question of whether a "substate governmental entity" (*id.* at p. 1010) in the form of a hospital authority created by the state legislature to "exercise public and essential governmental functions" (*id.* at p. 1007) is entitled to state-action immunity for permitting acquisitions that substantially lessened competition.[3] The court granted certiorari to answer two questions: (1) whether the hospital authorities acted pursuant to a clearly articulated and affirmatively expressed state policy to displace competition; and (2) if so, whether state-action immunity was nonetheless inapplicable as a result of the hospital authority's "minimal participation" and "limited supervision" of the hospitals' acquisitions and operations. (*Id.* at p. 1009.) The court answered the first question in the negative finding that "[g]rants of general corporate power that allow substate governmental entities to participate in a competitive marketplace" do not clearly articulate or affirmatively express a state policy to displace competition. (*Id.* at p. 1012.) Because the court concluded that the hospital authorities did not act pursuant to a clearly articulated and affirmatively expressed state policy to displace competition, the court did not reach the second question. (*Id.* at p. 1009.) Accordingly, the United States Supreme Court left open the question of whether *Midcal's* active supervision requirement applies to "substate governmental entities." Additionally, in a footnote, the court declined to answer an amicus curiae question of whether a "market participant" exception to state-action immunity applied because the argument was not raised in the lower courts. (*Phoebe Putney, supra,* at p. 1010, fn. 4.) However, the court recognized that *City of Columbia, supra,* left open the possibility of a market participant exception. (*Phoebe Putney, supra,* at p. 1010.) Therefore, the court in *Phoebe Putney* left open the question of whether a "substate governmental agency" is required to be actively supervised by the state to be entitled to state-action immunity, and recognized that there is a possible market participant exception to state-action immunity.

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[2] In *Ticor*, the potential for state supervision was not enough because the rates became effective unless they were rejected by the state within a set time. Furthermore, the facts of that case revealed that, at most, the rate filings were checked for mathematical accuracy and some were unchecked altogether. (*Ibid.*)

[3] The hospital authorities had the power, among other things, to acquire and operate hospitals and other public health facilities. (*Id.* at p. 1008.)

2.1 Summary of pre-*North Carolina* case law

The United States Supreme Court jurisprudence leading up to *North Carolina, supra,* 135 S.Ct. 1101, set forth varying requirements for state-action immunity that largely depend upon the character of the entity engaging in the anticompetitive conduct. Under the pre-*North Carolina* jurisprudence, the application of state-action immunity depends upon whether the entity engaging in the anticompetitive activity is the state, a municipality, a private party, or an agency delegated authority by the state. A state acting in its sovereign capacity is automatically exempt from the operation of antitrust laws. (See *Parker, supra,* 317 U.S. at p. 352; *Hoover, supra,* 466 U.S. at pp. 567-568.)[4] A municipality is entitled to state-action immunity if it engages in anticompetitive activities pursuant to a clearly articulated and affirmatively expressed state policy to displace competition. (*Town of Hallie, supra,* 471 U.S. at p. 44.) A private party is entitled to state-action immunity only if its anticompetitive conduct meets both the clear articulation and active supervision prongs of the *Midcal* test. (*Patrick, supra,* 486 U.S. at p. 100.) Lastly, the pre-*North Carolina* jurisprudence established that an entity that has been delegated state powers, and thus constitutes a state agency for limited purposes, is not automatically entitled to state-action immunity with regard to its anticompetitive activities. (*Goldfarb, supra,* 421 U.S. at pp. 791-792.) However, that jurisprudence provided less defined standards for determining when such an entity is entitled to state-action immunity.

For instance, in *Hoover*, the United States Supreme Court stated that when the activity is that of a "nonsovereign state representative," such as a committee appointed by a state supreme court, the activity must be conducted pursuant to a clearly articulated state policy to displace competition and the degree of the state's supervision of the activity is also "relevant to the inquiry." (*Hoover, supra,* 466 U.S. at p. 569.) Whereas, in *Phoebe Putney*, the court left open the question of whether *Midcal's* active supervision requirement applies to "substate governmental entities," such as hospital authorities cloaked by the state legislature with governmental authority. (*Phoebe Putney, supra,* 133 S.Ct. at pp. 1009-1010.) Additionally, in *City of Columbia*, the court noted the possibility that a state acting as a market participant rather than a regulator may not be ipso facto exempt under the state-action doctrine, and *Phoebe Putney* also recognized the potential application of the market participant exception to state-action immunity. (*Id.* at p. 1010, fn. 4; *City of Columbia, supra,* 499 U.S. at p. 379.) However, prior to *North Carolina*, no United States Supreme Court case had actually applied a market participant exception to deny state-action immunity to a state agency that engages in anticompetitive conduct.[5]

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[4] "[W]hen a state legislature adopts legislation, its actions constitute those of the State, [citation] and ipso facto are exempt from the operation of the antitrust laws." (*Hoover, supra,* at pp. 567-568.)

[5] In its discussion of states acting as market participants in *City of Columbia*, the United States Supreme Court referenced *Union Pacific Railroad Co. v. United States* (1941) 313 U.S. 450, (continued...)

Thus, the classification of an entity will guide a court in determining which, if any, of *Midcal's* clear articulation and active supervision requirements must be satisfied to entitle the entity to state-action immunity. In this regard, the pre-*North Carolina* jurisprudence provides guidance concerning what is required to satisfy *Midcal's* clear articulation and active supervision requirements.

Regarding clear articulation, the United States Supreme Court has stated that, although compulsion is often the best evidence, "a state policy that expressly *permits*, but does not compel, anticompetitive conduct may be 'clearly articulated' within the meaning of *Midcal*." (*Southern Motor Carriers Rate Conference, Inc. v. United States* (1985) 471 U.S. 48, 61-62; emphasis in original; hereafter *Southern Motor*.) It is not necessary for the state to explicitly require the anticompetitive activity because it can be presumed that anticompetitive effects logically result from broad authority to regulate. (*Town of Hallie, supra*, 471 U.S. at p. 42.) As long as the state statutes are not neutral[6] and "[contemplate] the kind of action complained of," this is sufficient to satisfy the clear articulation requirement of the state-action test. (*Id.* at p. 44.) Therefore, the clear articulation requirement is satisfied "if suppression of competition is the 'foreseeable result' of what the statute authorizes." (*City of Columbia, supra*, 499 U.S. at p. 373.)[7]

(...continued)
where the court held Kansas City liable for certain anticompetitive activity that it engaged in in its capacity as an owner and operator of a wholesale produce market. (*City of Columbia, supra*, at p. 375.) However, other than this brief discussion in *City of Columbia*, there has been no further elaboration by the United States Supreme Court concerning the application of the market participant exception.

Prior to *North Carolina*, several federal circuit courts of appeal were split regarding the recognition of a market participant exception. Some federal circuit courts of appeal recognized a market participant exception (see *A.D. Bedell Wholesale Co. v. Philip Morris Inc.* (3rd Cir. 2001) 263 F.3d 239, 265, fn. 55; *VIBO Corp. v. Conway* (6th Cir. 2012) 669 F.3d 675, 687; and *Washington State Electrical Contractors Ass'n. v. Forrest* (9th Cir. 1991) 930 F.2d 736, 737), and some did not (see *SSC Corp. v. Town of Smithtown* (2nd Cir. 1995) 66 F.3d 502, 517; *Limeco v. Division of Lime of Mississippi Dept. of Agriculture & Commerce* (5th Cir. 1985) 778 F.2d 1086, 1087; and *Paragould Cablevision v. City of Paragould* (8th Cir. 1991) 930 F.2d 1310, 1312-1313).

[6] The United States Supreme Court has held that a neutral home rule amendment to a state constitution that provides a municipal government with general authority to govern local affairs does not constitute "clear articulation." (*Community Communications Co. v. Boulder* (1982) 455 U.S. 40, 51-52.)

[7] For example, in *City of Columbia*, the suppression of competition was a foreseeable result of a state statute that authorized municipalities to regulate the use of land and the construction of buildings and other structures within their boundaries. (*Id.* at. pp. 370 & 373.) However, in *Phoebe Putney*, the suppression of competition was not a foreseeable result of a neutral grant of general corporate powers to a substate governmental entity. (*Phoebe Putney, supra*, 133 S. Ct. at pp. 1011-1012.)

(continued...)

Regarding active supervision, this requirement stems from the recognition that "Where a private party is engaging in the anticompetitive activity, there is a real danger that he is acting to further his own interests, rather than the government interests of the State." (*Town of Hallie, supra,* 471 U.S. at p. 47.) As such, "The active supervision prong of the *Midcal* test requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy." (*Patrick, supra,* 486 U.S. at p. 101.) Further, potential state supervision does not constitute active state supervision. (*Ticor, supra,* 504 U.S. at p. 638.)

In sum, the first prong of the *Midcal* test for state-action immunity is met if suppression of competition is the foreseeable result of a state statute. And the second prong of the *Midcal* test for state-action immunity is met if state officials have and exercise power to review anticompetitive decisions and disapprove those that fail to accord with state policy. In other words, the state supervision must be active rather than a mere potential for supervision. However, the *North Carolina* decision described below further elucidated when and how the *Midcal* test would apply with regard to an entity to which the state has delegated regulatory authority.

3. The *North Carolina* decision

The United States Supreme Court in *North Carolina* specifically addressed the issue of whether a state dental board controlled by active market participants that engaged in anticompetitive conduct was entitled to state-action immunity from liability under the Sherman Act. In that case, the entity claiming state-action immunity was the North Carolina State Board of Dental Examiners (SBDE), which was established as "'the agency of the State for the regulation of the practice of dentistry'" whose "principal duty is to create, administer, and enforce a licensing system for dentists." (*North Carolina, supra,* 135 S.Ct. at p. 1107.) The SBDE's duties included the authority to file suit to enjoin the unlawful practice of dentistry and the SBDE was authorized to promulgate rules and regulations governing the practice of dentistry in the state, provided those mandates were not inconsistent with state law and were approved by the North Carolina Rules Review Commission, whose members are appointed by the state legislature. (*Id.* at p. 1108.) The SBDE was comprised of eight members, six of whom were required to be licensed dentists engaged in the active practice of dentistry and to be elected by other licensed dentists in North Carolina through an election conducted by the SBDE. (*Ibid.*)[8] There was no mechanism for the removal of an elected member of the SBDE by a public official, and the SBDE members were required to swear an oath of office and to comply with the state's Administrative Procedure Act and open meeting laws. (*Ibid.*)

(...continued)

[8] The other two SBDE members were a licensed and practicing dental hygienist elected by other licensed hygienists and a "consumer" appointed by the Governor. (*Ibid.*)

The anticompetitive activity at issue in *North Carolina* was the SBDE's issuance of cease-and-desist letters on its official letterhead to nondentist teeth whitening service providers and product manufacturers that directed the recipients to cease "all activity constituting the practice of dentistry." (*North Carolina, supra,* 135 S.Ct. at p. 1108.)[9] At the time, neither North Carolina's statutory definition of the practice of dentistry nor the SBDE's official rules and regulations defined the practice of dentistry as specifically including, or not including, teeth whitening. (*Id.* at p. 1116.)

The court in *North Carolina* held that the SBDE was a nonsovereign actor controlled by active market participants, and as such "enjoys *Parker* immunity only if it satisfies two requirements: 'first that the "challenged restraint ... be one clearly articulated and affirmatively expressed as state policy," and second that the "policy ... be actively supervised by the State."' [Citations.]" (*North Carolina, supra,* 135 S.Ct. at p. 1110.) The court and the parties assumed that the clear articulation requirement was satisfied, but the court concluded that "the Board did not receive active supervision by the State when it interpreted the Act as addressing teeth whitening and when it enforced that policy by issuing cease-and-desist letters to nondentist teeth whiteners." (*Ibid.*)

The court explained that automatic state-action immunity does not apply when the state "delegates control over a market to a *non-sovereign actor,*" which is "one whose conduct does not automatically qualify as that of the sovereign State itself," and "[s]tate agencies are not simply by their governmental character sovereign actors for purposes of state-action immunity." (*North Carolina, supra,* 135 S.Ct. at pp. 1110-1111; emphasis added.) According to the court, a limitation on state-action immunity is "most essential when the State seeks to delegate its regulatory power to active market participants." (*Id.* at p. 1111.) Therefore, the court determined that state-action immunity "requires that the anticompetitive conduct of nonsovereign actors, especially those authorized by the State to regulate their own profession, result from procedures that suffice to make it the State's own." (*Ibid.*)

In deciding to apply both *Midcal* requirements, the court acknowledged that *Town of Hallie, supra,* exempted municipalities from the active supervision requirement. (*North Carolina, supra,* 135 S.Ct. at p. 1112.) The court distinguished *Town of Hallie* by explaining that active market participants "ordinarily have none of the features justifying the narrow exception" for municipalities, which are electorally accountable and exercise "a wide range of governmental powers across different economic spheres, substantially reducing the risk that it would pursue private interests while regulating any single field." (*North Carolina, supra,* at pp. 1112-1113.) Having made this distinction, the court concluded that "a state board on which *a controlling number of decisionmakers* are active market participants in the occupation the

[9] At the time the SBDE issued the cease-and-desist letters, several of its dentist members "earned substantial fees" for performing teeth whitening services. (*Ibid.*)

board regulates must satisfy *Midcal's* active supervision requirement in order to invoke state-action antitrust immunity." (*Id.* at p. 1114; emphasis added.)[10]

In applying the active supervision requirement, the court found no evidence of any decision by the state to initiate or concur with the SBDE's actions against nondentists.[11] Instead, the court found that the SBDE relied upon cease-and-desist letters "rather than any powers at its disposal that would invoke oversight by a *politically accountable official.*" (*Ibid.*; emphasis added.) The court then went on to describe general standards for active supervision, but cautioned that any inquiry regarding active supervision is "flexible and context-dependent." (*Ibid.*) In this regard, the court described the standards for active supervision as follows:

> "Active supervision need not entail day-to-day involvement in an agency's operations or micromanagement of its every decision. Rather, the question is whether the State's review mechanisms provide 'realistic assurance' that a nonsovereign actor's anticompetitive conduct 'promotes state policy, rather than merely the party's individual interests.' [Citations.] [¶] The Court has identified only a few constant requirements of active supervision: The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it [citation]; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy [citation]; and the 'mere potential for state supervision is not an adequate substitute for a decision by the State' [citation]. Further, the state supervisor may not itself be an active market participant. In general, however, the adequacy of supervision otherwise will depend on all the circumstances of a case." (*Id.* at pp. 1116-1117.)

In summary, the court found that active supervision is a fact-specific inquiry that requires, at a minimum, review of an anticompetitive decision by a state supervisor who is not an active market participant and who has the power to veto or modify the anticompetitive decision, which requires an actual decision by the state, rather than the mere potential for a decision.

The dissent in *North Carolina* pointed out several ambiguities in the court's opinion and noted that "it is not clear what sort of changes are needed to satisfy the test that the Court now adopts." (*North Carolina, supra,* 135 S.Ct. at p. 1123 (dis. opn. of Alito, J.).) For

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[10] Because the case did not present a claim for money damages, the court left open the question of whether under some circumstances state agency officials, including board members, may enjoy immunity from damages liability. However, the court provided that "the States may provide for the defense and indemnification of agency members in the event of litigation." (*Id.* at p. 1115.)

[11] Because the SBDE did not contend that its anticompetitive conduct was actively supervised by the state, there was no evidence to review and the court did not review any specific supervisory systems. (*North Carolina, supra,* 135 S.Ct. at p. 1116.)

example, the dissent questioned at what point active market participants constitute a "controlling number of [the] decisionmakers" of a state agency to invoke the active supervision requirement. (*Ibid.*) The dissent posited whether a controlling number is a majority, or if something less than a majority would suffice, such as where active market participants constitute a powerful voting bloc. (*Ibid.*) The dissent also questioned who constitutes an active market participant by postulating the following:

> "If Board members withdraw from practice during a short term of service but typically return to practice when their terms end, does that mean that they are not active market participants during their period of service?
>
> "What is the scope of the market in which a member may not participate while serving on the board? Must the market be relevant to the particular regulation being challenged or merely to the jurisdiction of the entire agency? Would the result in the present case be different if a majority of the Board members, though practicing dentists, did not provide teeth whitening services? What if they were orthodontists, periodontists, and the like? And how much participation makes a person 'active' in the market?" (*Ibid.*)

Ultimately, the dissent conceded that "The answers to these questions are not obvious, but the States must predict the answers in order to make informed choices about how to constitute their agencies." (*Ibid.*)

4. Legal standards for grant of state-action immunity

Based on the foregoing, it is our opinion that a court would apply the following legal standards to a claim for state-action immunity from the Sherman Act in light of the United States Supreme Court's decision in *North Carolina*.

4.1 State acting as sovereign

Actions of the state acting as sovereign, such as legislation or decisions of the state supreme court acting legislatively, *ipso facto* are exempt from the Sherman Act. (*North Carolina, supra*, 135 S.Ct. at p. 1110.)

4.2 Municipalities

Municipalities are entitled to state-action immunity if their anticompetitive conduct is pursuant to a clearly articulated and affirmatively expressed state policy to displace competition. (*City of Lafayette, supra*, 435 U.S. at pp. 410 & 413; *Town of Hallie, supra*, 471 U.S. at p. 44.)

4.3 Private parties

Private parties delegated authority by the state are entitled to state-action immunity only if their anticompetitive conduct is pursuant to a clearly articulated and affirmatively expressed state policy to displace competition, and the policy is actively supervised by the State. (*Patrick, supra*, 486 U.S. at p. 100.)

4.4 State agencies not controlled by active market participants

Although *North Carolina* did not specifically address state agencies not controlled by active market participants, the court did state that "State agencies are not simply by their governmental character sovereign actors for purposes of state-action immunity." (*North Carolina, supra,* 135 S.Ct. at p. 1111.) As such, the anticompetitive actions of a state agency are not automatically entitled to state-action immunity, unless they result from procedures that suffice to make it the state's own action. (*Ibid.*) Whether those procedures include both of *Midcal's* clear articulation and active supervision requirements was not specifically addressed by the court in *North Carolina;* however, the court reiterated that only the first requirement applies to municipalities because they are electorally accountable and there is minimal risk of municipal officers pursuing private, nonpublic aims. (*North Carolina, supra,* 135 S.Ct. at pp. 1112-1113.) Therefore, it is our opinion that, like municipalities, state agencies not controlled by active market participants are entitled to state-action immunity if their anticompetitive actions satisfy only *Midcal's* clear articulation requirement, as long as their actions pose minimal risk of furthering private interests over those of the state.

4.5 State agencies controlled by active market participants

A state agency or board on which "a controlling number of decisionmakers are active market participants" in the occupation that the state agency regulates is entitled to state-action immunity if it acts pursuant to a clearly articulated and affirmatively expressed state policy to displace competition, and is actively supervised by the state. (*North Carolina, supra,* 135 S.Ct. at p. 1114.) It is not clear what "a controlling number of decisionmakers" entails, but in our view, the more likely it is that the members will be able to control decisions of the agency or board, the more likely it is that a court will find them to constitute a "controlling number." For instance, a majority of the voting members would almost certainly be considered a controlling number, but a court could consider an influential voting bloc to also constitute a controlling number. (*Id.* at p. 1123.) Likewise, it is unclear what it means to be an "active market participant." (*Ibid.*) At the very least we think an active market participant would include a person currently licensed and practicing in the field being regulated by the state agency or board because of the greater likelihood that such a person will be influenced by private, rather than public, interests. Ultimately, we think a court would make such a determination on a contextual basis using a spectrum analysis. For example, at one end of the spectrum would be a person with no connection to the industry being regulated, and at the other end of the spectrum would be a person currently practicing in the precise industry being regulated. In our view, the closer a person's ties are to the industry being regulated, the greater the likelihood that the person will act pursuant to private rather than public interests, and the more likely a court would be to consider them an active market participant.

4.6 Clear articulation

A state policy to displace competition is clearly articulated when the displacement of competition is "the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature. In that scenario, the State must have foreseen and implicitly

endorsed the anticompetitive effects as consistent with its policy goals. [Citation.]" (*North Carolina, supra,* 135 S.Ct. at p. 1112.) Although "compulsion is often the best evidence that the State has a clearly articulated and affirmatively expressed policy to displace competition," it is not required. (*Southern Motor, supra,* 471 U.S. at p. 62.) As long as the state statute providing authorization is not neutral and "contemplate[s] the kind of action complained of," in our view, a court would find it sufficient to satisfy the clear articulation requirement of the state-action test. (*Town of Hallie, supra,* 471 U.S. at pp. 43-44.)

4.7 Active state supervision

Any inquiry regarding active state supervision is "flexible and context-dependent" and should focus on whether the state's "review mechanisms provide 'realistic assurance' that a nonsovereign actor's anticompetitive conduct 'promotes state policy, rather than merely the party's individual interests.' [Citations.]" (*North Carolina, supra,* 135 S.Ct. at p. 1116.) As such, we think a court would analyze the presence of active supervision on a spectrum such that the more the state supervision assures the promotion of state over private interests, the more likely a court would be to find sufficient active supervision for purposes of state-action immunity. However, it is our opinion that a court would require, at a minimum, that the three criteria specified in *North Carolina* be satisfied for a finding of active supervision: (1) the anticompetitive decision is reviewed by a state supervisor;[12] (2) the state supervisor has the actual power, rather than the mere potential, to veto or modify an anticompetitive decision; and (3) the state supervisor is not an active market participant. (*Id.* at pp. 1116-1117.)

5. Conclusion

Ultimately, the United States Supreme Court has a "settled policy of giving concrete meaning to the general language of the Sherman Act by a process of case-by-case adjudication of specific controversies." (*Cantor v. Detroit Edison Co.* (1976) 428 U.S. 579, 603; hereafter *Cantor.*)[13] Therefore, we cannot affirmatively provide every instance in which a

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[12] In finding no evidence of active supervision, the court noted that SBDE's anticompetitive actions did not invoke oversight by a "politically accountable official." (*Ibid.*) Therefore, one could argue that the state supervisor should be politically accountable; however, the minimum requirements articulated by the court for active supervision do not specify this requirement. Accordingly, although perhaps not required, supervision by a politically accountable official may influence a court to view the state's supervision on the side of the spectrum that favors a grant of state-action immunity.

[13] In *Cantor,* the court rejected the application of "a simple rule than can easily be applied in any case in which a state regulatory agency approves a proposal and orders a regulated company to comply with it." (*Ibid.*)

court would grant state-action immunity. However, it is our opinion that, in light of the decision in *North Carolina State Board of Dental Examiners v. Federal Trade Commission* (2015) 574 U.S. __ [135 S.Ct. 1101], a court would use the legal standards described above to decide whether to grant state-action immunity from Sherman Act liability.

Very truly yours,

Diane F. Boyer-Vine
Legislative Counsel

Joanna E. Varner

By
Joanna E. Varner
Deputy Legislative Counsel

JEV:sjk

TO BE PUBLISHED IN THE OFFICIAL REPORTS

OFFICE OF THE ATTORNEY GENERAL
State of California

KAMALA D. HARRIS
Attorney General

OPINION	:	No. 15-402
of	:	September 10, 2015
KAMALA D. HARRIS Attorney General	:	
SUSAN DUNCAN LEE Deputy Attorney General	:	

THE HONORABLE JERRY HILL, MEMBER OF THE STATE SENATE, has requested an opinion on the following question:

What constitutes "active state supervision" of a state licensing board for purposes of the state action immunity doctrine in antitrust actions, and what measures might be taken to guard against antitrust liability for board members?

CONCLUSIONS

"Active state supervision" requires a state official to review the substance of a regulatory decision made by a state licensing board, in order to determine whether the decision actually furthers a clearly articulated state policy to displace competition with regulation in a particular market. The official reviewing the decision must not be an active member of the market being regulated, and must have and exercise the power to approve, modify, or disapprove the decision.

Measures that might be taken to guard against antitrust liability for board members include changing the composition of boards, adding lines of supervision by state officials, and providing board members with legal indemnification and antitrust training.

ANALYSIS

In *North Carolina State Board of Dental Examiners v. Federal Trade Commission*,[1] the Supreme Court of the United States established a new standard for determining whether a state licensing board is entitled to immunity from antitrust actions.

Immunity is important to state actors not only because it shields them from adverse judgments, but because it shields them from having to go through litigation. When immunity is well established, most people are deterred from filing a suit at all. If a suit is filed, the state can move for summary disposition of the case, often before the discovery process begins. This saves the state a great deal of time and money, and it relieves employees (such as board members) of the stresses and burdens that inevitably go along with being sued. This freedom from suit clears a safe space for government officials and employees to perform their duties and to exercise their discretion without constant fear of litigation. Indeed, allowing government actors freedom to exercise discretion is one of the fundamental justifications underlying immunity doctrines.[2]

Before *North Carolina Dental* was decided, most state licensing boards operated under the assumption that they were protected from antitrust suits under the state action immunity doctrine. In light of the decision, many states—including California—are reassessing the structures and operations of their state licensing boards with a view to determining whether changes should be made to reduce the risk of antitrust claims. This opinion examines the legal requirements for state supervision under the *North Carolina Dental* decision, and identifies a variety of measures that the state Legislature might consider taking in response to the decision.

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[1] *North Carolina State Bd. of Dental Examiners v. F. T. C.* (2015) ___ U.S. ___, 135 S. Ct. 1101 (*North Carolina Dental*).

[2] See *Mitchell v. Forsyth* (1985) 472 U.S. 511, 526; *Harlow v. Fitzgerald* (1982) 457 U.S. 800, 819.

I. *North Carolina Dental* Established a New Immunity Standard for State Licensing Boards

A. The *North Carolina Dental* Decision

The North Carolina Board of Dental Examiners was established under North Carolina law and charged with administering a licensing system for dentists. A majority of the members of the board are themselves practicing dentists. North Carolina statutes delegated authority to the dental board to regulate the practice of dentistry, but did not expressly provide that teeth-whitening was within the scope of the practice of dentistry.

Following complaints by dentists that non-dentists were performing teeth-whitening services for low prices, the dental board conducted an investigation. The board subsequently issued cease-and-desist letters to dozens of teeth-whitening outfits, as well as to some owners of shopping malls where teeth-whiteners operated. The effect on the teeth-whitening market in North Carolina was dramatic, and the Federal Trade Commission took action.

In defense to antitrust charges, the dental board argued that, as a state agency, it was immune from liability under the federal antitrust laws. The Supreme Court rejected that argument, holding that a state board on which a controlling number of decision makers are active market participants must show that it is subject to "active supervision" in order to claim immunity.[3]

B. State Action Immunity Doctrine Before *North Carolina Dental*

The Sherman Antitrust Act of 1890[4] was enacted to prevent anticompetitive economic practices such as the creation of monopolies or restraints of trade. The terms of the Sherman Act are broad, and do not expressly exempt government entities, but the Supreme Court has long since ruled that federal principles of dual sovereignty imply that federal antitrust laws do not apply to the actions of states, even if those actions are anticompetitive.[5]

This immunity of states from federal antitrust lawsuits is known as the "state action doctrine."[6] The state action doctrine, which was developed by the Supreme Court

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[3] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1114.

[4] 15 U.S.C. §§ 1, 2.

[5] *Parker v. Brown* (1943) 317 U.S. 341, 350-351.

[6] It is important to note that the phrase "state action" in this context means something

in *Parker v. Brown*,[7] establishes three tiers of decision makers, with different thresholds for immunity in each tier.

In the top tier, with the greatest immunity, is the state itself: the sovereign acts of state governments are absolutely immune from antitrust challenge.[8] Absolute immunity extends, at a minimum, to the state Legislature, the Governor, and the state's Supreme Court.

In the second tier are subordinate state agencies,[9] such as executive departments and administrative agencies with statewide jurisdiction. State agencies are immune from antitrust challenge if their conduct is undertaken pursuant to a "clearly articulated" and "affirmatively expressed" state policy to displace competition.[10] A state policy is sufficiently clear when displacement of competition is the "inherent, logical, or ordinary result" of the authority delegated by the state legislature.[11]

The third tier includes private parties acting on behalf of a state, such as the members of a state-created professional licensing board. Private parties may enjoy state action immunity when two conditions are met: (1) their conduct is undertaken pursuant to a "clearly articulated" and "affirmatively expressed" state policy to displace competition, and (2) their conduct is "actively supervised" by the state.[12] The

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very different from "state action" for purposes of analysis of a civil rights violation under section 1983 of title 42 of the United States Code. Under section 1983, *liability* attaches to "state action," which may cover even the inadvertent or unilateral act of a state official not acting pursuant to state policy. In the antitrust context, a conclusion that a policy or action amounts to "state action" results in *immunity* from suit.

[7] *Parker v. Brown*, *supra*, 317 U.S. 341.

[8] *Hoover v. Ronwin* (1984) 466 U.S. 558, 574, 579-580.

[9] Distinguishing the state itself from subordinate state agencies has sometimes proven difficult. Compare the majority opinion in *Hoover v. Ronwin*, *supra*, 466 U.S. at p. 581 with dissenting opinion of Stevens, J., at pp. 588-589. (See *Costco v. Maleng* (9th Cir. 2008) 522 F.3d 874, 887, subseq. hrg. 538 F.3d 1128; *Charley's Taxi Radio Dispatch Corp. v. SIDA of Haw., Inc.* (9th Cir. 1987) 810 F.2d 869, 875.)

[10] See *Town of Hallie v. City of Eau Claire* (1985) 471 U.S. 34, 39.

[11] *F.T.C. v. Phoebe Putney Health Systems, Inc.* (2013) ___ U.S. ___, 133 S.Ct. 1003, 1013; see also *Southern Motor Carriers Rate Conference, Inc. v. U.S.* (1985) 471 U.S. 48, 57 (state policy need not compel specific anticompetitive effect).

[12] *Cal. Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.* (1980) 445 U.S. 97, 105 (*Midcal*).

fundamental purpose of the supervision requirement is to shelter only those private anticompetitive acts that the state approves as actually furthering its regulatory policies.[13] To that end, the mere possibility of supervision—such as the existence of a regulatory structure that is not operative, or not resorted to—is not enough. "The active supervision prong . . . requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy."[14]

C. State Action Immunity Doctrine After *North Carolina Dental*

Until the Supreme Court decided *North Carolina Dental*, it was widely believed that most professional licensing boards would fall within the second tier of state action immunity, requiring a clear and affirmative policy, but not active state supervision of every anticompetitive decision. In California in particular, there were good arguments that professional licensing boards[15] were subordinate agencies of the state: they are formal, ongoing bodies created pursuant to state law; they are housed within the Department of Consumer Affairs and operate under the Consumer Affairs Director's broad powers of investigation and control; they are subject to periodic sunset review by the Legislature, to rule-making review under the Administrative Procedure Act, and to administrative and judicial review of disciplinary decisions; their members are appointed by state officials, and include increasingly large numbers of public (non-professional) members; their meetings and records are subject to open-government laws and to strong prohibitions on conflicts of interest; and their enabling statutes generally provide well-guided discretion to make decisions affecting the professional markets that the boards regulate.[16]

Those arguments are now foreclosed, however, by *North Carolina Dental*. There, the Court squarely held, for the first time, that "a state board on which a controlling

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[13] *Patrick v. Burget* (1988) 486 U.S. 94, 100-101.

[14] *Ibid.*

[15] California's Department of Consumer Affairs includes some 25 professional regulatory boards that establish minimum qualifications and levels of competency for licensure in various professions, including accountancy, acupuncture, architecture, medicine, nursing, structural pest control, and veterinary medicine—to name just a few. (See http://www.dca.gov/about_ca/entities.shtml.)

[16] Cf. 1A Areeda & Hovenkamp, *supra*, ¶ 227, p. 208 (what matters is not what the body is called, but its structure, membership, authority, openness to the public, exposure to ongoing review, etc.).

number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity."[17] The effect of *North Carolina Dental* is to put professional licensing boards "on which a controlling number of decision makers are active market participants" in the third tier of state-action immunity. That is, they are immune from antitrust actions as long as they act pursuant to clearly articulated state policy to replace competition with regulation of the profession, *and* their decisions are actively supervised by the state.

Thus arises the question presented here: What constitutes "active state supervision"?[18]

D. Legal Standards for Active State Supervision

The active supervision requirement arises from the concern that, when active market participants are involved in regulating their own field, "there is a real danger" that they will act to further their own interests, rather than those of consumers or of the state.[19] The purpose of the requirement is to ensure that state action immunity is afforded to private parties only when their actions actually further the state's policies.[20]

There is no bright-line test for determining what constitutes active supervision of a professional licensing board: the standard is "flexible and context-dependent."[21] Sufficient supervision "need not entail day-to-day involvement" in the board's operations or "micromanagement of its every decision."[22] Instead, the question is whether the review mechanisms that are in place "provide 'realistic assurance'" that the anticompetitive effects of a board's actions promote state policy, rather than the board members' private interests.[23]

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[17] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1114; *Midcal*, *supra*, 445 U.S at p. 105.

[18] Questions about whether the State's anticompetitive policies are adequately articulated are beyond the scope of this Opinion.

[19] *Patrick v. Burget*, *supra*, 486 U.S. at p. 100, citing *Town of Hallie v. City of Eau Claire*, *supra*, 471 U.S. at p. 47; see *id.* at p. 45 ("A private party . . . may be presumed to be acting primarily on his or its own behalf").

[20] *Patrick v. Burget*, *supra*, 486 U.S. at pp. 100-101.

[21] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1116.

[22] *Ibid.*

[23] *Ibid.*

The *North Carolina Dental* opinion and pre-existing authorities allow us to identify "a few constant requirements of active supervision":[24]

- The state supervisor who reviews a decision must have the power to reverse or modify the decision.[25]
- The "mere potential" for supervision is not an adequate substitute for supervision.[26]
- When a state supervisor reviews a decision, he or she must review the substance of the decision, not just the procedures followed to reach it.[27]
- The state supervisor must not be an active market participant.[28]

Keeping these requirements in mind may help readers evaluate whether California law already provides adequate supervision for professional licensing boards, or whether new or stronger measures are desirable.

II. Threshold Considerations for Assessing Potential Responses to *North Carolina Dental*

There are a number of different measures that the Legislature might consider in response to the *North Carolina Dental* decision. We will describe a variety of these, along with some of their potential advantages or disadvantages. Before moving on to those options, however, we should put the question of immunity into proper perspective.

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[24] *Id. at* pp. 1116-1117.

[25] *Ibid.*

[26] *Id.* at p. 1116, citing *F.T.C. v. Ticor Title Ins. Co.* (1992) 504 U.S. 621, 638. For example, a passive or negative-option review process, in which an action is considered approved as long as the state supervisor raises no objection to it, may be considered inadequate in some circumstances. (*Ibid.*)

[27] *Ibid.*, citing *Patrick v. Burget*, *supra*, 486 U.S. at pp. 102-103. In most cases, there should be some evidence that the state supervisor considered the particular circumstances of the action before making a decision. Ideally, there should be a factual record and a written decision showing that there has been an assessment of the action's potential impact on the market, and whether the action furthers state policy. (See *In the Matter of Indiana Household Moves and Warehousemen, Inc.* (2008) 135 F.T.C. 535, 555-557; see also Federal Trade Commission, Report of the State Action Task Force (2003) at p. 54.)

[28] *North Carolina Dental*, *supra*, 135 S.Ct. at pp. 1116-1117.

There are two important things keep in mind: (1) the loss of immunity, if it is lost, does not mean that an antitrust violation has been committed, and (2) even when board members participate in regulating the markets they compete in, many—if not most—of their actions do not implicate the federal antitrust laws.

In the context of regulating professions, "market-sensitive" decisions (that is, the kinds of decisions that are most likely to be open to antitrust scrutiny) are those that create barriers to market participation, such as rules or enforcement actions regulating the scope of unlicensed practice; licensing requirements imposing heavy burdens on applicants; marketing programs; restrictions on advertising; restrictions on competitive bidding; restrictions on commercial dealings with suppliers and other third parties; and price regulation, including restrictions on discounts.

On the other hand, we believe that there are broad areas of operation where board members can act with reasonable confidence—especially once they and their state-official contacts have been taught to recognize actual antitrust issues, and to treat those issues specially. Broadly speaking, promulgation of regulations is a fairly safe area for board members, because of the public notice, written justification, Director review, and review by the Office of Administrative Law as required by the Administrative Procedure Act. Also, broadly speaking, disciplinary decisions are another fairly safe area because of due process procedures; participation of state actors such as board executive officers, investigators, prosecutors, and administrative law judges; and availability of administrative mandamus review.

We are not saying that the procedures that attend these quasi-legislative and quasi-judicial functions make the licensing boards altogether immune from antitrust claims. Nor are we saying that rule-making and disciplinary actions are per se immune from antitrust laws. What we are saying is that, assuming a board identifies its market-sensitive decisions and gets active state supervision for those, then ordinary rule-making and discipline (faithfully carried out under the applicable rules) may be regarded as relatively safe harbors for board members to operate in. It may require some education and experience for board members to understand the difference between market-sensitive and "ordinary" actions, but a few examples may bring in some light.

North Carolina Dental presents a perfect example of a market-sensitive action. There, the dental board decided to, and actually succeeded in, driving non-dentist teeth-whitening service providers out of the market, even though nothing in North Carolina's laws specified that teeth-whitening constituted the illegal practice of dentistry. Counter-examples—instances where no antitrust violation occurs—are far more plentiful. For example, a regulatory board may legitimately make rules or impose discipline to prohibit license-holders from engaging in fraudulent business practices (such as untruthful or

deceptive advertising) without violating antitrust laws.[29] As well, suspending the license of an individual license-holder for violating the standards of the profession is a reasonable restraint and has virtually no effect on a large market, and therefore would not violate antitrust laws.[30]

Another area where board members can feel safe is in carrying out the actions required by a detailed anticompetitive statutory scheme.[31] For example, a state law prohibiting certain kinds of advertising or requiring certain fees may be enforced without need for substantial judgment or deliberation by the board. Such detailed legislation leaves nothing for the state to supervise, and thus it may be said that the legislation itself satisfies the supervision requirement.[32]

Finally, some actions will not be antitrust violations because their effects are, in fact, pro-competitive rather than anti-competitive. For instance, the adoption of safety standards that are based on objective expert judgments have been found to be pro-competitive.[33] Efficiency measures taken for the benefit of consumers, such as making information available to the purchasers of competing products, or spreading development costs to reduce per-unit prices, have been held to be pro-competitive because they are pro-consumer.[34]

III. Potential Measures for Preserving State Action Immunity

A. Changes to the Composition of Boards

The *North Carolina Dental* decision turns on the principle that a state board is a group of private actors, not a subordinate state agency, when "a controlling number of decisionmakers are active market participants in the occupation the board regulates."[35]

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[29] See generally *California Dental Assn. v. F.T.C.* (1999) 526 U.S. 756.

[30] See *Oksanen v. Page Memorial Hospital* (4th Cir. 1999) 945 F.2d 696 (*en banc*).

[31] See *324 Liquor Corp. v. Duffy* (1987) 479 U.S. 335, 344, fn. 6.

[32] 1A Areeda & Hovenkamp, Antitrust Law, *supra*, ¶ 221, at p. 66; ¶ 222, at pp. 67, 76.

[33] See *Allied Tube & Conduit Corp. v. Indian Head, Inc.* (1988) 486 U.S. 492, 500-501.

[34] *Broadcom Corp. v. Qualcomm Inc.* (3rd Cir. 2007) 501 F.3d 297, 308-309; see generally Bus. & Prof. Code, § 301.

[35] 135 S.Ct. at p. 1114.

This ruling brings the composition of boards into the spotlight. While many boards in California currently require a majority of public members, it is still the norm for professional members to outnumber public members on boards that regulate healing-arts professions. In addition, delays in identifying suitable public-member candidates and in filling public seats can result in de facto market-participant majorities.

In the wake of *North Carolina Dental*, many observers' first impulse was to assume that reforming the composition of professional boards would be the best resolution, both for state actors and for consumer interests. Upon reflection, however, it is not obvious that sweeping changes to board composition would be the most effective solution.[36]

Even if the Legislature were inclined to decrease the number of market-participant board members, the current state of the law does not allow us to project accurately how many market-participant members is too many. This is a question that was not resolved by the *North Carolina Dental* decision, as the dissenting opinion points out:

> What is a "controlling number"? Is it a majority? And if so, why does the Court eschew that term? Or does the Court mean to leave open the possibility that something less than a majority might suffice in particular circumstances? Suppose that active market participants constitute a voting bloc that is generally able to get its way? How about an obstructionist minority or an agency chair empowered to set the agenda or veto regulations?[37]

Some observers believe it is safe to assume that the *North Carolina Dental* standard would be satisfied if public members constituted a majority of a board. The

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[36] Most observers believe that there are real advantages in staffing boards with professionals in the field. The combination of technical expertise, practiced judgment, and orientation to prevailing ethical norms is probably impossible to replicate on a board composed entirely of public members. Public confidence must also be considered. Many consumers would no doubt share the sentiments expressed by Justice Breyer during oral argument in the *North Carolina Dental* case: "[W]hat the State says is: We would like this group of brain surgeons to decide who can practice brain surgery in this State. I don't want a group of bureaucrats deciding that. I would like brain surgeons to decide that." (*North Carolina Dental*, *supra*, transcript of oral argument p. 31, available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/13-534_l6h1.pdf (hereafter, Transcript).)

[37] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1123 (dis. opn. of Alito, J).

obvious rejoinder to that argument is that the Court pointedly did not use the term "majority;" it used "controlling number." More cautious observers have suggested that "controlling number" should be taken to mean the majority of a quorum, at least until the courts give more guidance on the matter.

North Carolina Dental leaves open other questions about board composition as well. One of these is: Who is an "active market participant"?[38] Would a retired member of the profession no longer be a participant of the market? Would withdrawal from practice during a board member's term of service suffice? These questions were discussed at oral argument,[39] but were not resolved. Also left open is the scope of the market in which a member may not participate while serving on the board.[40]

Over the past four decades, California has moved decisively to expand public membership on licensing boards.[41] The change is generally agreed to be a salutary one for consumers, and for underserved communities in particular.[42] There are many good reasons to consider continuing the trend to increase public membership on licensing boards—but we believe a desire to ensure immunity for board members should not be the decisive factor. As long as the legal questions raised by *North Carolina Dental* remain unresolved, radical changes to board composition are likely to create a whole new set of policy and practical challenges, with no guarantee of resolving the immunity problem.

B. Some Mechanisms for Increasing State Supervision

Observers have proposed a variety of mechanisms for building more state oversight into licensing boards' decision-making processes. In considering these alternatives, it may be helpful to bear in mind that licensing boards perform a variety of

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[38] *Ibid.*

[39] Transcript, *supra*, at p. 31.

[40] *North Carolina Dental*, *supra*, 135 S.Ct. at p. 1123 (dis. opn. of Alito, J). Some observers have suggested that professionals from one practice area might be appointed to serve on the board regulating another practice area, in order to bring their professional expertise to bear in markets where they are not actively competing.

[41] See Center for Public Interest Law, A Guide to California's Health Care Licensing Boards (July 2009) at pp. 1-2; Shimberg, Occupational Licensing: A Public Perspective (1982) at pp. 163-165.

[42] See Center for Public Interest Law, *supra*, at pp. 15-17; Shimberg, *supra*, at pp. 175-179.

distinct functions, and that different supervisory structures may be appropriate for different functions.

For example, boards may develop and enforce standards for licensure; receive, track, and assess trends in consumer complaints; perform investigations and support administrative and criminal prosecutions; adjudicate complaints and enforce disciplinary measures; propose regulations and shepherd them through the regulatory process; perform consumer education; and more. Some of these functions are administrative in nature, some are quasi-judicial, and some are quasi-legislative. Boards' quasi-judicial and quasi-legislative functions, in particular, are already well supported by due process safeguards and other forms of state supervision (such as vertical prosecutions, administrative mandamus procedures, and public notice and scrutiny through the Administrative Procedure Act). Further, some functions are less likely to have antitrust implications than others: decisions affecting only a single license or licensee in a large market will rarely have an anticompetitive effect within the meaning of the Sherman Act. For these reasons, it is worth considering whether it is less urgent, or not necessary at all, to impose additional levels of supervision with respect to certain functions.

Ideas for providing state oversight include the concept of a superagency, such as a stand-alone office, or a committee within a larger agency, which has full responsibility for reviewing board actions de novo. Under such a system, the boards could be permitted to carry on with their business as usual, except that they would be required to refer each of their decisions (or some subset of decisions) to the superagency for its review. The superagency could review each action file submitted by the board, review the record and decision in light of the state's articulated regulatory policies, and then issue its own decision approving, modifying, or vetoing the board's action.

Another concept is to modify the powers of the boards themselves, so that all of their functions (or some subset of functions) would be advisory only. Under such a system, the boards would not take formal actions, but would produce a record and a recommendation for action, perhaps with proposed findings and conclusions. The recommendation file would then be submitted to a supervising state agency for its further consideration and formal action, if any.

Depending on the particular powers and procedures of each system, either could be tailored to encourage the development of written records to demonstrate executive discretion; access to administrative mandamus procedures for appeal of decisions; and the development of expertise and collaboration among reviewers, as well as between the reviewers and the boards that they review. Under any system, care should be taken to structure review functions so as to avoid unnecessary duplication or conflicts with other agencies and departments, and to minimize the development of super-policies not

adequately tailored to individual professions and markets. To prevent the development of "rubber-stamp" decisions, any acceptable system must be designed and sufficiently staffed to enable plenary review of board actions or recommendations at the individual transactional level.

As it stands, California is in a relatively advantageous position to create these kinds of mechanisms for active supervision of licensing boards. With the boards centrally housed within the Department of Consumer Affairs (an "umbrella agency"), there already exists an organization with good knowledge and experience of board operations, and with working lines of communication and accountability. It is worth exploring whether existing resources and minimal adjustments to procedures and outlooks might be converted to lines of active supervision, at least for the boards' most market-sensitive actions.

Moreover, the Business and Professions Code already demonstrates an intention that the Department of Consumer Affairs will protect consumer interests as a means of promoting "the fair and efficient functioning of the free enterprise market economy" by educating consumers, suppressing deceptive and fraudulent practices, fostering competition, and representing consumer interests at all levels of government.[43] The free-market and consumer-oriented principles underlying *North Carolina Dental* are nothing new to California, and no bureaucratic paradigms need to be radically shifted as a result.

The Business and Professions Code also gives broad powers to the Director of Consumer Affairs (and his or her designees)[44] to protect the interests of consumers at every level.[45] The Director has power to investigate the work of the boards and to obtain their data and records;[46] to investigate alleged misconduct in licensing examinations and qualifications reviews;[47] to require reports;[48] to receive consumer complaints[49] and to initiate audits and reviews of disciplinary cases and complaints about licensees.[50]

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[43] Bus. & Prof. Code, § 301.

[44] Bus. & Prof. Code, §§ 10, 305.

[45] See Bus. & Prof. Code, § 310.

[46] Bus. & Prof. Code, § 153.

[47] Bus. & Prof. Code, § 109.

[48] Bus. & Prof. Code, § 127.

[49] Bus. & Prof. Code, § 325.

[50] Bus. & Prof. Code, § 116.

In addition, the Director must be provided a full opportunity to review all proposed rules and regulations (except those relating to examinations and licensure qualifications) before they are filed with the Office of Administrative Law, and the Director may disapprove any proposed regulation on the ground that it is injurious to the public.[51] Whenever the Director (or his or her designee) actually exercises one of these powers to reach a substantive conclusion as to whether a board's action furthers an affirmative state policy, then it is safe to say that the active supervision requirement has been met.[52]

It is worth considering whether the Director's powers should be amended to make review of certain board decisions mandatory as a matter of course; or to make the Director's review available upon the request of a board. It is also worth considering whether certain existing limitations on the Director's powers should be removed or modified. For example, the Director may investigate allegations of misconduct in examinations or qualification reviews, but the Director currently does not appear to have power to review board decisions in those areas, or to review proposed rules in those areas.[53] In addition, the Director's power to initiate audits and reviews appears to be limited to disciplinary cases and complaints about licensees.[54] If the Director's initiative is in fact so limited, it is worth considering whether that limitation continues to make sense. Finally, while the Director must be given a full opportunity to review most proposed regulations, the Director's disapproval may be overridden by a unanimous vote of the board.[55] It is worth considering whether the provision for an override maintains its utility, given that such an override would nullify any "active supervision" and concomitant immunity that would have been gained by the Director's review.[56]

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[51] Bus. & Prof. Code, § 313.1.

[52] Although a written statement of decision is not specifically required by existing legal standards, developing a practice of creating an evidentiary record and statement of decision would be valuable for many reasons, not the least of which would be the ability to proffer the documents to a court in support of a motion asserting state action immunity.

[53] Bus. & Prof. Code, §§ 109, 313.1.

[54] Bus. & Prof. Code, § 116.

[55] Bus. & Prof. Code, § 313.1.

[56] Even with an override, proposed regulations are still subject to review by the Office of Administrative Law.

C. Legislation Granting Immunity

From time to time, states have enacted laws expressly granting immunity from antitrust laws to political subdivisions, usually with respect to a specific market.[57] However, a statute purporting to grant immunity to private persons, such as licensing board members, would be of doubtful validity. Such a statute might be regarded as providing adequate authorization for anticompetitive activity, but active state supervision would probably still be required to give effect to the intended immunity. What is quite clear is that a state cannot grant blanket immunity by fiat. "[A] state does not give immunity to those who violate the Sherman Act by authorizing them to violate it, or by declaring that their action is lawful . . . ."[58]

IV. Indemnification of Board Members

So far we have focused entirely on the concept of immunity, and how to preserve it. But immunity is not the only way to protect state employees from the costs of suit, or to provide the reassurance necessary to secure their willingness and ability to perform their duties. Indemnification can also go a long way toward providing board members the protection they need to do their jobs. It is important for policy makers to keep this in mind in weighing the costs of creating supervision structures adequate to ensure blanket state action immunity for board members. If the costs of implementing a given supervisory structure are especially high, it makes sense to consider whether immunity is an absolute necessity, or whether indemnification (with or without additional risk-management measures such as training or reporting) is an adequate alternative.

As the law currently stands, the state has a duty to defend and indemnify members of licensing boards against antitrust litigation to the same extent, and subject to the same exceptions, that it defends and indemnifies state officers and employees in general civil litigation. The duty to defend and indemnify is governed by the Government Claims Act.[59] For purposes of the Act, the term "employee" includes officers and uncompensated servants.[60] We have repeatedly determined that members of a board,

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[57] See 1A Areeda & Hovenkamp, Antitrust Law, *supra*, 225, at pp. 135-137; e.g. *Al Ambulance Service, Inc. v. County of Monterey* (9th Cir. 1996) 90 F.3d 333, 335 (discussing Health & Saf. Code, § 1797.6).

[58] *Parker v. Brown*, *supra*, 317 U.S. at 351.

[59] Gov. Code, §§ 810-996.6.

[60] See Gov. Code § 810.2.

commission, or similar body established by statute are employees entitled to defense and indemnification.[61]

A. Duty to Defend

Public employees are generally entitled to have their employer provide for the defense of any civil action "on account of an act or omission in the scope" of employment.[62] A public entity may refuse to provide a defense in specified circumstances, including where the employee acted due to "actual fraud, corruption, or actual malice."[63] The duty to defend contains no exception for antitrust violations.[64] Further, violations of antitrust laws do not inherently entail the sort of egregious behavior that would amount to fraud, corruption, or actual malice under state law. There would therefore be no basis to refuse to defend an employee on the bare allegation that he or she violated antitrust laws.

B. Duty to Indemnify

The Government Claims Act provides that when a public employee properly requests the employer to defend a claim, and reasonably cooperates in the defense, "the public entity shall pay any judgment based thereon or any compromise or settlement of the claim or action to which the public entity has agreed."[65] In general, the government is liable for an injury proximately caused by an act within the scope of employment,[66] but is not liable for punitive damages.[67]

One of the possible remedies for an antitrust violation is an award of treble damages to a person whose business or property has been injured by the violation.[68] This raises a question whether a treble damages award equates to an award of punitive damages within the meaning of the Government Claims Act. Although the answer is not

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[61] E.g., 81 Ops.Cal.Atty.Gen. 199, 200 (1998); 57 Ops.Cal.Atty.Gen. 358, 361 (1974).

[62] Gov. Code, § 995.

[63] Gov. Code, § 995.2, subd. (a).

[64] Cf. *Mt. Hawley Insurance Co. v. Lopez* (2013) 215 Cal.App.4th 1385 (discussing Ins. Code, § 533.5).

[65] Gov. Code, § 825, subd. (a).

[66] Gov. Code, § 815.2.

[67] Gov. Code, § 818.

[68] 15 U.S.C. § 15(a).

entirely certain, we believe that antitrust treble damages do *not* equate to punitive damages.

The purposes of treble damage awards are to deter anticompetitive behavior and to encourage private enforcement of antitrust laws.[69] And, an award of treble damages is automatic once an antitrust violation is proved.[70] In contrast, punitive damages are "uniquely justified by and proportioned to the actor's particular reprehensible conduct as well as that person or entity's net worth . . . in order to adequately make the award 'sting' . . . ."[71] Also, punitive damages in California must be premised on a specific finding of malice, fraud, or oppression.[72] In our view, the lack of a malice or fraud element in an antitrust claim, and the immateriality of a defendant's particular conduct or net worth to the treble damage calculation, puts antitrust treble damages outside the Government Claims Act's definition of punitive damages.[73]

C. Possible Improvements to Indemnification Scheme

As set out above, state law provides for the defense and indemnification of board members to the same extent as other state employees. This should go a long way toward reassuring board members and potential board members that they will not be exposed to undue risk if they act reasonably and in good faith. This reassurance cannot be complete, however, as long as board members face significant uncertainty about how much litigation they may have to face, or about the status of treble damage awards.

Uncertainty about the legal status of treble damage awards could be reduced significantly by amending state law to specify that treble damage antitrust awards are not punitive damages within the meaning of the Government Claims Act. This would put them on the same footing as general damages awards, and thereby remove any uncertainty as to whether the state would provide indemnification for them.[74]

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[69] *Clayworth v. Pfizer, Inc.* (2010) 49 Cal.4th 758, 783-784 (individual right to treble damages is "incidental and subordinate" to purposes of deterrence and vigorous enforcement).

[70] 15 U.S.C. § 15(a).

[71] *Piscitelli v. Friedenberg* (2001) 87 Cal.App.4th 953, 981-982.

[72] Civ. Code, §§ 818, 3294.

[73] If treble damages awards were construed as constituting punitive damages, the state would still have the option of paying them under Government Code section 825.

[74] Ideally, treble damages should not be available at all against public entities and public officials. Since properly articulated and supervised anticompetitive behavior is

As a complement to indemnification, the potential for board member liability may be greatly reduced by introducing antitrust concepts to the required training and orientation programs that the Department of Consumer Affairs provides to new board members.[75] When board members share an awareness of the sensitivity of certain kinds of actions, they will be in a much better position to seek advice and review (that is, active supervision) from appropriate officials. They will also be far better prepared to assemble evidence and to articulate reasons for the decisions they make in market-sensitive areas. With training and practice, boards can be expected to become as proficient in making and demonstrating sound market decisions, and ensuring proper review of those decisions, as they are now in making and defending sound regulatory and disciplinary decisions.

V. Conclusions

North Carolina Dental has brought both the composition of licensing boards and the concept of active state supervision into the public spotlight, but the standard it imposes is flexible and context-specific. This leaves the state with many variables to consider in deciding how to respond.

Whatever the chosen response may be, the state can be assured that *North Carolina Dental*'s "active state supervision" requirement is satisfied when a non-market-

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permitted to the state and its agents, the deterrent purpose of treble damages does not hold in the public arena. Further, when a state indemnifies board members, treble damages go not against the board members but against public coffers. "It is a grave act to make governmental units potentially liable for massive treble damages when, however 'proprietary' some of their activities may seem, they have fundamental responsibilities to their citizens for the provision of life-sustaining services such as police and fire protection." (*City of Lafayette, La. v. Louisiana Power & Light Co.* (1978) 435 U.S. 389, 442 (dis. opn. of Blackmun, J.).)

In response to concerns about the possibility of treble damage awards against municipalities, Congress passed the Local Government Antitrust Act (15 U.S.C. §§ 34-36), which provides that local governments and their officers and employees cannot be held liable for treble damages, compensatory damages, or attorney's fees. (See H.R. Rep. No. 965, 2nd Sess., p. 11 (1984).) For an argument that punitive sanctions should never be levied against public bodies and officers under the Sherman Act, see 1A Areeda & Hovenkamp, *supra,* ¶ 228, at pp. 214-226. Unfortunately, because treble damages are a product of federal statute, this problem is not susceptible of a solution by state legislation.

[75] Bus. & Prof. Code, § 453.

participant state official has and exercises the power to substantively review a board's action and determines whether the action effectuates the state's regulatory policies.

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FTC Staff Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants*

I. Introduction

States craft regulatory policy through a variety of actors, including state legislatures, courts, agencies, and regulatory boards. While most regulatory actions taken by state actors will not implicate antitrust concerns, some will. Notably, states have created a large number of regulatory boards with the authority to determine who may engage in an occupation (*e.g.*, by issuing or withholding a license), and also to set the rules and regulations governing that occupation. Licensing, once limited to a few learned professions such as doctors and lawyers, is now required for over 800 occupations including (in some states) locksmiths, beekeepers, auctioneers, interior designers, fortune tellers, tour guides, and shampooers.[1]

In general, a state may avoid all conflict with the federal antitrust laws by creating regulatory boards that serve only in an advisory capacity, or by staffing a regulatory board exclusively with persons who have no financial interest in the occupation that is being regulated. However, across the United States, "licensing boards are largely dominated by active members of their respective industries . . ."[2] That is, doctors commonly regulate doctors, beekeepers commonly regulate beekeepers, and tour guides commonly regulate tour guides.

Earlier this year, the U.S. Supreme Court upheld the Federal Trade Commission's determination that the North Carolina State Board of Dental Examiners ("NC Board") violated the federal antitrust laws by preventing non-dentists from providing teeth whitening services in competition with the state's licensed dentists. *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101 (2015). NC Board is a state agency established under North Carolina law and charged with administering and enforcing a licensing system for dentists. A majority of the members of this state agency are themselves practicing dentists, and thus they have a private incentive to limit

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* This document sets out the views of the Staff of the Bureau of Competition. The Federal Trade Commission is not bound by this Staff guidance and reserves the right to rescind it at a later date. In addition, FTC Staff reserves the right to reconsider the views expressed herein, and to modify, rescind, or revoke this Staff guidance if such action would be in the public interest.

[1] Aaron Edlin & Rebecca Haw, *Cartels By Another Name: Should Licensed Occupations Face Antitrust Scrutiny*, 162 U. PA. L. REV. 1093, 1096 (2014).

[2] *Id.* at 1095.

competition from non-dentist providers of teeth whitening services. NC Board argued that, because it is a state agency, it is exempt from liability under the federal antitrust laws. That is, the NC Board sought to invoke what is commonly referred to as the "state action exemption" or the "state action defense." The Supreme Court rejected this contention and affirmed the FTC's finding of antitrust liability.

In this decision, the Supreme Court clarified the applicability of the antitrust state action defense to state regulatory boards controlled by market participants:

> "The Court holds today that a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal's* [*Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980)] active supervision requirement in order to invoke state-action antitrust immunity." *N.C. Dental*, 135 S. Ct. at 1114.

In the wake of this Supreme Court decision, state officials have requested advice from the Federal Trade Commission regarding antitrust compliance for state boards responsible for regulating occupations. This outline provides FTC Staff guidance on two questions. *First*, when does a state regulatory board require active supervision in order to invoke the state action defense? *Second*, what factors are relevant to determining whether the active supervision requirement is satisfied?

Our answers to these questions come with the following caveats.

- Vigorous competition among sellers in an open marketplace generally provides consumers with important benefits, including lower prices, higher quality services, greater access to services, and increased innovation. For this reason, a state legislature should empower a regulatory board to restrict competition only when necessary to protect against a credible risk of harm, such as health and safety risks to consumers. The Federal Trade Commission and its staff have frequently advocated that states avoid unneeded and burdensome regulation of service providers.[3]

- Federal antitrust law does not require that a state legislature provide for active supervision of any state regulatory board. A state legislature may, and generally should, prefer that a regulatory board be subject to the requirements of the federal antitrust

[3] *See, e.g.*, Fed. Trade Comm'n Staff Policy Paper, *Policy Perspectives: Competition and the Regulation of Advanced Practice Registered Nurses* (Mar. 2014), https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf; Fed. Trade Comm'n & U.S. Dept. of Justice, Comment before the South Carolina Supreme Court Concerning Proposed Guidelines for Residential and Commercial Real Estate Closings (Apr. 2008), https://www.ftc.gov/news-events/press-releases/2008/04/ftcdoj-submit-letter-supreme-court-south-carolina-proposed.

laws. If the state legislature determines that a regulatory board should be subject to antitrust oversight, then the state legislature need not provide for active supervision.

➢ Antitrust analysis – including the applicability of the state action defense – is fact-specific and context-dependent. The purpose of this document is to identify certain overarching legal principles governing when and how a state may provide active supervision for a regulatory board. We are not suggesting a mandatory or one-size-fits-all approach to active supervision. Instead, we urge each state regulatory board to consult with the Office of the Attorney General for its state for customized advice on how best to comply with the antitrust laws.

➢ This FTC Staff guidance addresses only the active supervision prong of the state action defense. In order successfully to invoke the state action defense, a state regulatory board controlled by market participants must also satisfy the clear articulation prong, as described briefly in Section II. below.

➢ This document contains guidance developed by the staff of the Federal Trade Commission. Deviation from this guidance does not necessarily mean that the state action defense is inapplicable, or that a violation of the antitrust laws has occurred.

II. Overview of the Antitrust State Action Defense

"Federal antitrust law is a central safeguard for the Nation's free market structures . . . . The antitrust laws declare a considered and decisive prohibition by the Federal Government of cartels, price fixing, and other combinations or practices that undermine the free market." *N.C. Dental*, 135 S. Ct. at 1109.

Under principles of federalism, "the States possess a significant measure of sovereignty." *N.C. Dental*, 135 S. Ct. at 1110 (*quoting Community Communications Co. v. Boulder*, 455 U.S. 40, 53 (1982)). In enacting the antitrust laws, Congress did not intend to prevent the States from limiting competition in order to promote other goals that are valued by their citizens. Thus, the Supreme Court has concluded that the federal antitrust laws do not reach anticompetitive conduct engaged in by a State that is acting in its sovereign capacity. *Parker v. Brown*, 317 U.S. 341, 351-52 (1943). For example, a state legislature may "impose restrictions on occupations, confer exclusive or shared rights to dominate a market, or otherwise limit competition to achieve public objectives." *N.C. Dental*, 135 S. Ct. at 1109.

Are the actions of a state regulatory board, like the actions of a state legislature, exempt from the application of the federal antitrust laws? In *North Carolina State Board of Dental Examiners*, the Supreme Court reaffirmed that a state regulatory board is not the sovereign. Accordingly, a state regulatory board is not necessarily exempt from federal antitrust liability.

More specifically, the Court determined that "a state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates" may invoke the state action defense only when two requirements are satisfied: first, the challenged restraint must be clearly articulated and affirmatively expressed as state policy; and second, the policy must be actively supervised by a state official (or state agency) that is not a participant in the market that is being regulated. *N.C. Dental*, 135 S. Ct. at 1114.

- The Supreme Court addressed the clear articulation requirement most recently in *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003 (2013). The clear articulation requirement is satisfied "where the displacement of competition [is] the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature. In that scenario, the State must have foreseen and implicitly endorsed the anticompetitive effects as consistent with its policy goals." *Id.* at 1013.

- The State's clear articulation of the intent to displace competition is not alone sufficient to trigger the state action exemption. The state legislature's clearly-articulated delegation of authority to a state regulatory board to displace competition may be "defined at so high a level of generality as to leave open critical questions about how

and to what extent the market should be regulated." There is then a danger that this delegated discretion will be used by active market participants to pursue private interests in restraining trade, in lieu of implementing the State's policy goals. *N.C. Dental*, 135 S. Ct. at 1112.

- The active supervision requirement "seeks to avoid this harm by requiring the State to review and approve interstitial policies made by the entity claiming [antitrust] immunity." *Id.*

Where the state action defense does not apply, the actions of a state regulatory board controlled by active market participants may be subject to antitrust scrutiny. Antitrust issues may arise where an unsupervised board takes actions that restrict market entry or restrain rivalry. The following are some scenarios that have raised antitrust concerns:

- A regulatory board controlled by dentists excludes non-dentists from competing with dentists in the provision of teeth whitening services. *Cf. N.C. Dental,* 135 S. Ct. 1101.

- A regulatory board controlled by accountants determines that only a small and fixed number of new licenses to practice the profession shall be issued by the state each year. *Cf. Hoover v. Ronwin*, 466 U.S. 558 (1984).

- A regulatory board controlled by attorneys adopts a regulation (or a code of ethics) that prohibits attorney advertising, or that deters attorneys from engaging in price competition. *Cf. Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977); *Goldfarb v. Va. State Bar*, 421 U.S. 773 (1975).

III. Scope of FTC Staff Guidance

A. This Staff guidance addresses the applicability of the state action defense under the federal antitrust laws. Concluding that the state action defense is inapplicable does not mean that the conduct of the regulatory board necessarily violates the federal antitrust laws. A regulatory board may assert defenses ordinarily available to an antitrust defendant.

1. **Reasonable restraints on competition do not violate the antitrust laws, even where the economic interests of a competitor have been injured.**

Example 1: A regulatory board may prohibit members of the occupation from engaging in fraudulent business practices without raising antitrust concerns. A regulatory board also may prohibit members of the occupation from engaging in untruthful or deceptive advertising. *Cf. Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999).

Example 2: Suppose a market with several hundred licensed electricians. If a regulatory board suspends the license of one electrician for substandard work, such action likely does not unreasonably harm competition. *Cf. Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696 (4th Cir. 1991) (en banc).

2. **The ministerial (non-discretionary) acts of a regulatory board engaged in good faith implementation of an anticompetitive statutory regime do not give rise to antitrust liability. See 324 Liquor Corp. v. Duffy, 479 U.S. 335, 344 n. 6 (1987).**

Example 3: A state statute requires that an applicant for a chauffeur's license submit to the regulatory board, among other things, a copy of the applicant's diploma and a certified check for $500. An applicant fails to submit the required materials. If for this reason the regulatory board declines to issue a chauffeur's license to the applicant, such action would not be considered an unreasonable restraint. In the circumstances described, the denial of a license is a ministerial or non-discretionary act of the regulatory board.

3. **In general, the initiation and prosecution of a lawsuit by a regulatory board does not give rise to antitrust liability unless it falls within the "sham exception." Professional Real Estate Investors v. Columbia Pictures Industries, 508 U.S. 49 (1993); California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508 (1972).**

Example 4: A state statute authorizes the state's dental board to maintain an action in state court to enjoin an unlicensed person from practicing dentistry. The members of the dental board have a basis to believe that a particular individual is practicing dentistry but does not hold a valid license. If the dental board files a lawsuit against that individual, such action would not constitute a violation of the federal antitrust laws.

B. Below, FTC Staff describes when active supervision of a state regulatory board is required in order successfully to invoke the state action defense, and what factors are relevant to determining whether the active supervision requirement has been satisfied.

1. When is active state supervision of a state regulatory board required in order to invoke the state action defense?

General Standard: "[A] state board on which a controlling number of decisionmakers are active market participants in the occupation the board regulates must satisfy *Midcal*'s active supervision requirement in order to invoke state-action antitrust immunity." *N.C. Dental*, 135 S. Ct. at 1114.

Active Market Participants: A member of a state regulatory board will be considered to be an active market participant in the occupation the board regulates if such person (i) is licensed by the board or (ii) provides any service that is subject to the regulatory authority of the board.

- If a board member participates in any professional or occupational sub-specialty that is regulated by the board, then that board member is an active market participant for purposes of evaluating the active supervision requirement.

- It is no defense to antitrust scrutiny, therefore, that the board members themselves are not directly or personally affected by the challenged restraint. For example, even if the members of the NC Dental Board were orthodontists who do not perform teeth whitening services (as a matter of law or fact or tradition), their control of the dental board would nevertheless trigger the requirement for active state supervision. This is because these orthodontists are licensed by, and their services regulated by, the NC Dental Board.

- A person who temporarily suspends her active participation in an occupation for the purpose of serving on a state board that regulates her former (and intended future) occupation will be considered to be an active market participant.

Method of Selection: The method by which a person is selected to serve on a state regulatory board is not determinative of whether that person is an active market participant in the occupation that the board regulates. For example, a licensed dentist is deemed to be an active market participant regardless of whether the dentist (i) is appointed to the state dental board by the governor or (ii) is elected to the state dental board by the state's licensed dentists.

***A Controlling Number, Not Necessarily a Majority, of Actual Decisionmakers*:**

➢ Active market participants need not constitute a numerical majority of the members of a state regulatory board in order to trigger the requirement of active supervision. A decision that is controlled, either as a matter of law, procedure, or fact, by active participants in the regulated market (*e.g.*, through veto power, tradition, or practice) must be actively supervised to be eligible for the state action defense.

➢ Whether a particular restraint has been imposed by a "controlling number of decisionmakers [who] are active market participants" is a fact-bound inquiry that must be made on a case-by-case basis. FTC Staff will evaluate a number of factors, including:

✓ The structure of the regulatory board (including the number of board members who are/are not active market participants) and the rules governing the exercise of the board's authority.

✓ Whether the board members who are active market participants have veto power over the board's regulatory decisions.

Example 5: The state board of electricians consists of four non-electrician members and three practicing electricians. Under state law, new regulations require the approval of five board members. Thus, no regulation may become effective without the assent of at least one electrician member of the board. In this scenario, the active market participants effectively have veto power over the board's regulatory authority. The active supervision requirement is therefore applicable.

✓ The level of participation, engagement, and authority of the non-market participant members in the business of the board – generally and with regard to the particular restraint at issue.

✓ Whether the participation, engagement, and authority of the non-market participant board members in the business of the board differs from that of board members who are active market participants – generally and with regard to the particular restraint at issue.

✓ Whether the active market participants have in fact exercised, controlled, or usurped the decisionmaking power of the board.

Example 6: The state board of electricians consists of four non-electrician members and three practicing electricians. Under state law, new regulations require the approval of a majority of board members. When voting on proposed regulations, the non-electrician members routinely defer to the preferences of the electrician members. Minutes of

board meetings show that the non-electrician members generally are not informed or knowledgeable concerning board business – and that they were not well informed concerning the particular restraint at issue. In this scenario, FTC Staff may determine that the active market participants have exercised the decisionmaking power of the board, and that the active supervision requirement is applicable.

Example 7: The state board of electricians consists of four non-electrician members and three practicing electricians. Documents show that the electrician members frequently meet and discuss board business separately from the non-electrician members. On one such occasion, the electrician members arranged for the issuance by the board of written orders to six construction contractors, directing such individuals to cease and desist from providing certain services. The non-electrician members of the board were not aware of the issuance of these orders and did not approve the issuance of these orders. In this scenario, FTC Staff may determine that the active market participants have exercised the decisionmaking power of the board, and that the active supervision requirement is applicable.

2. What constitutes active supervision?

FTC Staff will be guided by the following principles:

- "[T]he purpose of the active supervision inquiry . . . is to determine whether the State has exercised sufficient independent judgment and control" such that the details of the regulatory scheme "have been established as a product of deliberate state intervention" and not simply by agreement among the members of the state board. "Much as in causation inquiries, the analysis asks whether the State has played a substantial role in determining the specifics of the economic policy." The State is not obliged to "[meet] some normative standard, such as efficiency, in its regulatory practices." *Ticor*, 504 U.S. at 634-35. "The question is not how well state regulation works but whether the anticompetitive scheme is the State's own." *Id.* at 635.

- It is necessary "to ensure the States accept political accountability for anticompetitive conduct they permit and control." *N.C. Dental*, 135 S. Ct. at 1111. *See also Ticor*, 504 U.S. at 636.

- "The Court has identified only a few constant requirements of active supervision: The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy; and the 'mere potential for state supervision is not an adequate substitute for a decision by the State.' Further, the state supervisor may not itself be an active market participant." *N.C. Dental*, 135 S. Ct. at 1116–17 (citations omitted).

- The active supervision must precede implementation of the allegedly anticompetitive restraint.

- "[T]he inquiry regarding active supervision is flexible and context-dependent." "[T]he adequacy of supervision . . . will depend on all the circumstances of a case." *N.C. Dental*, 135 S. Ct. at 1116–17. Accordingly, FTC Staff will evaluate each case in light of its own facts, and will apply the applicable case law and the principles embodied in this guidance reasonably and flexibly.

3. What factors are relevant to determining whether the active supervision requirement has been satisfied?

FTC Staff will consider the presence or absence of the following factors in determining whether the active supervision prong of the state action defense is satisfied.

- The supervisor has obtained the information necessary for a proper evaluation of the action recommended by the regulatory board. As applicable, the supervisor has ascertained relevant facts, collected data, conducted public hearings, invited and received public comments, investigated market conditions, conducted studies, and reviewed documentary evidence.

  - ✓ The information-gathering obligations of the supervisor depend in part upon the scope of inquiry previously conducted by the regulatory board. For example, if the regulatory board has conducted a suitable public hearing and collected the relevant information and data, then it may be unnecessary for the supervisor to repeat these tasks. Instead, the supervisor may utilize the materials assembled by the regulatory board.

- The supervisor has evaluated the substantive merits of the recommended action and assessed whether the recommended action comports with the standards established by the state legislature.

- The supervisor has issued a written decision approving, modifying, or disapproving the recommended action, and explaining the reasons and rationale for such decision.

  - ✓ A written decision serves an evidentiary function, demonstrating that the supervisor has undertaken the required meaningful review of the merits of the state board's action.

  - ✓ A written decision is also a means by which the State accepts political accountability for the restraint being authorized.

Scenario 1: Example of satisfactory active supervision of a state board regulation designating teeth whitening as a service that may be provided only by a licensed dentist, where state policy is to protect the health and welfare of citizens and to promote competition.

- The state legislature designated an executive agency to review regulations recommended by the state regulatory board. Recommended regulations become effective only following the approval of the agency.

- The agency provided notice of (i) the recommended regulation and (ii) an opportunity to be heard, to dentists, to non-dentist providers of teeth whitening, to the public (in a newspaper of general circulation in the affected areas), and to other interested and affected persons, including persons that have previously identified themselves to the agency as interested in, or affected by, dentist scope of practice issues.

- The agency took the steps necessary for a proper evaluation of the recommended regulation. The agency:

  - ✓ Obtained the recommendation of the state regulatory board and supporting materials, including the identity of any interested parties and the full evidentiary record compiled by the regulatory board.

  - ✓ Solicited and accepted written submissions from sources other than the regulatory board.

  - ✓ Obtained published studies addressing (i) the health and safety risks relating to teeth whitening and (ii) the training, skill, knowledge, and equipment reasonably required in order to safely and responsibly provide teeth whitening services (if not contained in submission from the regulatory board).

  - ✓ Obtained information concerning the historic and current cost, price, and availability of teeth whitening services from dentists and non-dentists (if not contained in submission from the regulatory board). Such information was verified (or audited) by the Agency as appropriate.

  - ✓ Held public hearing(s) that included testimony from interested persons (including dentists and non-dentists). The public hearing provided the agency with an opportunity (i) to hear from and to question providers, affected customers, and experts and (ii) to supplement the evidentiary record compiled by the state board. (As noted above, if the state regulatory board has previously conducted a suitable public hearing, then it may be unnecessary for the supervising agency to repeat this procedure.)

- The agency assessed all of the information to determine whether the recommended regulation comports with the State's goal to protect the health and

welfare of citizens and to promote competition.

- The agency issued a written decision accepting, rejecting, or modifying the scope of practice regulation recommended by the state regulatory board, and explaining the rationale for the agency's action.

Scenario 2: Example of satisfactory active supervision of a state regulatory board administering a disciplinary process.

A common function of state regulatory boards is to administer a disciplinary process for members of a regulated occupation. For example, the state regulatory board may adjudicate whether a licensee has violated standards of ethics, competency, conduct, or performance established by the state legislature.

Suppose that, acting in its adjudicatory capacity, a regulatory board controlled by active market participants determines that a licensee has violated a lawful and valid standard of ethics, competency, conduct, or performance, and for this reason, the regulatory board proposes that the licensee's license to practice in the state be revoked or suspended. In order to invoke the state action defense, the regulatory board would need to show both clear articulation and active supervision.

- In this context, active supervision may be provided by the administrator who oversees the regulatory board (*e.g.*, the secretary of health), the state attorney general, or another state official who is not an active market participant. The active supervision requirement of the state action defense will be satisfied if the supervisor: (i) reviews the evidentiary record created by the regulatory board; (ii) supplements this evidentiary record if and as appropriate; (iii) undertakes a de novo review of the substantive merits of the proposed disciplinary action, assessing whether the proposed disciplinary action comports with the policies and standards established by the state legislature; and (iv) issues a written decision that approves, modifies, or disapproves the disciplinary action proposed by the regulatory board.

Note that a disciplinary action taken by a regulatory board affecting a single licensee will typically have only a de minimis effect on competition. A pattern or program of disciplinary actions by a regulatory board affecting multiple licensees may have a substantial effect on competition.

The following do <u>not</u> constitute active supervision of a state regulatory board that is controlled by active market participants:

- The entity responsible for supervising the regulatory board is itself controlled by active market participants in the occupation that the board regulates. *See N.C. Dental*, 135 S. Ct. at 1113-14.

- A state official monitors the actions of the regulatory board and participates in deliberations, but lacks the authority to disapprove anticompetitive acts that fail to accord with state policy. *See Patrick v. Burget*, 486 U.S. 94, 101 (1988).

- A state official (*e.g.*, the secretary of health) serves ex officio as a member of the regulatory board with full voting rights. However, this state official is one of several members of the regulatory board and lacks the authority to disapprove anticompetitive acts that fail to accord with state policy.

- The state attorney general or another state official provides advice to the regulatory board on an ongoing basis.

- An independent state agency is staffed, funded, and empowered by law to evaluate, and then to veto or modify, particular recommendations of the regulatory board. However, in practice such recommendations are subject to only cursory review by the independent state agency. The independent state agency perfunctorily approves the recommendations of the regulatory board. *See Ticor*, 504 U.S. at 638.

- An independent state agency reviews the actions of the regulatory board and approves all actions that comply with the procedural requirements of the state administrative procedure act, without undertaking a substantive review of the actions of the regulatory board. *See Patrick*, 486 U.S. at 104-05.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Veterinary Medical Board
1747 N. Market Blvd., Suite 230, Sacramento, CA 95834
Telephone: 916-515-5220 Fax:: 916-928-6849 | www.vmb.ca.gov

MEMORANDUM

DATE	April 24, 2015
TO	Veterinary Medical Board
FROM	Candace Raney and Elizabeth Bynum DCA/Veterinary Medical Board
SUBJECT	Standard of Care

Some Board members have said that they would like clarification regarding the terms "standard of care" and "minimum standards". The following is an attempt to explain how the "standard of care" has been interpreted by different parties, and also how the two standards may be distinguished from each other.

The "standard of care" is a term used in cases where negligence is alleged. The California Civil Jury Instructions set forth the standard of care in this way:

> "Standard of Care for Health Care Professionals
> [A/An][*insert type of medical practitioner*] is negligent if [he/she] fails to use the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful [*insert type of medical practitioner*] would use in the same or similar circumstances. This level of skill, knowledge, and care is sometimes referred to as 'the standard of care.'"

Failure to meet the standard by one who owes a duty of care exposes the actor for liability for negligence.

The Attorney General's office, in a June 29, 2010 legal opinion addressed to Assemblyman Anthony J. Portantino, broadly defined a practitioner's standard of care as "that degree of learning and skill ordinarily possessed by [practitioners] of good standing, practicing in the same or a similar locality and under similar circumstances."[1] "Similar circumstances" has been read to mean that specialists, for instance, are held to the standard of skill, knowledge, and care ordinarily possessed and exercised by other reasonably careful and prudent specialists in the

[1] Letter from Susan Duncan Lee, Supervising Deputy Attorney General, and Taylor S. Carey, Deputy Attorney General, to the Honorable Anthony J. Portantino, dated June 29, 2010, pp. 3-4.

same or similar circumstances at the time in question.[2] It is thus necessary that like is compared to like when the standard of care is applied, with similarity of locality and circumstances.

To show a departure from the standard of care, it is necessary to rely on expert testimony. In the case of *Quigley v. McClellan*, the court set forth expert testimony requirements for establishing a veterinarian malpractice claim using the standard of care:

> "To establish a veterinarian malpractice claim, a plaintiff is required to present expert testimony establishing the appropriate standard of care in the relevant community…Standard of care 'is a matter peculiarly within the knowledge of experts; it presents the basic issue in a malpractice action and can only be proved by their testimony'…This is because '[t]he standard of care in a [veterinarian] malpractice case requires the [veterinarian] exercise in diagnosis and treatment that reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the [veterinary] medical profession under similar circumstances.'"[3]

The laws and regulations applicable to the Veterinary Medical Board can further define standards of care. In *In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*, Board of Pharmacy Case No. 3802; OAH No. 2011010644, which was made a precedential decision by the Pharmacy Board, a pharmacist was accused of prescribing too many medications and not verifying the legitimacy of those prescriptions called in by other pharmacists. The complainant in this case "asserted that a pharmacist has the duty to verify that a prescription written for controlled substances was issued for a legitimate medical purpose under existing standards of care and under the corresponding responsibility law as expressed in Health and Safety Code section 11153."[4] "Corresponding responsibility," about which the court said "[t]he pharmacist's burden is to be alert, to make reasonable inquiry when circumstances require, and to refuse to fill a questionable prescription for a controlled substance when nothing establishes that the prescription at issue was issued for a legitimate medical purpose,"[5] was held to be "both a standard of care and a duty imposed by statute."[6] Likewise, it is possible that a standard of care may sometimes be derived from specific statutory or regulatory provisions of the Veterinary Medicine Practice Act and its corresponding regulations.

The standard of care resists more concrete definitions than that found in case law, because it is always evolving. As another healing arts board, the Dental Board, noted in the minutes of its February 27-28, 2014 meeting, "Legally, the established standards of care in dentistry are indefinable and cannot be found in textbooks…Because the standard of care evolves due to court rulings, advances in dental research, continuing education, and the

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[2] *Medical Board of California Expert Reviewer Guide*, p. 4.
[3] *Quigley v. McClellan*, 214 Cal.App. 4th 1276, 1283.
[4] *In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*, Board of Pharmacy Case No. 3802; OAH No. 2011010644, p. 28.
[5] *Id*., p. 27.
[6] *Id*., p. 30.

progression of the practice of dentistry, there is no possible way for the Board to define it…". The same can be said for the practice of veterinary medicine.

"Minimum standards," as opposed to the "standard of care," is a term found in California Code of Regulations Section 2032, which provides:

> "2032 Minimum Standards of Practice.
> The delivery of veterinary care shall be provided in a competent and humane manner. All aspects of veterinary medicine shall be performed in a manner consistent with current veterinary medical practice in this state."

Incompetence is defined in the *Merriam Webster Dictionary* as "lack of the ability to do something well: the quality or state of not being competent." Minimum standards addresses competence, while the standard of care addresses negligence. Negligence basically means that one knows what to do, but does not do it in a manner that a reasonably careful practitioner would do it in the same or similar circumstances. Incompetence means that one does not even know how to do something. This difference in wording distinguishes the two standards from each other.

Licensees of the Veterinary Medical Board must meet both the standard of care and minimum standards in their practice of veterinary medicine or technology. Section 4883(i) of the Veterinary Medicine Practice Act provides that the Board may deny, revoke, or suspend a license or registration or asses a fine for either or both of negligence and incompetence in the practice of veterinary medicine. Thus, the standard of care and minimum standards can be invoked where relevant to allege negligence and/or incompetence in the practice of veterinary medicine.

Candace Raney
Elizabeth Bynum

CONTACT:
cures@doj.ca.gov
(916) 227-3843

December 18, 2015

RE: CURES 2.0 Universal Launch and Streamlined Registration

The Department of Justice (DOJ) and the Department of Consumer Affairs (DCA) are pleased to announce substantial milestones in the enhancement of the state's Controlled Substance Utilization Review and Evaluation System (CURES).

Beginning January 8, 2016, the upgraded prescription drug monitoring program – commonly referred to as "**CURES 2.0**" – will be automatically released to all users in compliance with the system's minimum security requirements.[1] This upgraded database offers a significantly improved user experience and features a number of added functionalities, including the ability to delegate report queries and new practitioner-identified patient alerts.

Also beginning January 8, 2016, a streamlined registration process will be implemented for new users. This fully-automated process will enable licensed health care prescribers and pharmacists to request access to CURES and validate their credentials entirely online using a secure web browser.

All health care practitioners authorized to prescribe or dispense Schedule II-IV controlled substances must be registered to use CURES no later than July 1, 2016.[2] To register using the automated system, simply visit oag.ca.gov/cures, click on the Registration link, and follow the instructions. Registrants will need their state license information and prescribers must provide federal DEA license information to register.

To learn more, visit oag.ca.gov/cures-pdmp/faqs. For assistance, contact the CURES helpdesk at (916) 227-3843 or cures@doj.ca.gov.

[1] CURES 2.0 users will be required to use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system.
[2] Pursuant to Health & Safety Code Section 11165.1 as amended by California Assembly Bill No. 679, California 2015-2016 Regular Session

FREQUENTLY ASKED QUESTIONS

What information may be obtained from CURES?

The Controlled substance Utilization Review and Evaluation System (CURES) stores Schedule II, III, and IV controlled substance prescription information reported as dispensed in California. CURES contains the following information: patient name, patient date of birth, patient address, prescriber name, prescriber DEA number, pharmacy name, pharmacy license number, date prescription was dispensed, prescription number, drug name, drug quantity and strength, and number of refills remaining.

Who has access to CURES information?

As outlined in Health & Safety Code section 11165.1(a)(1)(A), prescribers authorized to prescribe, order, administer, furnish, or dispense Schedule II, III, or IV controlled substances, and pharmacists, may access CURES data for patient care purposes.

Additionally, pursuant to Health & Safety Code section 11165(c)(2), CURES data is available to appropriate state, local, and federal public agencies, law enforcement, and regulatory boards for disciplinary, civil, or criminal purposes. The Department of Justice (DOJ) may also provide data to other agencies and entities for educational, peer review, statistical, or research purposes, provided that patient identity information is not disclosed.

Who is required to register for CURES?

Prescribers must submit an application before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later. Registration requirements are not based on dispensing, prescribing, or administering activities but, rather, on possession of a Drug Enforcement Administration Controlled Substance Registration Certificate AND valid California licensure as any one of the following:

- Dentist
- Medical Physician
- Physician Assistant
- Podiatrist

Naturopathic Physician	Registered Certified Nurse Midwife
Optometrist	Registered Nurse Practitioner (Furnishing)
Osteopathic Physician	Veterinarian

Pharmacists must submit an application before July 1, 2016, or upon licensure, whichever occurs later. Registration requirements are not based on dispensing, prescribing, or administering activities but, rather, on valid California licensure as a Pharmacist.

What do I do if the information in CURES is not correct?

Data contained in CURES is reported to the DOJ by pharmacies and direct dispensers. If you are a patient with incorrect information on your CURES report, please notify the reporting pharmacy of the error. Only the original reporting pharmacy or dispenser may submit prescription corrections to the DOJ.

For information on how to submit controlled substance prescription data or data corrections, pharmacies and direct dispensers may contact Atlantic Associates, Inc. by email at CACures@aainh.com or by phone at (800) 539-3370.

What Internet browsers are required for CURES 2.0 access?

CURES 2.0 users must use Microsoft Internet Explorer version 11.0 or higher, Mozilla Firefox, Google Chrome, or Safari. Earlier versions of Internet Explorer are not supported by CURES 2.0 for security considerations.

CURES 1.0 will continue to be made available to clinical users for an indeterminate time to facilitate uninterrupted access to CURES data while health care systems upgrade to CURES 2.0-compatible browsers.

What is the registration process for access to CURES 2.0?

Registration, for California licensed prescribers and pharmacists, is fully automated. Applicants must complete the online registration form and provide a valid email address, medical or pharmacist license number, and DEA registration certificate number (prescribers only.) DOJ will validate identity and license electronically with the Department of Consumer Affairs and the Drug Enforcement Administration.

Do current CURES 1.0 users need to re-apply for CURES 2.0 access?

No. Existing CURES users do not need to apply for access to CURES 2.0. These users are able to access the CURES 2.0 with their current User ID and password. Upon initial login to CURES 2.0, users are required to update their security questions and answers and re-establish a new password. The user must also review their CURES account profile to verify their information is accurate, make necessary updates, and acknowledge CURES Terms and Conditions. Once this has been completed, the user may begin searching patient prescription information in CURES 2.0.

What happens to providers who have submitted application documents under the old registration requirements but have not yet been granted access?

Prescribers and pharmacists who submitted application documents using the old registration method will continue to have their registrations processed. If approved, these applicants will be granted access to CURES.

If a current CURES user is locked out of the system, how can he/she regain access?

CURES 2.0 users are provided easy, intuitive, online assistance for password reset, forgot UserID and forgot password. Links to these services are on the CURES 2.0 login page. Additionally, users may contact the CURES Help Desk at (916) 227-3843 or cures@doj.ca.gov .

Additionally questions…

FREQUENTLY ASKED QUESTIONS

What is CURES 2.0?

CURES 2.0 is the state's upgraded and modernized prescription drug monitoring program, implemented through Senate Bill 809 (DeSaulnier, 2013). The system stores Schedule II, III, and IV controlled substance prescription information reported as dispensed in California for review by licensed prescribers.

How do I register and access CURES 2.0?

Starting on January 1, 2016, all current CURES users who visit the CURES website using a secure web browser will be automatically directed to the 2.0 system, where they can update their information and then immediately gain access to the new database. Prescribers and pharmacists not currently registered with CURES may use any secure browser to sign up entirely online.

What web browsers are required to meet the CURES 2.0 minimum security standards?

Users must use Microsoft Internet Explorer version 11.0 or higher, Mozilla Firefox, Google Chrome, or Safari to access CURES 2.0 or apply for access using automated registration.

Outdated browser technologies frequently contain known vulnerabilities that can be exploited by hackers;[1] Microsoft has announced plans to end lifecycle support for older versions of Internet Explorer beginning in 2016 and will no longer provide security patches to users of these browsers. Because the CURES database contains sensitive medical information requiring heightened protection against data breaches, only secure browsers may be used.

What if I don't meet the minimum security requirements?

Users attempting to access the CURES database using unsecure browsers will be automatically directed to the old CURES 1.0 system and will not have access to the new system's features. However, the old system will be phased out in the coming months, and users will need to update their browsers to continue accessing CURES. All users of the old system are strongly encouraged to make this transition as soon as possible.

Who must register with CURES by July 1, 2016?

Prescribers must register if they are in possession of:

1. A Drug Enforcement Administration (DEA) Controlled Substance Registration Certificate for Schedule II – IV controlled substances *and*
2. A valid California license in an applicable health care profession.

All licensed Pharmacists in California must register with the system.

Backlog Question…

I have already put in a paper registration for CURES, do I need to do anything?

[1] *Protect Your Computer from Viruses, Hackers, & Spies*, CA DOJ Privacy Enforcement and Protection Unit, 2015

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR PAIN

MEDICAL BOARD OF CALIFORNIA

NOVEMBER 2014

Edmund G. Brown Jr., Governor
David Serrano Sewell, J.D., President, Medical Board of California
Kimberly Kirchmeyer, Executive Director, Medical Board of California

Guidelines for Prescribing Controlled Substances for Pain

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PREAMBLE

Protection of the public is the highest priority for the Medical Board of California (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality medical practice and California law dictate that the people of California have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life for patients who suffer from pain, particularly chronic pain.

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." This was used to provide guidance to physicians prescribing controlled substances. Several legislative changes since 1994 necessitated revising these guidelines; most recently in 2007.

In November 2011, the Centers for Disease Control and Prevention declared prescription drug abuse to be a nationwide epidemic. Drug overdose is now the leading cause of accidental deaths, exceeding deaths due to motor vehicle accidents. A majority of those overdose deaths involved prescription drugs. The diversion of opioid medications to non-medical uses has also contributed to the increased number of deaths, although the problem is not limited to the aberrant, drug-seeking patient. Injuries are occurring among general patient populations, with some groups at high risk, (e.g., those with depression). Consequently, the Board called for revision of the guidelines to provide additional direction to physicians who prescribe controlled substances for pain.

These guidelines are intended to help physicians improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain. Opioid analgesics are widely accepted as appropriate and effective for alleviating moderate-to-severe acute pain, pain associated with cancer, and persistent end-of-life pain. [1] Although some of the recommendations cited in these guidelines might be appropriate for other types of pain, they are not meant for the treatment of patients in hospice or palliative care settings and are not in any way intended to limit treatment where improved function is not anticipated and pain relief is the primary goal. These guidelines underscore the extraordinary complexity in treating pain and how long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up, and close supervision are ensured. Since opioids are only one of many options to mitigate pain, and because prescribing opioids carries a substantial level of risk, these guidelines offer several non-opioid treatment alternatives. These guidelines are not intended to mandate the standard of care. The Board recognizes that deviations from these guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Medicine is practiced one patient at a time and each patient has individual needs and vulnerabilities. Physicians are encouraged to document their rationale for each

[1] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

prescribing decision. Physicians should understand that if one is ever the subject of a quality of care complaint, peer expert review will be sought by the Board. The expert reviewer must consider the totality of circumstances surrounding the physician's prescribing practice (e.g., issues relating to access of care, paucity of referral sources, etc.) Specifically, experts are instructed to "define the standard of care in terms of the level of skill, knowledge, and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question."[2]

In an effort to provide physicians with as many sources of information as possible, these guidelines link to numerous references relating to prescribing. Additionally, numerous appendices are attached. The Board recognizes that some of the links/appendices may not be consistent with either each other or the main text of the guidelines. The intent for including as many sources of information as practicable is so that physicians can consider varying perspectives to arrive at the best patient-appropriate treatment decision. The Board does not endorse one treatment option over another and encourages physicians to undertake independent research on this continuously evolving subject matter.

UNDERSTANDING PAIN

The diagnosis and treatment of pain is integral to the practice of medicine. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives long-term opioid therapy.

The California Medical Association[3] has defined and clarified key concepts relating to pain, excerpted below:

Pain: The definition of pain proposed by the International Association for the Study of Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." It has also been said that "Pain is what the patient says it is." Both definitions acknowledge the subjective nature of pain and are reminders that, with the rare exception of patients who intentionally deceive, a patient's self-report and pain behavior are likely the most reliable indicators of pain and pain severity. As a guide for clinical decision-making, however, both of these definitions are inadequate. In addition, it is important to remember that the subjectivity of pain, particularly when the cause is not apparent, can lead to the stigmatization of those with pain.

[2] Medical Board of California Expert Reviewer Guidelines (rev. January, 2013)
[3] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Acute and Chronic Pain: Traditionally, pain has been classified by its duration. In this perspective, "acute" pain is relatively short-duration, arises from obvious tissue injury, and usually fades with healing. "Chronic" pain, in contrast, has been variously defined as lasting longer than would be anticipated for the usual course of a given condition, or pain that lasts longer than arbitrary cut-off times, such as 3 or 6 months. Temporal pain labels, however, provide no information about the biological nature of the pain itself, which is often of critical importance.

Nociceptive and Neuropathic Pain: A more useful nomenclature classifies pain on the basis of its patho-physiological process. Nociceptive pain is caused by the activation of nociceptors, and is generally, though not always, short-lived and is associated with the presence of an underlying medical condition. It is a "normal" process; a physiological response to an injurious stimulus. Nociceptive pain is a symptom. Neuropathic pain, on the other hand, results either from an injury to the nervous system or from inadequately-treated nociceptive pain. It is an abnormal response to a stimulus; a pathological process. It is a neuro-biological disease. Neuropathic pain is caused by abnormal neuronal firing in the absence of active tissue damage. It may be continuous or episodic and varies widely in how it is perceived. Neuropathic pain is complex and can be difficult to diagnose and to manage because available treatment options are limited.

A key aspect of both nociceptive and neuropathic pain is the phenomenon of sensitization, which is a state of hyper-excitability in either peripheral nociceptors or neurons in the central nervous system. Sensitization may lead to either hyperalgia or allodynia. Sensitization may arise from intense, repeated or prolonged stimulation of nociceptors, or from the influence of compounds released by the body in response to tissue damage or inflammation. Importantly, many patients – particularly those with persistent pain --- present with "compound" pain that has both nociceptive and neuropathic components, a situation which complicates assessment and treatment.

Differentiating between nociceptive and neuropathic pain is critical because the two respond differently to pain treatments. Neuropathic pain, for example, typically responds poorly to both opioid analgesics and non-steroidal anti-inflammatory drug (NSAID) agents. Other classes of medications, such as anti-epileptics, antidepressants or local anesthetics, may provide more effective relief for neuropathic pain.

Cancer and Non-Cancer Pain: Pain associated with cancer is sometimes given a separate classification, although it is not distinct from a patho-physiological perspective. Cancer-related pain includes pain caused by the disease itself and/or painful diagnostic or therapeutic procedures [and the sequelae of those processes]. The treatment of cancer-related pain may be influenced by the life expectancy of the patient, by co-morbidities and by the fact that such pain may be of exceptional severity and duration. A focus of recent attention by the public, regulators, legislators, and physicians has been chronic pain that is not associated with cancer. A key feature of such pain, which may be caused by conditions such as musculoskeletal injury, lower back trauma and dysfunctional wound healing, is that the severity of pain may not correspond well to identifiable levels of tissue damage.

Tolerance, Dependence and Addiction: Related to the nomenclature of pain itself is continuing confusion not only among the public, but also in the medical community, about terms used to describe the effects of drugs on the brain and on behavior. To help clarify and standardize understanding, the American Society of Addiction Medicine (ASAM), the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS) have recommended the following definitions:

> *Tolerance:* A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time.
>
> *Physical Dependence:* A state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist.
>
> *Addiction:* A primary, chronic, neurobiological disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm and craving.

Pain as an Illness: Finally, it may be helpful to point out that pain can be regarded as an illness as well as a symptom or a disease. "Illness" defines the impact a disease has on an organism and is characterized by epiphenomena or co-morbidities with bio-psycho-social dimensions. Effective care of any illness, therefore, requires attention to all of these dimensions. Neuropathic pain, end-of-life pain and chronic pain should all be viewed as illnesses.

SPECIAL PATIENT POPULATIONS

All patients may experience pain. Below are treatment considerations for differing patient populations or scenarios. As previously addressed, these guidelines are intended to particularly address the use of opioids in the long-term treatment of chronic, non-cancer pain. However, since many of the recommendations cited in these guidelines might be appropriate for other types of pain, other scenarios are listed below to provide additional guidance in prescribing opioids, when appropriate.

Acute Pain[4]

Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies likely will not provide adequate pain relief. When opioid medications are prescribed for treatment of acute pain, the number dispensed should be for a short duration and no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

[4] Utah Department of Health (Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain, 2009).

Long (and intermediate) duration-of-action opioids or extended-release/long-acting opioids (ER/LA) should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely, if ever, indicated for treatment of acute pain. The use of opioids should be re-evaluated carefully, including the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

It is important to emphasize that numerous (but not all) recommendations cited in these guidelines may not be relevant for the physician treating a patient for acute pain. For example, a physician treating a patient who presents to an emergency department or primary care physician with a medical condition manifested by objective signs (e.g., a fractured ulna or kidney stones discernible with imaging studies) would not necessarily need to undertake an opioid trial, perform a psychological assessment, utilize a pain management agreement, confer with the Prescription Drug Monitoring Program database, order a drug toxicology screen, etc.

Emergency Departments
Treating patients in an emergency department (ED) or urgent care clinic presents unique challenges in that, oftentimes, there is limited ability to procure adequate patient history and the primary physician is not available. Drug seeking patients may take advantage of this in order to secure controlled substances.

The American College of Emergency Physicians (ACEP) Clinical Policy - Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department (Appendix 1) - identifies acute low back pain as a common presenting complaint in the ED. Opioids are frequently prescribed, expected or requested for such presentations. Consequently, ACEP clinical policy recommends:

(1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether non-opioid analgesics and non-pharmacologic therapies will be adequate for initial pain management.
(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or non-opioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.
(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (e.g.,<1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

For patients presenting to the ED with an acute exacerbation of non-cancer chronic pain, ACEP recommends the following:

(1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED.
(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (e.g., < 1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs.

ACEP recommends that the use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

End-of-Life Pain[5]
Pain management at the end of life seeks to improve or maintain a patient's overall quality of life in addition to relieving suffering. This focus is important because sometimes a patient may have priorities that compete with, or supersede, the relief of pain. For some patients, mental alertness sufficient to allow lucid interactions with loved ones may be more important than physical comfort. Optimal pain management, in such cases, may mean lower doses of an analgesic and the experience, by the patient, of higher levels of pain.

Fear of inducing severe or even fatal respiratory depression may lead to the clinician[6] under-prescribing and reluctance by patients to take an opioid medication. Despite this fear, studies have revealed no correlation between opioid dose, timing of opioid administration and time of death in patients using opioids in the context of terminal illness. A consult with a specialist in palliative medicine in these situations may be advisable.

Cancer Pain
Pain is one of the most common symptoms of cancer, as well as being one of the most feared cancer symptoms. Opioid pain medications are the mainstay of cancer pain management, and are appropriate to consider for cancer patients with moderate to severe pain, regardless of the known or suspected pain mechanism. However, some cancer survivors with moderate-to-severe pain may additionally or alternatively benefit from the use of non-opioid treatments, and opioids may not be necessary. Other treatments such as surgeries, radiation therapy, and other procedures may provide sufficient pain relief so that opioids are not necessary.

ER/LA opioid formulations may lessen the inconvenience associated with the use of short-acting opioids. Patient-controlled analgesia using an ambulatory infusion device may provide optimal patient control and effective analgesia. The full range of adjuvant medications should be considered for patients with cancer pain, with the caveat that such patients are often on already complicated pharmacological regimens, which raises the risk of adverse reactions associated with polypharmacy.[7]

[5] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).
[6] The term "clinician" throughout the document means "physician."
[7] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Older Adults
With appropriate precautions opioid therapy for elderly patients can be efficacious. It is important to begin with lower starting doses, slower titration, longer dosing intervals, and more frequent monitoring. Tapering of benzodiazepines is important to reduce the potential for respiratory depression.

For additional information, see Appendix 2.

Pediatric Patients
Extreme caution should be used in prescribing opioids for pediatric patients. A trial of opioid therapy may be considered with well-defined somatic or neuropathic pain conditions when non-opioid alternatives have failed or are unlikely to be effective for acute pain. Additionally, close monitoring and consultation should be undertaken.

For additional information, see Appendix 3.

Pregnant Women
Clinicians should encourage minimal or no use of opioids during pregnancy unless the potential benefits clearly outweigh risks. Pregnant patients taking long-term opioid therapy should be tapered to the lowest effective dose slowly enough to avoid withdrawal symptoms, and then therapy should be discontinued if possible.

Additional information on the appropriate use of opioids for pregnant patients is available from the American Congress of Obstetricians and Gynecologists (ACOG) committee opinion titled *Opioid Abuse, Dependence, and Addiction in Pregnancy*.

Patients Covered by Workers' Compensation[8]
This population of patients presents its own unique circumstances. Injured workers are generally sent to an occupational medicine facility for treatment. Ideally, the injured worker recovers and returns to work in full capacity. If recovery or healing does not occur as expected, early triage and appropriate, timely treatment is essential to restore function and facilitate a return to work.

The use of opioids in this population of patients can be problematic. Some evidence suggests that early treatment with opioids may actually delay recovery and a return to work. Conflicts of motivation may also exist in patients on workers' compensation, such as when a person may not want to return to an unsatisfying, difficult or hazardous job. Clinicians are advised to apply the same careful methods of assessment, creation of treatment plans and monitoring used for other pain patients but with the added consideration of the psycho-social dynamics inherent in the workers' compensation system. Injured workers should be afforded the full range of treatment options that are appropriate for the given condition causing the disability and impairment.

[8] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

For additional information on treating patients covered by Workers' Compensation please see *State of California Division of Workers' Compensation Guideline for the Use of Opioids to Treat Work-Related Injuries*.

Patients with History of Substance Use Disorder[9]

Use of opioids for patients with a history of substance use disorder is challenging because such patients are more vulnerable to drug misuse, abuse and addiction. In patients who are actively using illicit drugs, the potential benefits of opioid therapy are likely to be outweighed by potential risks, and such therapy should not be prescribed outside of highly controlled settings (such as an opioid treatment program with directly observed therapy). In other patients, the potential benefits of opioid therapy may outweigh potential risks. Although evidence is lacking on best methods for managing such patients, potential risks may be minimized by more frequent and intense monitoring compared with lower risk patients, authorization of limited prescription quantities and consultation or co-management with a specialist in addiction medicine. Clinicians should use the [Controlled Substance Utilization Review and Evaluation System (CURES)/Prescription Drug Monitoring Program (PDMP)] CURES/PDMP to identify patients who obtain drugs from multiple sources.

If either the patient's medical history, self-report or scores on screening assessment tools such as the Opioid Risk Tool (Appendix 4) suggest an above-average risk of substance abuse, clinicians should consider the following steps in proceeding with a pain management strategy:

- Exhaust all non-opioid pain management methodologies prior to considering opioid therapy;
- Consult with a specialist in addiction medicine;
- Create a written treatment plan and patient agreement and review carefully with the patient, obtaining their signed informed consent;
- Closely monitor and assess pain, functioning and aberrant behaviors;
- Regularly check with a PDMP for compliance with prescribed amounts of opioids (using cross-state PDMP systems whenever they are available);
- While the patient is on long-term opioid therapy, implement urine drug testing, if possible; or
- If misuse or abuse of opioid analgesics is suspected or confirmed, initiate a non-confrontational in-person meeting, use a non-judgmental approach to asking questions, present options for referral, opioid taper/discontinuation or switching to non-opioid treatments, and avoid "abandoning" the patient or abruptly stopping opioid prescriptions.

Psychiatric Patients

A higher risk for deleterious side effects exists for patients with psychiatric diagnoses who are receiving opioid treatment. Opioids should only be prescribed for well-defined

[9] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

somatic or neuropathic pain conditions. Physicians should titrate slowly, closely monitor the patient and seek consultation from the appropriate specialist.

Patients Prescribed Benzodiazepines
Patients taking benzodiazepines and opioids are at an increased risk for respiratory depression, particularly elderly patients. Physicians should consider a trial of benzodiazepine tapering in patients concomitantly using opioids or other respiratory depressant medications. If a trial of tapering is not indicated or is unsuccessful, opioids should be titrated more slowly and at lower doses. For additional information, see Benzodiazepines: How They Work and How to Withdraw.

Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder
Patients prescribed methadone or buprenorphine for treatment of a substance use disorder may need relief from acute and/or chronic pain, beyond that provided by their maintenance medication. For more information on pain relief for persons on methadone or buprenorphine, see *Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy*.

PATIENT EVALUATION AND RISK STRATIFICATION

When considering long-term use of opioids for chronic, non-cancer pain, given the potential risks of opioid analgesics, careful and thorough patient assessment is critical. Risk stratification is one of the most important things a physician can do to mitigate potentially adverse consequences of opioid prescribing. The nature and extent of the clinical assessment depends on the type of pain and the context in which it occurs. This includes but is not limited to:

- Completing a medical history and physical examination (Appendix 5).
- Performing a psychological evaluation.
    - Psychological assessment should include risk of addictive disorders. Screening tools that can be considered for use include:
        - CAGE-AID (Appendix 6);
        - PHQ-9 (Appendix 7);
        - Opioid Risk Tool (ORT) (Appendix 4); and
        - SOAPP®-R (Appendix 8).
        - Note: Although the above-listed assessment tools are well-established with proven effectiveness, physicians must be aware that seasoned diverters know the right answers to these tools so they look "normal."
- Establishing a diagnosis and medical necessity (review past medical records, laboratory studies, imaging studies, etc. and order new ones, if necessary or if previous studies are outdated). Screening tools that can be considered for use include:
    - Pain Intensity and Interference (pain scale) (Appendix 9); and
    - Sheehan Disability Scale.
- Exploring non-opioid therapeutic options.

Opioid medications may not be the appropriate first line of treatment for a patient with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. Resources that can be consulted include:
    - Therapeutic Options for Pain Management (Appendix 10); and
    - Non-Opioid Pain Management Tool (Appendix 11).
- Evaluating both potential benefits and potential risks of opioid therapy.
- Being cognizant of aberrant or drug seeking behaviors.
- As a universal precaution, undertaking urine drug testing.
- Reviewing the CURES/PDMP report for the patient. This allows a physician to check to see if a patient is receiving controlled substances from other prescribers in California (assuming the prescription is being filled at a California pharmacy).

CONSULTATION

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, or an addiction or mental health specialist as needed. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available.

Physicians who prescribe long-term opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed.

TREATMENT PLAN AND OBJECTIVES

When considering long-term use of opioids for chronic, non-cancer pain, the physician and the patient should develop treatment goals together. The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Pain relief is important, but it is difficult to measure objectively. Therefore, it cannot be the primary indicator to assess the success of the treatment. Effective pain relief improves functioning, whereas addiction decreases functionality. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including

medications other than opioids) and non-pharmacologic. It also should specify measurable goals and objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function.

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered. The treatment plan should also include an "exit strategy" for discontinuing opioid therapy in the event the tapering or termination of opioid therapy becomes necessary.

PATIENT CONSENT

When considering long-term use of opioids, or in other medically appropriate situations, the physician should discuss the risks and benefits of the treatment plan with the patient, with persons designated by the patient, or with the patient's conservator if the patient is without medical decision-making capacity. If opioids are prescribed, the patient (and possibly family members, if appropriate) should be counseled on safe ways to store and dispose of medications. For convenience, patient consent and a pain management agreement can be combined into one document.

Patient consent typically addresses:

- The potential risks and anticipated benefits of long-term opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as nausea, opioid-induced constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Gegmann et al., 2008) and cognitive impairment.
- The likelihood that some medications will cause tolerance and physical dependence to develop.
- The risk of drug interactions and over-sedation.
- The risk of respiratory depression.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.

PAIN MANAGEMENT AGREEMENT

Use of a pain management agreement is recommended for patients:

- On short-acting opioids at the time of third visit within two months;
- On long-acting opioids; or
- Expected to require more than three months of opioids.

Pain management agreements typically outline the joint responsibilities of the physician and the patient and should include:

- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.

- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication to prevent misuse by other household members).
- The patient's agreement to share information with family members and other close contacts on how to recognize and respond to an opiate overdose, including administering an opioid antagonist, such as naloxone, if necessary.(Appendix 12)
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice and one pharmacy.
- The patient's agreement to periodic drug testing (blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills, if appropriate and in accordance with the patient's pain management agreement.

Samples of pain management agreements:

- Patient Pain Medication Agreement and Consent (Appendix 13)
- Treatment Plan Using Prescription Opioids (Appendix 14)

COUNSELING PATIENTS ON OVERDOSE RISK AND RESPONSE

Empirical evidence has shown that lay persons can be trained to recognize the signs of an opiate overdose and to safely administer naloxone, an opiate antagonist. Programs that have trained lay persons in naloxone administration have reported more than 10,000 overdose reversals.[10]

It is important to educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened.
- Periods of ataxic (irregular) or other sleep-disordered breathing.
- Having trouble breathing.
- Exhibiting extreme drowsiness and slow breathing.
- Having slow, shallow breathing with little chest movement or no breathing.
- Having an increased or decreased heartbeat.
- Feeling faint, very dizzy, confused or has heart palpitations.
- Blue skin/lips.
- Non-responsiveness to painful stimulation.

[10] Centers for Disease Control and Prevention. Community-based opioid overdose prevention programs providing naloxone-United States, 2010. Morbidity and mortality weekly report, February 17, 2012 / 61(06);101-105

Effective January 1, 2015, California pharmacists will be able to furnish an opioid overdose reversal drug in accordance with standardized procedures or protocols, naloxone, to family members of patients at risk for overdose, those who might be in contact with an individual at risk for overdose, or anyone who requests the drug without a prescription.

SAMHSA's Opiate Overdose Toolkit and Prescribe to Prevent contain numerous documents relating to overdose prevention and management.

INITIATING OPIOID TRIAL

Safer alternative treatments should be considered before initiating opioid therapy for chronic pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 45 days) and with specific evaluation points. The *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*[11] reveals that "[o]ver half of persons receiving 90 days of continuous opioid therapy remain on opioids years later. Factors most strongly associated with continuation were intermittent prior opioid exposure, daily opioid dose≥120 mg MED, and possible opioid misuse. Since high dose and opioid misuse have been shown to increase the risk of adverse outcomes, special caution is warranted when prescribing more than 90 days of opioid therapy in these patients."

The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety.

According to the California Medical Association:[12]

> Oral administration, especially for the treatment of chronic pain, is generally preferred because it is convenient, flexible and associated with stable drug levels. Intravenous administration provides rapid pain relief and, along with rectal, sublingual and subcutaneous administration, may be useful in patients who cannot take medications by mouth. Continuous infusions produce consistent drug blood levels but are expensive, require frequent professional monitoring and may limit patient mobility.
>
> Transdermal administration is a convenient alternate means of continuous drug delivery that does not involve needles or pumps. Patient-controlled analgesia (PCA) allows patients to self-administer pain medications and may be useful if analgesia is required for 12 hours or more and mobility is not required. Intrathecal delivery of opioids is a viable option for patients with chronic pain who have not responded to other treatment options, or for whom the required doses result in unacceptable side-effects. Patients with intrathecal delivery systems typically require ongoing ambulatory monitoring and supportive care.

[11] Journal of General Internal Medicine article (December 2011, Volume 26, Issue 12, pp 1450-1457).
[12] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Patients on a steady dose of an opioid medication may experience pain that breaks through the analgesic effects of the steady-state drug. Paper or electronic pain diaries may help patients track these breakthrough episodes and spot correlations between the episodes and variables in their lives. A short-acting opioid is typically prescribed for treatment by patients with breakthrough pain.

Continuation of opioid therapy after an appropriate trial should be based on outcomes such as: making progress toward functional goals; presence and nature of side effects; pain status; and a lack of evidence of medication misuse, abuse, or diversion. Patients with no, or modest, previous opioid exposure should be started at the lowest appropriate initial dosage of a short-acting opioid and titrated upward to decrease the risk of adverse effects. The selection of a starting dose and manner of titration are clinical decisions made on a case-by-case basis because of the many variables involved. Some patients, such as frail older persons or those with co-morbidities, may require an even more cautious therapy initiation. Short-acting opioids are usually safer for initial therapy since they have a shorter half-life and may be associated with a lower risk of overdose from drug accumulation. The general approach is to "start low and go slow."

Since opioids are known in some circumstances to worsen pain (hyperalgesia), instances of ongoing pain may suggest opioid insensitivity (or an inadequate dose). Careful assessment must be undertaken. If hyperalgesia is suspected, a dose reduction, opioid rotation or tapering to cessation could be considered.

Dosing Recommendations For Opioid Naïve Patients
There is a plethora of data available regarding recommended dosages for various analgesics. Because this is continuously evolving, physicians are encouraged to review the Food and Drug Administration's website and other relevant information sources.

Morphine Equivalent Dose (MED)
There are differing opinions among reputable experts and organizations as to what MED should trigger a consultation. The Board recommends that physicians proceed cautiously (yellow flag warning) once the MED reaches 80 mg/day. Referral to an appropriate specialist should be considered when higher doses are contemplated. There is no absolute safe ceiling dose of opioids, however, and caution and monitoring are appropriate for applications of these medications.

The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently.

ONGOING PATIENT ASSESSMENT

When a trial of an opioid medication is successful and the physician and patient decide to continue opioid therapy, regular review and monitoring should be undertaken for the duration of treatment.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale or other validated assessment tools, may be helpful and time effective.

Consider the 5-As method for chronic pain management assessment:

Analgesia:	the patient is experiencing a reduction in pain.
Activity:	the patient is demonstrating an improvement in level of function.
Adverse:	the patient is not experiencing side effects.
Aberrance:	the patient is complying with the pain management agreement and there are no signs of medication abuse or diversion.
Affect:	the patient's behavior and mood are appropriate.

"Opioid rotation," the switching from one opioid to another in order to better balance analgesia and side effects, may be used if pain relief is inadequate, if side effects are bothersome or unacceptable, or if an alternative route of administration is suggested. Opioid rotation must be done with great care, particularly when converting from an immediate-release formulation to an extended-release/long-acting (ER/LA) product. Equianalgesic charts, conversion tables and calculators must be used cautiously with titration and appropriate monitoring. Patients may exhibit incomplete cross-tolerance to different types of opioids because of differences in the receptors or receptor sub-types to which different opioids bind, hence physicians may want to use initially lower-than-calculated doses of the switched-to opioid.

COMPLIANCE MONITORING

Physicians who prescribe opioids or other controlled substances for pain should ensure the provisions of a pain management agreement are being heeded. Strategies for monitoring compliance may include:

CURES/PDMP Report
The CURES/PDMP report can be useful in establishing whether or not an individual is receiving controlled substances from multiple prescribers. The CURES/PDMP report should be requested frequently for patients who are being treated for pain as well as addiction.

Drug Testing
A patient's report of medication use is not always reliable; therefore, drug testing can be an important monitoring tool.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately. For example,

when a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist. Urine toxicology tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies and interpreting laboratory data. Laboratories vary in their testing methodologies, thresholds and standards. Results from drug screens may involve diverse drug classes and interpreting them requires clinical understanding well beyond opioids.

"Variability may result from differences between laboratories. Some labs, for example, only report values above a certain preset threshold. So, a patient might have a measureable level of drug, but since it does not exceed the given threshold, it is reported as negative finding. This might lead the physician to suspect that a prescribed drug, which should be present at the time of testing, is absent."[13]

"Limitations to Urine Drug Testing (UDT): There is currently no way to tell from a urine drug test the exact amount of drug ingested or taken, when the last dose was taken, or the source of the drug. A recent systematic review of the use of drug treatment agreements and urine drug testing to discourage misuse when opioids are prescribed for chronic non-cancer pain, found weak, heterogeneous evidence that these strategies were associated with less misuse. Limited research did find that UDT was a valuable tool to detect use of non-prescribed drugs and confirm adherence to prescribed medications beyond that identified by patient self-report or impression of the treating physician."[14] "Consequently, additional testing, including quantitative blood levels of prescribed medications and other laboratory testing, may be deemed necessary to monitor and treat patients receiving chronic opioid treatment and is considered part of a medically necessary treatment and monitoring program."[15]

It is important to be aware of cost barriers related to a patient's ability to pay for the testing. There are numerous Clinical Laboratory Improvement Amendments waived office drug testing kits which are inexpensive and which physicians may wish to consider for use for initial drug testing. However, unexpected results from office-based testing should be confirmed by the more-sensitive laboratory testing before the patient's plan of care is changed.

Pill Counting

Periodic pill counting can be a useful strategy to confirm medication adherence and to minimize diversion (selling, sharing or giving away medications).

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[13] Responsible Opioid Prescribing, A Clinician's Guide, Second Edition, 2012, Scott Fishman, M.D.; Federation of State Medical Boards (FSMB), FSMB Foundation, and University of Nebraska Medical Center.

[14] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part D: Comparison Of Recommendations From Existing Opioid Guidelines.

[15] State Of California Division Of Workers' Compensation Guideline For The Use Of Opioids To Treat Work-Related Injuries (Forum Posting, April 2014) Part B Recommendations.

The physician must decide whether or not to revise or augment a pain management agreement and/or treatment plan if the patient's progress is unsatisfactory.
If it is suspected that a patient may be abusing or diverting prescribed medications, or using "street" drugs, a careful re-assessment of the treatment plan must be undertaken. A patient's failure to adhere to a pain management agreement is not necessarily proof of abuse or diversion. Failure to comply may be the consequence of inadequate pain relief, confusion regarding the prescription, a language barrier or economic concerns. A physician should arrange for an in-person meeting in order to have a non-judgmental conversation to clarify his or her concerns. If abuse is confirmed, minimally, consultation with an addiction medicine specialist or mental health specialist trained in substance abuse disorders and/or referral to a substance use disorder treatment program that provides medication-assisted therapy (MAT) should be immediately facilitated. Physicians who prescribe long-term opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors usually require a firmer, immediate response. The degree to which the patient has breached the pain agreement and/or the presence of criminal activity should govern the physician's response. Although an immediate face-to-face meeting with the patient to re-evaluate the treatment plan may be appropriate, in some instances it may be necessary to taper opioid therapy and/or terminate the physician patient relationship. In situations where the patient has engaged in prescription forgery, prescription theft or assaultive behaviors directed towards physician or staff, the physician is strongly encouraged to contact the police/Drug Enforcement Agency (DEA). For other criminal behaviors, the physician is encouraged to contact legal counsel to determine whether it is appropriate to report to law enforcement. Failing to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death.

DISCONTINUING OPIOID THERAPY

Discontinuing or tapering of opioid therapy may be required for many reasons and ideally, an "exit strategy" should be included in the treatment plan for all patients receiving opioids at the outset of treatment. Reasons may include:

- Resolution or healing of the painful condition;
- Intolerable side effects;
- Failure to achieve anticipated pain relief or functional improvement (although ensure that this failure is not the result of inadequate treatment);
- Evidence of non-medical or inappropriate use;
- Failure to comply with monitoring, such as urine drug screening (although ensure that this failure is not the result of a cost issue);
- Failure to comply with pain management agreement;

- Exhibition of drug-seeking behaviors (although ensure this behavior is not the result of inadequate treatment) or diversion, such as:
    - Selling prescription drugs;
    - Forging prescriptions;
    - Stealing or borrowing drugs;
    - Aggressive demand for opioids;
    - Injecting oral/topical opioids;
    - Unsanctioned use of opioids;
    - Unsanctioned dose escalation;
    - Concurrent use of illicit drugs;
    - Getting opioids from multiple prescribers and/or multiple pharmacies; or
    - Recurring emergency department visits for chronic pain management.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely-structured tapering regimen. Opioid withdrawal symptoms are uncomfortable, but are generally not life threatening. Opioids can be stopped abruptly when the risks outweigh the benefits. This is not true for benzodiazepine withdrawals, which can be life threatening. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist. "Approaches to weaning range from a slow 10% reduction per week to a more aggressive 25 to 50% reduction every few days. In general, a slower taper will produce fewer unpleasant symptoms of withdrawal."[16] For strategies on tapering and weaning, see Appendix 15. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate.

If complete termination of care is necessary (as opposed to termination of a specific treatment modality), physicians should treat the patient until the patient has had a reasonable time to find an alternative source of care, and ensure that the patient has adequate medications, if appropriate, to avoid unnecessary risk from withdrawal symptoms. Physicians can be held accountable for patient abandonment if medical care is discontinued without adequate provision for subsequent care. If a patient is known to be abusing a medication, initiating a detoxification protocol may be appropriate. Consultation with an attorney and/or one's malpractice insurance carrier may be prudent in such cases. Physicians may want to also consult health plan contracts to ensure compliance. The Board also provides guidance on how to terminate/sever the patient relationship.

If a patient is dismissed for not honoring treatment agreements, consider referral to addiction resources. This can also include a 12-step program.

[16] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

MEDICAL RECORDS

Every physician must maintain adequate and accurate medical records. The content of a patient's medical record may vary considerably, depending on numerous factors. For a physician treating a patient with opioids for chronic, non-cancer pain, an adequate medical record includes, but is not limited to, the documentation of:

- the patient's medical history;
- results of the physical examination and all laboratory tests ordered by the physician;
- patient consent;
- pain management agreement;
- results of the risk assessment, including results of any screening instruments used;
- description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity);
- instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement;
- notes on evaluations by, and consultations with, specialists;
- any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors (these may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers);
- authorization for release of information to other treatment providers as appropriate and/or legally required; and
- results of CURES/PDMP data searches.

The medical record should include all prescription orders for opioid analgesics and other controlled substances, whether written, telephoned or electronic. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed, if the pharmacy that the patient will use is known. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review.

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient.

SUPERVISING ALLIED HEALTH PROFESSIONALS

Physicians who supervise physician assistants or nurse practitioners who prescribe opioids should be aware of the specific regulations and requirements governing them and those whom they supervise.

COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS

California laws:

- California laws regarding controlled substances
- Guide to the Laws Governing the Practice of Medicine

Federal laws:

- Title 21 United States Code (USC) Controlled Substances Act

Other information:

- Pharmacist corresponding responsibilities

Appendix 1 - Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

Clinical Policy: Critical Issues in the Prescribing of Opioids for Adult Patients in the Emergency Department

From the American College of Emergency Physicians Opioid Guideline Writing Panel
Stephen V. Cantrill, MD (Chair)
Michael D. Brown, MD, MSc (Methodologist)
Russell J. Carlisle, MD
Kathleen A. Delaney, MD
Daniel P. Hays, PharmD, BCPS
Lewis S. Nelson, MD
Robert E. O'Connor, MD, MPH (ACEP Board Liaison)
AnnMarie Papa, DNP, RN, CEN, NE-BC (ENA Representative)
Karl A. Sporer, MD
Knox H. Todd, MD, MPH
Rhonda R. Whitson, RHIA (Clinical Practice Manager, ACEP)

Providing Technical Assistance:

Leonard J. Paulozzi, MD, MPH, Medical Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention
Chet Pogostin, DVM, MPA, Deputy Director, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention
Bob A. Rappaport, MD, Director, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, Food and Drug Administration
Jacqueline Spaulding, MD, Medical Officer, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, Food and Drug Administration

Approved by the ACEP Board of Directors, June 14, 2012

Supported by the Emergency Nurses Association, July 18, 2012

This clinical policy was funded under contract 200-2011-M-38670 with the Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury.

DISCLAIMER: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry, or the Food and Drug Administration.

0196-0644/$-see front matter

http://dx.doi.org/10.1016/j.annemergmed.2012.06.013

[Ann Emerg Med. 2012;60:499-525.]

ABSTRACT

This clinical policy deals with critical issues in prescribing of opioids for adult patients treated in the emergency department (ED). This guideline is the result of the efforts of the American College of Emergency Physicians, in consultation with the Centers for Disease Control and Prevention, and the Food and Drug Administration. The critical questions addressed in this clinical policy are: (1) In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse? (2) In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications? (3) In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids? (4) In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

INTRODUCTION

Pain is a major symptom of many patients presenting to the emergency department (ED), with up to 42% of ED visits being related to painful conditions.[1] Pain management has received increased emphasis in the past decade, including The Joint Commission's focus on patient analgesia[2] and increasing institutional emphasis placed on patient satisfaction surveys covering pain management. Much literature, including the most recent Institute of Medicine report on this topic, has stressed that health care providers have not done as well as possible in the area of pain management.[3] A possible unintended consequence of these efforts is the increase in prescription drug abuse, especially opioid abuse, the fastest-growing drug abuse problem in the United States.[4]

As part of this issue, there has been a startling increase in unintentional drug overdoses and related deaths since the late 1990s.[5,6] Reported overdose deaths involving opioid analgesics increased from 4,030 in 1999 to 14,800 in 2008.[7,8] Data from 2008 reveal that drug overdoses were the second leading cause of injury death in the United States, after motor vehicle crashes.[9] Currently, deaths from opioid analgesics are significantly greater in number than those from cocaine and heroin combined.[8]

The efforts of clinicians to improve their treatment of pain, along with pharmaceutical industry marketing, have been factors in contributing to a significant increase in the sale and distribution of opioids in the United States. For example, the sales of opioid analgesics to hospitals, pharmacies, and practitioners quadrupled between 1999 and 2010.[8] Drug sales and distribution data of opioids show an increase from 180 mg morphine equivalents per person in the United States in 1997 to 710 mg per person in 2010.[8,10] This is the equivalent of 7.1 kg of opioid medication per 10,000 population, or enough to supply every American adult with 5 mg of hydrocodone every 4 hours for a month.[8]

The dilemma of treating pain appropriately while avoiding adverse events is further complicated by insufficient data supporting the long-term use of opioids in the treatment of chronic noncancer pain. Although selective use of opioids in the treatment of acute pain is traditionally accepted, the treatment of chronic noncancer pain is more complex. Many authors have begun to question the routine long-term use of opioids for the treatment of chronic noncancer pain.[11-13] Multiple practice guidelines have been developed to address this issue.[14-19] However, most recommendations in this area are of a consensus nature, being based on experiential or low-quality evidence.

Data from 2009 show that there were more than 201.9 million opioid prescriptions dispensed in the United States during that year.[20] It is difficult to obtain reliable data concerning the degree to which this is an emergency medicine issue, but during 2009, in the 10- to 19-year-old and 20- to 29-year-old patient groups, emergency medicine ranked third among all specialties in terms of number of opioid prescriptions, writing approximately 12% of the total prescriptions in each age group. In the 30- to 39-year-old group, emergency medicine ranked fourth.[20] Although these data do not deal with total doses dispensed by specialty, it is commonly postulated that the population served in EDs as a whole is at high risk for opioid abuse.[21]

The significant increase in opioid-related deaths has raised the concern of many.[5,6,8] This problem has also been observed in the pediatric population.[22-24] Action at the national level includes the recent proposal from the Food and Drug Administration for the establishment of physician education programs for the prescribing of long-acting and extended-release opioids as part of their national opioid risk evaluation and mitigation strategy (the REMS program).[25] State efforts to address this issue have included the development of statewide opioid prescribing guidelines, such as those developed by the Utah Department of Health[17] and statewide ED opioid prescribing guidelines, such as those developed in Washington State by the Washington chapter of the American College of Emergency Physicians (ACEP) working with other state organizations.[16] Some individual EDs and emergency physician groups have also promulgated opioid prescribing guidelines. Some of these policies also deal with the necessity of patient education about the safe use and proper disposal of opioid medications. Early data indicate that, in some cases, these guidelines may decrease prescription opioid overdose.[26] Anecdotal experience suggests that public policies such as these may change patient perceptions of appropriate prescribing and mitigate complaints arising from more stringent prescribing practices. ACEP has approved related policy statements about optimizing the treatment of pain in patients with acute presentations and the implementation of electronic prescription drug monitoring programs.[27,28]

This clinical policy addresses several issues believed to be important in the prescribing of opioids by emergency physicians for adult patients treated and released from the ED for whom opioids may be an appropriate treatment modality. Although relieving pain and reducing suffering are primary emergency physician responsibilities, there is a concurrent duty to limit the personal and societal harm that can result from prescription drug misuse and abuse. Because long-acting or extended-release opioids are not indicated for the treatment of acute pain, the aim of this clinical policy is to provide evidence-based recommendations for prescribing short-acting opioids for adult ED patients with painful acute or chronic conditions while attempting to address the increasing frequency of adverse events, abuse, and overdose of prescribed opioid analgesics.

METHODOLOGY

This clinical policy was created after careful review and critical analysis of the medical literature. The critical questions were formulated in the PICO (patient, intervention, comparison, outcome)[29] format to strengthen the clarity and scientific rigor of the questions. Searches of MEDLINE, MEDLINE InProcess, and the Cochrane Library were performed. All searches were limited to English-language sources, human studies, adults, and years 2000 to 2011. Specific key words/phrases and years used in the searches are identified under each critical question. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members were included.

This policy is a product of the ACEP clinical policy development process, including expert review, and is based on the literature; when literature was not available, consensus of panel members was used. Expert review comments were received from emergency physicians, toxicologists, pain and addiction medicine specialists, pharmacologists, occupational medicine specialists, and individual members of the American Academy of Clinical Toxicology, American Academy of Family Physicians, American Academy of Pain Medicine, American Chronic Pain Association, American College of Occupational and Environmental Medicine, American College of Osteopathic Emergency Physicians, American College of Physicians, American Pain Society, American Society of Health-System Pharmacists, American Society of Interventional Pain Physicians, Emergency Medicine Resident's Association, and Emergency Nurses Association. Their responses were used to further refine and enhance this policy; however, their responses do not imply endorsement of this clinical policy. Clinical policies are scheduled for revision every 3 years; however, interim reviews are conducted when technology or the practice environment changes significantly. The Centers for Disease Control and Prevention was the funding source for this clinical policy.

All articles used in the formulation of this clinical policy were graded by at least 2 subcommittee members for quality and strength of evidence. The articles were classified into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic studies, respectively (Appendix A). Articles were then graded on dimensions related to the study's methodological features: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (eg, selection, detection, transfer), external validity (ie, generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula, taking into account the design and study quality (Appendix B). Articles with fatal flaws or that were not relevant to the critical question were given an "X" grade and were not used in formulating recommendations for this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may have varied according to the question, and it is possible for a single article to receive different levels of grading as different critical questions were answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of this policy. Evidence grading sheets may be viewed at http://www.acep.org/clinicalpolicies/?pg=1.

Clinical findings and strength of recommendations about patient management were then made according to the following criteria:

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (ie, based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues).

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (ie, based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies).

Level C recommendations. Other strategies for patient management that are based on Class III studies, or in the absence of any adequate published literature, based on panel consensus.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, and publication bias, among others, might lead to such a downgrading of recommendations.

This policy is not intended to be a complete manual on the evaluation and management of adult ED patients with painful conditions where prescriptions for opioids are being considered, but rather is a focused examination of critical issues that have

particular relevance to the current practice of emergency medicine.

The goal of the ACEP Opioid Guideline Panel is to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain enough quality information to answer a critical question, the members of the ACEP Opioid Guideline Panel believe that it is equally important to alert emergency physicians to this fact.

Recommendations offered in this policy are not intended to represent the only management options that the emergency physician should consider. ACEP clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

Scope of Application. This guideline is intended for physicians working in hospital-based EDs.

Inclusion Criteria. This guideline is intended for adult patients presenting to the ED with acute noncancer pain or an acute exacerbation of chronic noncancer pain.

Exclusion Criteria. This guideline is not intended to address the long-term care of patients with cancer or chronic noncancer pain.

CRITICAL QUESTIONS

1. In the adult ED patient with noncancer pain for whom opioid prescriptions are considered, what is the utility of state prescription drug monitoring programs in identifying patients who are at high risk for opioid abuse?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. The use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping.

Key words/phrases for literature searches: opioid, drug prescriptions, drug monitoring, drug utilization review, substance abuse detection, drug-seeking behavior, drug and narcotic control, substance-related disorders, physician's practice patterns, program evaluation, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Emergency physicians must balance oligoanalgesia (undertreatment or ineffectual treatment of pain) with concerns about drug diversion* and doctor shopping.†[30-33] Therefore, the development of mechanisms to address these issues is justified. The expanded use of prescription drug monitoring programs to curb prescription opioid misuse was recommended in the 2011 Prescription Drug Abuse Prevention Plan released by the White House Office of National Drug Control Policy.[34] Prescription drug monitoring programs are state-based monitoring programs for certain controlled substances that are prescribed by licensed practitioners and dispensed by pharmacies. Although existing in various forms for more than 3 decades, the first effort to standardize prescription drug monitoring practice was the passage in 2005 of the National All Schedules Prescription Electronic Reporting Act (NASPER). Unfortunately, this federal legislative mandate that intended to harmonize prescription drug monitoring programs across the various states has yet to be fully funded.

Prescription drug monitoring programs ideally serve multiple functions, including identifying patients who engage in doctor shopping, and patients, providers, or pharmacies who engage in diversion of controlled substances and providing information about prescribing trends for surveillance and evaluation purposes. Such information may serve to benefit the patients, the health care system, epidemiologists, policymakers, regulatory agencies, and law enforcement.[35] Certain large health care systems, particularly closed prescribing systems such as the Veterans Administration and health maintenance organizations, maintain databases that allow prescribers to view recent prescriptions of enrolled clients or patients. Forty-one states have operational prescription drug monitoring programs of various complexity and capability, with an additional 7 states having prescription drug monitoring program legislation in place but with programs that are not yet operational.[36] Most states allow health care providers and pharmacists to access the programs for patients under their care. Other groups such as law enforcement and regulatory boards may also have access. One program tracks only schedule II drug prescriptions, whereas most track drug prescriptions of schedule II to IV or II to V drugs.

Despite prescription drug monitoring programs providing an intuitive perception of benefit for the medical community, there are limited data to indicate any benefit of these programs for improving patient outcomes or reducing the misuse of prescription drugs.[37] In part, this relates to the limited optimization of and standardization between the programs and the lack of a mechanism to allow interstate communication.[35]

*Drug diversion: The diversion of drugs for nonmedical use through routes that do not involve the direct prescription of the drug by a provider. Diverted drugs might be provided by family or friends, purchased on the street market, or obtained through fraudulent prescription. Epidemiologic data suggest that most opioids used nonmedically are obtained through these means.

†Doctor shopping: The practice of obtaining prescriptions for controlled substances from multiple providers, which is regarded as a possible indication of abuse or diversion. There is no rigorous definition, and various authors have defined it in different ways, from 2 or more prescribers within 30 days, greater than 4 during 1 year, and greater than 5 during 1 year.[30-32] It has also been defined as the amount of drug obtained through doctor shopping compared with the amount intended to be prescribed.[33] The use of "pill mills," in which a prescriber provides ready access to prescriptions or pills, can be considered a form of doctor shopping.

One study has demonstrated that compared with states without a prescription monitoring program, those with such a program had a slower rate of increase in opioid misuse.[38]

In an attempt to quantify the effect of a prescription drug monitoring program, Baehren et al[39] conducted a prospective study (Class III) of 18 providers who cared for a convenience sample of adult patients with pain in a single Ohio ED. After the clinical assessment of a patient, the researchers queried the providers about 3 patient-specific issues: (1) the likelihood of querying the state's prescription drug monitoring program, called Ohio Automated Rx Reporting System; (2) the likelihood of providing an opioid prescription at discharge; and (3) if yes, which opioid and what quantity. They were then provided with a printout of the patient data from the prescription drug monitoring program and asked to reassess the same questions. Of the 179 patients with complete data, information from the Ohio Automated Rx Reporting System altered prescribing practice in 74 of 179 (41%). The majority (61%) of these patients received fewer or no opioids, whereas 39% received more. The change in management was attributed to the number of previous prescriptions, 30 of 74 (41%); number of previous prescribers, 23 of 74 (31%); number of pharmacies used, 19 of 74 (26%); and number of addresses listed, 12 of 74 (16%). A limitation of this study was that 4 prescribers accounted for almost two thirds of the total patient encounters. In this study, knowledge of the information provided by a prescription drug monitoring program had an important impact on the prescription practices for controlled substances in an ED, although the actual effect of prescription drug monitoring program data on patient outcomes in this study is unknown.

Although not specifically evaluating the benefit of prescription drug monitoring programs on identifying high-risk patients, Hall et al,[32] in a Class III study, reviewed characteristics of decedents who died of prescription drugs in West Virginia and reported that opioid analgesics accounted for 93% of deaths. Cross-referencing the medical examiner's detailed analysis of the cause of death with the West Virginia prescription monitoring program, the authors determined the prescription history of the drug associated with each fatality. Patients who had received controlled drugs from 5 or more prescribers in the year before death were defined as engaging in "doctor shopping," whereas those whose death was not associated with a valid prescription were considered to have obtained their drugs through "diversion." Of the 295 deaths that were reviewed, the mean age of patients who died was 39 years, and 92% were between ages 18 and 54 years. Diversion was associated with 186 (63%) of the fatalities, and doctor shopping was associated with 63 (21%) of the fatalities. Of the 295 total decedents, 279 (95%) had at least 1 indicator of substance abuse, and these differed according to whether the drug was obtained through diversion or doctor shopping. Deaths involving diversion were associated with a history of substance abuse (82.3% versus 71.6%; odds ratio [OR] 1.8; 95% confidence interval [CI] 1.0 to 3.4), nonmedical route of pharmaceutical administration (26.3% versus 15.6%; OR 1.9; 95% CI 1.0 to 3.8), and a contributory illicit drug (19.4% versus 10.1%; OR 2.1; 95% CI 1.0 to 4.9). Patients with evidence of doctor shopping were significantly more likely to have had a previous overdose (30.2% versus 13.4%; OR 2.8; 95% CI 1.4 to 5.6) and significantly less likely to have used contributory alcohol (7.9% versus 19.8%; OR 0.3; 95% CI 0.1 to 0.9). Few patients (8.1%) were involved in both doctor shopping and diversion. The study suggests that the information provided by a prescription drug monitoring program, with correct interpretation and action based on that knowledge, might have prevented some inappropriate prescribing and poor outcomes in this patient population.

In another Class III study, Pradel et al[33] monitored prescribing trends for buprenorphine in a select area of France, using a prescription drug database during a multiple-year period. During this time, a prescription drug monitoring program was implemented, allowing a before-after comparison of the buprenorphine prescribing pattern for more than 2,600 patients. The doctor shopping drug quantity, which was defined as the total drug quantity received by the patient minus the quantity prescribed by an individual provider, increased from 631 g in the first 6 months of 2000 to a peak of 1,151 g in the first 6 months of 2004, equivalent to 143,750 days of treatment at 8 mg/day. The doctor shopping ratio, determined as the ratio of the quantity delivered to the quantity prescribed, increased steadily from early 2000 (14.9% of the grams of drug prescribed) to a peak value in the first 6 months of 2004 (21.7%). After implementation of the prescription drug monitoring program in early 2004, this value decreased rapidly, in fewer than 2 years reaching the value observed in 2000. The points of inflection of the doctor shopping curves (quantity and ratio) coincided with the implementation of the prescription drug monitoring program, suggesting an immediate benefit of this program. The prescribed quantity did not change after the implementation, indicating that access to treatment may not have changed. Eighty percent of the total doctor shopping quantity of buprenorphine was obtained by approximately 200 (8%) of the total patients. However, it is difficult to make any inferences about the effect of a decrease in doctor shopping, given the fractional amount of total prescribing accounted for by this practice.[33] The authors suggested that the doubling in the street price of buprenorphine after the prescription drug monitoring program implementation was an indicator of success.

An observational study of opioid-related deaths by Paulozzi et al[37] highlights some important considerations in the assessment of the effectiveness of prescription drug monitoring programs. The authors assessed the mortality rate from 1999 to 2005 from schedule II and III prescription opioids in the United States and compared states that had prescription drug monitoring programs with those that did not. They further divided states with prescription drug monitoring programs into those that proactively informed prescribers, generally by mail, of potential

misuse and those that did not. This study found no difference in the mortality rates over time for states with and without a prescription drug monitoring program, nor did states with proactive prescription drug monitoring programs perform better than those with programs that were not proactive. There was a nonsignificantly lower rate of consumption of schedule II opioids and a significantly higher rate of consumption of hydrocodone (schedule III) in states that had a prescription drug monitoring program. A major limitation of this study is that the variability in the prescription drug monitoring program structure, including the ability of health care providers to access the database, was not considered. Current applicability is somewhat limited by substantial changes in the manner in which prescription drug monitoring programs function since the study was conducted, including the extent of physician access and the definition of patient inclusion criteria. Because of the practical limitation of the delay in informing the prescriber of a patient's potential drug misuse, the proactive notification aspect of these programs would have minimal effect on emergency medical practice in states that cannot provide prescription drug monitoring program data in real time.

In conclusion, there are no studies that directly evaluate the effect of real-time, voluntary access to a prescription drug monitoring program on prescribing practices of emergency physicians. In addition, the broader effect of such access on diversion, abuse, doctor shopping, mortality, and the possibility of pain undertreatment remains undefined. Prescription drug monitoring programs have many limitations in their current format, including complex access issues, limitations on access permission, thresholds for patient listing, timeliness, interstate communication, and whether the data are presented to the physician automatically or require physician effort to retrieve. Furthermore, the recent addition of prescription drug monitoring programs in several states and continuing changes in the structure or function of existing programs limit the direct application of even recently published research. Legislation designed to improve prescription drug monitoring program operation (eg, NASPER) has stalled or remained underfunded, and concerns over patient confidentiality have often trumped public health concerns. Until an interstate, frequently updated, multiple-drug-schedule, easily accessible, widely used prescription drug monitoring system is implemented, the likelihood of success is limited.[35]

2. In the adult ED patient with acute low back pain, are prescriptions for opioids more effective during the acute phase than other medications?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) For the patient being discharged from the ED with acute low back pain, the emergency physician should ascertain whether nonopioid analgesics and nonpharmacologic therapies will be adequate for initial pain management.

(2) Given a lack of demonstrated evidence of superior efficacy of either opioid or nonopioid analgesics and the individual and community risks associated with opioid use, misuse, and abuse, opioids should be reserved for more severe pain or pain refractory to other analgesics rather than routinely prescribed.

(3) If opioids are indicated, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

Key words/phrases for literature searches: acute low back pain, opioid, and variations and combinations of the key words/phrases.

Acute low back pain is a common ED presenting complaint. Opioids are frequently prescribed, expected, or requested for such presentations.[40,41] In a recent study, it was estimated that low back pain–related disorders result in approximately 2.6 million annual ED visits in the United States. Of medications either administered in the ED or prescribed at discharge, the most frequently used classes were opioids (61.7%; 95% CI 59.2% to 64.2%), nonsteroidal anti-inflammatory drugs (NSAIDs) (49.6%; 95% CI 46.7% to 52.3%), and muscle relaxants (42.8%; 95% CI 40.2% to 45.4%).[41] The opioid analgesics most commonly prescribed for low back pain, hydrocodone and oxycodone products, are also those most prevalent in a Government Accountability Office study of frequently abused drugs.[42] Low back pain as a presenting complaint was also observed in a recent study to be associated with patients at higher risk for opioid abuse.[43] Low back pain, although a common acute presentation, is also often persistent and recurrent, with 33% of patients continuing to complain of moderate-intensity pain and 15% of severe pain at 1 year from initial presentation. Symptoms recur in 50% to 80% of people within the first year.[44] In one study, 19% reported opioid use at a 3-month follow-up.[40] Emergency physicians, as a specialty, are among the higher prescribers of opioid pain relievers for patients aged 10 to 40 years.[20] Recent data show simultaneous increases in overall opioid sales rates and prescription opioid–related deaths and addiction rates and suggest that widespread use of opioids has adverse consequences for patients and communities.[8]

There is a paucity of literature that addresses the use of opioids after ED discharge for acute low back pain versus the use of NSAIDs or the combination of NSAIDs and muscle relaxants. Two meta-analyses published in the last 5 years identified relatively few valid studies that address the use of opioids for low back pain.[45,46]

In a Class III 2008 Cochrane review, NSAIDs were compared with opioids and muscle relaxants for the treatment of low back pain.[46] Three studies were reviewed that compared opioids (2 of which are no longer in use) with NSAIDs for treatment of acute low back pain, including 1 study considered by the Cochrane reviewers to be of higher quality.[47] None of

the individual studies found statistically significant differences in pain relief. A Class III review by McIntosh and Hall[45] of clinical evidence for treatment of acute low back pain similarly found no evidence for superiority of opioids over other therapies and no direct information to demonstrate that opioids were better than no active therapy; however, the authors concluded that the opioid-related studies were too small to detect any clinically important differences.

A Class III Cochrane review of NSAID treatment for acute low back pain evaluated 65 studies (including more than 11,000 patients) of mixed methodological quality that compared various NSAIDs with placebo, other drugs, other therapies, and other NSAIDs.[46] The review authors concluded that NSAIDs are slightly effective for short-term symptomatic relief in patients with acute and chronic low back pain without sciatica (pain and tingling radiating down the leg). In patients with acute sciatica, no difference in effect between NSAIDs and placebo was found but moderate efficacy was found for opioids. The systematic review also reported that NSAIDs are no more effective than other drugs (acetaminophen, opioids, and muscle relaxants). Placebo and acetaminophen had fewer adverse effects than NSAIDs, and NSAIDS had fewer adverse effects than muscle relaxants or opioids.

A 2003 Cochrane review of muscle relaxants for low back pain (Class X because it did not address the role of opioids) found that muscle relaxants were effective for short-term symptomatic relief in patients with acute and chronic low back pain.[48] However, muscle relaxants were associated with a high incidence of adverse effects. This study cited strong evidence in 4 trials involving a total of 294 people that oral nonbenzodiazepine muscle relaxants are more effective than placebo in patients with acute low back pain for short-term pain relief, global efficacy, and improvement of physical outcomes.

Although no superiority has been demonstrated for opioids over other therapies for treatment of acute low back pain, groups have recommended against use of opioids as first-line therapy for treatment of this problem.[49,50] A guideline for diagnosis and treatment of low back pain endorsed by the American College of Physicians and the American Pain Society recommends opioids only for severe, disabling pain that is not controlled or not likely to be controlled with acetaminophen or NSAIDs.[49] In their 2007 guidelines, the American College of Occupational and Environmental Medicine stated that routine use of opioids for acute, subacute, or chronic low back pain is not recommended.[50]

Several observational non-ED studies also suggest caution with regard to opioid prescribing for back pain. Franklin et al,[51] in a retrospective study (Class X because of the non-ED patient population), found that workers with acute low back injury and worker's compensation claims who were treated with prescription opioids within 6 weeks of acute injury for more than 7 days had a significantly higher risk for long-term disability. In a subsequent Class III population-based prospective study of opioid use among injured Washington State workers with low back pain, Franklin et al[52] observed a strong association between the amount of prescribed opioids received early after injury and long-term use of prescription opioids. A retrospective study of 98 workers with acute low back pain and subsequent disability claims by Mahmud et al[53] found that patients whose treatment of new work-related low back pain involved opioid use for 7 days or more were more likely to have long-term disability (relative risk 2.58; 95% CI 1.22 to 5.47); however, the direct applicability of this study (Class X) was limited because most patients were not seen in the ED. In another study that addressed associations of long-term outcome with opioid therapy for nonspecific low back pain, Volinn et al[54] found that the odds of chronic work loss were 11 to 14 times greater for claimants treated with schedule II ("strong") opioids compared with those not treated with opioids at all. They further observed that the strong associations between schedule II use and long-term disability suggest that for most workers, opioid therapy did not arrest the cycle of work loss and pain. Although this study was also graded as Class X because of the population selected and failure to directly address acute or immediate benefit, the results highlight potential problems of treating acute low back pain with opioids.[54] Unfortunately, causation cannot be directly inferred from these studies because of possible confounding.

In summary, although opioids currently offer the most potent form of pain relief, there is essentially no published evidence that the prescription of opioid analgesics for acute low back pain provides benefit over other available medications or vice versa. Several observational studies suggest associations of both prescription of "strong" opioids or longer prescription duration (greater than 7 days) and early opioid prescribing with worsened functional outcomes. Additionally, as noted, the overall increased rate of opioid sales has been strongly associated with adverse effects in the community (overdose, addiction, aberrant use, and death).[8] Therefore, it can be recommended that opioids not be routinely prescribed for acute low back pain but reserved for select ED patients with more severe pain (eg, sciatica) or pain refractory to other drug and treatment modalities. Prescriptions for opioids should always be provided for limited amounts and for a limited period. Extra caution (such as use of prescription drug monitoring programs and seeking of collateral patient information such as patient visit history) may be indicated for patients identified as possibly having an increased risk for substance dependence or abuse.

3. In the adult ED patient for whom opioid prescription is considered appropriate for treatment of new-onset acute pain, are short-acting schedule II opioids more effective than short-acting schedule III opioids?

Recommendations

Level A recommendations. None specified.

Level B recommendations. For the short-term relief of acute musculoskeletal pain, emergency physicians may prescribe short-acting opioids such as oxycodone or hydrocodone

products while considering the benefits and risks for the individual patient.

Level C recommendations. Research evidence to support superior pain relief for short-acting schedule II over schedule III opioids is inadequate.

Key words/phrases for literature searches: opioids, schedule II narcotics, schedule III narcotics, acute pain, acute disease, emergency service, and variations and combinations of the key words/phrases.

Schedules II and III are classifications established by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and determined by the Drug Enforcement Administration. Among other criteria, classification decisions for specific drugs are based on judgments about the potential for their abuse. Schedule II opioids include morphine (eg, MS Contin), oxymorphone (eg, Opana), oxycodone (eg, Roxicodone) and oxycodone combination products (eg, Percocet, Percodan), as well as hydromorphone (eg, Dilaudid) and fentanyl (eg, Duragesic patch, Actiq). Schedule III opioids include combination products, such as hydrocodone (15 mg or less) combined with acetaminophen (eg, Vicodin, Lortab) or ibuprofen (eg, Vicoprofen), as well as some of the codeine combination products.[55] Schedule classifications for opioids may change over time in response to a number of factors, including their perceived risk of abuse. Calls to reclassify hydrocodone combination products (eg, Vicodin, Lortab) from schedule III to schedule II have increased in recent years in response to increasing levels of abuse of these substances.

These recommendations address only new-onset acute pain. Long-acting or extended-released schedule II products such as oxycodone ER (OxyContin), methadone, fentanyl patches, or morphine extended-release (MS Contin) are indicated for chronic pain and should not be used for acute pain.[56] Long-acting and extended-release opioids are for use in opioid-tolerant patients only and are not intended for use as an "as-needed" analgesic. In addition, the immediate-release oral transmucosal formulations of fentanyl are indicated only for breakthrough pain relief in cancer patients who are already taking sustained-release medications and are opioid tolerant. These formulations should not be used for acute new-onset pain.

As part of the decision to prescribe opioids for new onset of acute pain, the care provider can select between short-acting schedule II or III agents (Table). In general, equianalgesic doses of opioids are equally efficacious in relieving pain. Therefore, *a priori*, there is no reason to consider an equianalgesic dose of a short-acting schedule II opioid more effective in providing pain relief than a short-acting schedule III opioid. However, some studies have compared schedule II and III opioids combined with nonopioid analgesics with one another. Two prospective randomized controlled trials have compared the efficacy of short-acting oxycodone, a schedule II drug, with hydrocodone combination products (schedule III) and found them to be equal.[57,58] In 2005, Marco et al[57] compared single doses of oxycodone 5 mg with hydrocodone 5 mg (both combined with 325 mg acetaminophen). In this single-site Class II study of 67 adolescent and adult subjects with acute fractures, no differences in analgesic efficacy were observed at 30 or 60 minutes. Constipation rates were higher for hydrocodone. In a 2002 Class I study, Palangio et al[58] compared oxycodone 5 mg combined with acetaminophen 325 mg (schedule II) with hydrocodone 7.5 mg combined with ibuprofen 200 mg (schedule III) in a prospective, multicenter, multidose, randomized controlled trial of 147 adults with acute or recurrent low back pain. During an 8-day study period, no differences were found in pain relief, doses taken, global evaluations of efficacy, health status, or pain interference with work. As noted above, equianalgesic doses of opioids have similar efficacy in the treatment of acute pain, no matter their Drug Enforcement Administration classification. Given this understanding, it was not unexpected that 2 randomized controlled trials comparing schedule II with III agents found no differences in analgesic efficacy.

Table. Short-acting oral opioid formulations. Dose and interval are recommended starting dosing ranges.

Medication	Initial Dose/Interval	Schedule
Codeine/APAP	30-60 mg* PO Q4-6h PRN	III
Codeine	30-60 mg PO Q4-6h PRN	II
Hydrocodone/APAP	5-15 mg* PO Q4-6h PRN	III
Hydromorphone	2-4 mg PO Q4-6h PRN	II
Morphine	15-30 mg PO Q4-6h PRN	II
Oxycodone/APAP	5-15 mg* PO Q4-6h PRN	II
Oxycodone	5-15 mg PO Q4-6h PRN	II
Oxymorphone	10-20 mg PO Q4-6h PRN	II

APAP, acetaminophen; *h*, hour; *mg*, milligram; *PO*, by mouth; *PRN*, as needed; *Q*, every.
*Listed dose is of the opioid component. Note that the acetaminophen component is now limited to 325 mg or less per pill.

4. In the adult ED patient with an acute exacerbation of noncancer chronic pain, do the benefits of prescribing opioids on discharge from the ED outweigh the potential harms?

Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. (1) Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic noncancer pain seen in the ED.

(2) If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration (eg, <1 week), and the prescriber should consider the patient's risk for opioid misuse, abuse, or diversion.

(3) The clinician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and

consider past prescription patterns from information sources such as prescription drug monitoring programs.

Key words/phrases for literature searches: opioid, patient discharge, pain, emergency service, and variations and combinations of the key words/phrases with exclusion of cancer.

Patients with chronic noncancer pain, either already taking opioids or not, commonly present to the ED for treatment of acute exacerbation of their pain. There have been no studies that evaluate the efficacy or potential harms of prescribing opioids specifically for these patients on discharge from the ED. Thus, given the paucity of evidence, this critical question cannot be definitively answered. Despite the biological plausibility that treating any acute exacerbation of pain with parenteral or oral opioids should decrease pain intensity, no studies were found to support this hypothesis.

Only 2 randomized controlled trials were identified that addressed the use of short-acting opioids for the treatment of breakthrough pain in patients taking opioids for chronic noncancer pain; transmucosal fentanyl was the intervention for both trials.[59,60] Because of methodological problems, valid estimates for efficacy of the intervention could not be determined, but adverse event rates among both treated populations were common and similar (range 63% to 65%) (Class III).

A systematic review of nonrandomized studies by Devulder et al[61] examined the effect of rescue medications on overall analgesic efficacy and adverse events. They examined 48 studies of patients treated with long-acting opioids for chronic noncancer pain and compared the analgesic efficacy and adverse events among those that allowed short-acting opioid rescue medications for breakthrough pain with those that did not allow such rescue medications. Although graded Class X because of lack of randomized studies and the limitation of harms studied to adverse effects only, no significant difference in the analgesic efficacy between the rescue and nonrescue studies was found. There was also no difference between these 2 groups in the incidence of nausea, constipation, or somnolence. Kalso et al,[62] in a Class III systematic review, found that 80% of patients receiving opioids for chronic noncancer pain had at least 1 adverse event, including nausea (32%), constipation (41%), and somnolence (29%).

Studies of the use of opioids for chronic pain indicate that adverse effects of these drugs are common. Several studies assessed the adverse effects with the use of tramadol with acetaminophen in the treatment of patients with chronic low back pain.[63-65] All of the studies had high dropout rates and reported adverse event rates of nausea, dizziness, and somnolence between 8% and 17%. Allan et al,[66] in a nonblinded Class III study comparing transdermal fentanyl versus oral morphine, found a constipation rate of 48% in the morphine-treated patients compared with a rate of 31% in the fentanyl-treated patients. Constipation was also the major adverse effect in a Class III study by Hale et al[67] comparing oxymorphone extended release, oxycodone controlled release, and placebo. Furlan et al,[68] in a Class II meta-analysis of 41 randomized studies of opioid use in the treatment of chronic noncancer pain, found that constipation and nausea were the only significant adverse effects. Holmes et al,[69] however, in a Class III study, assessed an opioid screening instrument, the Pain Medication Questionnaire, in chronic noncancer pain patients and found that those patients with a higher score were more likely to have a substance abuse problem or request early refills of their opioid prescription. In a retrospective Class III cohort study, Jensen et al[70] conducted a 10-year follow-up on patients discharged from a pain clinic and found that chronic opioid treatment may put patients at risk for chronic depression. Unfortunately, near-universal shortcomings of these studies include the exclusion of patients with a history of substance abuse, other significant medical problems, or psychiatric disease, and lack of follow-up to detect long-term effects such as aberrant drug-related behaviors, addiction, or overdose. Therefore, studies such as these can be confounded, making the ability to draw conclusions about causality difficult.

Questions of opioid effectiveness involve the assessment of reduction in pain and improvement in function for the patient, potential patient adverse effects, and the potential harm to the community (eg, opioid diversion and abuse) from the drugs prescribed. Hall et al,[32] in a Class III retrospective analysis of 295 unintentional prescription overdose deaths, found that 93% were due to opioids, 63% represented pharmaceutical drug diversion, 21% of the patients had engaged in doctor shopping, and 95% of the patients had a history of substance abuse. Although no studies have addressed the effects related to dose and duration of prescribed opioids in this specific patient population, 2 general studies have shown a correlation between high daily opioid dose and overdose death.[71,72]

Patient assessment tools such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), Opioid Risk Tool (ORT), Diagnosis, Intractability, Risk, and Efficacy (DIRE), and others to assess the risk of prescription opioid misuse and abuse have yet to be fully validated in the ED in terms of sensitivity, specificity, and utility.[73] Many, however, believe that use of these tools, as imperfect as they are, represents a beginning in the ability to better quantify potential risks related to opioid prescribing for outpatients.

Many patients undergoing treatment for chronic noncancer pain have pain contracts/treatment agreements with their primary care providers. These should be honored if possible in treating any acute exacerbation of their pain.[74,75] As discussed in critical question 1, use of prescription drug monitoring programs may also assist the emergency physician in making appropriate clinical decisions about the use of outpatient opioid prescriptions for these patients.

FUTURE RESEARCH

Provider pain management practices related to opioids are highly variable. In part, this variability reflects the lack of evidence to guide many of these therapeutic decisions.[76]

Although there is high-quality research assessing the treatment of acute pain with opioid analgesics during the ED encounter, there is a paucity of studies assessing the benefits of prescribing opioids for discharged ED patients with acute pain and chronic noncancer pain, especially in comparison to other analgesic drugs and pain treatment modalities. Therefore, clinical decisions and practice recommendations must rely on practice experience and consensus rather than research evidence.

ED populations typically include patients with unmet substance abuse treatment needs and psychiatric comorbidities, and many of these patients present with acute pain.[77] In almost all pain studies, these patients are excluded, leaving clinicians with little evidence-based guidance for their pain management. There are also significant research gaps in clearly understanding the long-term harms of opioids, including drug abuse and addiction, aberrant drug-related behaviors, and diversion. As mentioned above, further research and validation is needed on ED patient abuse and addiction-related assessment tools. Additional studies to characterize individual patient-related risks for opioid abuse are also greatly needed.

Although there has been recent widespread adoption of prescription monitoring programs, there remains a dearth of evidence about the effectiveness of these programs in altering physician prescribing patterns or diminishing the adverse effects of opioids in the community. For research in this area to advance, further refinement of prescribing metrics (quantity, duration, and frequency) and public health measures is required. Comparison of the functionality and effectiveness of the various state prescription drug monitoring program models may provide additional insight into developing best practices that could be adopted nationally, including the sharing of data between states. Important distinctions among the states, such as immediate online prescriber access to the prescription monitoring program, should be examined for their relative contributions. However, this type of analysis must consider baseline variability among states for prescription opioid misuse (versus heroin or methadone, for example) and other state-specific issues (such as prescription-writing regulations).

With respect to the treatment of acute low back pain in the ED, there is a need for quality studies comparing the effectiveness of the more commonly prescribed opioids (hydrocodone and oxycodone congeners and other semisynthetic opioids) and nonopioid therapies, with attention to confounding variables such as depression or other psychopathology. Further study is needed to validate or refute the reported associations of early or potent opioid prescribing with increased rates of disability.[51] Given the frequency of acute low back pain as an ED presentation and its association with perceived drug-seeking behavior,[78] and with apparent higher risk for misuse,[43] more attention needs to be paid to discriminatory historical or physical factors that may be predictive of drug-seeking or abuse to allow better matching of treatment modality for individual patients.

Future studies should include additional multiple-dose analgesic protocols to better understand the postdischarge experience of patients with acute pain and what would constitute optimum patient follow-up provisions. Investigators should include clinically relevant study periods (days to weeks), which vary by diagnosis; thus, trials should be stratified by specific presenting complaints, pain site, discharge diagnosis, and classification of pain type, ie, nociceptive, neuropathic, and visceral pain. In addition to measuring pain and adverse effects, functional outcomes, such as return to work or pain-related quality-of-life measures, should be included.[79] Straightforward observational studies are needed to determine the relative duration of different acute pain presentations, thus informing decisions to prescribe an appropriate number of opioid doses per prescription. Current prescribing practice often involves a "one size fits all" pattern that is encouraged by electronic prescribing software. Prescribing practices that ignore variable durations of acute pain syndromes will predictably result in undertreatment for some patients and overtreatment for others. The latter increases the likelihood that unused opioids will be diverted into nonmedical use in communities at risk.

Additional research should include evaluation of the appropriateness of patient satisfaction as a quality metric as related to patient expectations of opioids and the prevalence of providers reporting pressure through low patient satisfaction scores or administrative complaints to provide opioids when the providers believe these drugs are not medically indicated. This issue may gain increased importance with the institution of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, which may tie some reimbursement to patient satisfaction scores. Additional work is needed to investigate what constitutes an appropriate educational curriculum in both medical school and residency for physician education concerning safe, appropriate, and judicious use of opioids.

Research addressing the treatment of chronic noncancer pain would be enhanced by the use of accepted case definitions, standardized definitions of adverse events, and validated pain measurements. Case definitions should use a similar definition of chronic, nociceptive (musculoskeletal or visceral) versus neuropathic pain, or pain by disease type (headache, low back pain, etc). Research reporting also requires more refined descriptions of opioid potency and routes of administration.

Although opioids represent a treatment modality that has long been used in patient care, it is clear by the paucity of definitive answers to the questions posed in this document and the significant number of future research issues that much work remains to be done to clarify the best use of opioids in the care of patients.

Relevant industry relationships/potential conflicts of interest: *Dr. Sporer is a consultant to Alcomed, a pharmaceutical company. Dr. Todd serves on the Professional Advisory Board of the*

American Chronic Pain Association and has previously been a consultant to the pharmaceutical industry.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical questions.

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Evidentiary Table.

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hall et al[32]	2008	Retrospective, population based, observational study	Comparison of West Virginia medical examiner data with patient data from the state prescription monitoring program and opioid abuse treatment program records	Behaviors of those who died of a pharmaceutical overdose; diversion; doctor shopping; substance abuse history; type of drug	295 deaths; 67% male; 92% aged 18-54 y; 63% pharmaceutical diversion; 21% doctor shopping; 95% substance abuse history; 93% opioids	Actual source of opioids involved in death not known; single state; not validated definitions; retrospective	III
Pradel et al[33]	2009	Database	Review of prescription drug database (not prescription monitoring program) to identify amount of buprenorphine delivered, prescribed, and obtained by doctor shopping; extension of 2004 study, used multiple time period comparisons; evaluation of trends in doctor shopping over time	Determined prescribed quantity of buprenorphine, delivered quantity, and the doctor shopping quantity	Although there was some variation over time, the trend for prescribing stayed constant overall and doctor shopping decreased after 2004, associated with the change in the mechanism by which prescriptions are monitored	Reasons for multiple providers or overlapping or interrupted prescriptions unclear; did not examine risk factors for abuse	III
Baehren et al[39]	2010	Prospective, uncontrolled	Physicians prescribing analgesics for nonacute pain were asked details about the patient's prescription and then again after being informed of the prescription monitoring program search result for that patient	Change in prescription for the specific patient	179 enrolled; management changed in 41%; 61% received fewer opioids, 39% received more	Convenience sample; majority of data from 4 prescribers	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
McIntosh and Hall[45]	2011	Review of randomized controlled trials, systematic reviews, and observational studies found searching MEDLINE 1966-12/2009, EMBASE 1980 to 12/2009, and Cochrane database up to 12/2009; 49 studies met inclusion criteria	Multiple treatment modalities for acute low back pain, including oral drugs, local injections, and nondrug treatment	Clinical improvement of low back pain	NSAIDs shown to effectively improve symptoms compared with placebo, but use associated with gastrointestinal adverse effects; muscle relaxants may reduce pain and improve clinical assessment but are associated with adverse effects including drowsiness, dizziness, nausea	The studies examining the effects of analgesics such as acetaminophen or opioids were generally too small to detect any clinically important differences	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Roelofs et al[46]	2008	Cochrane review: search of MEDLINE, EMBASE, and Cochrane central registry of controlled trials up to 7/2007; 65 trials qualified for review	NSAIDs and COX-2 inhibitors administered to treat low back pain	Clinical improvement of low back pain	Review authors found NSAIDs are not more effective than other drugs (acetaminophen, opioids, and muscle relaxants); placebo and acetaminophen had fewer adverse effects than NSAIDs, although the latter had fewer adverse effects than muscle relaxants and opioids; the new COX-2 NSAIDs do not seem to be more effective than traditional NSAIDs but are associated with fewer adverse effects, particularly stomach ulcers, although other literature has shown that some COX-2 NSAIDs are associated with increased cardiovascular risk	7 studies reported on acute low back pain, 5 of which, including 1 higher-quality study, did not find any statistical differences between NSAIDs and opioids or muscle relaxants; there is moderate evidence that NSAIDs are not more effective than other drugs for acute low back pain	III
Videman et al[47]	1984	Double-blind parallel study	70 patients; comparative trial of meptazinol vs diflunisal for up to 3 wk	Patients examined at 1-wk intervals for task capability, range of motion, and subjective pain self-assessment	Both regimens produced marked improvement in most parameters, similar adverse effect profiles	No mention of patient randomization	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Franklin et al[52]	2009	Prospective cohort; Washington State workers with back injury; n=1,883	Prospective cohort of workers with back injuries interviewed at 18 days (medial) and 1 y after injury; pharmacy data obtained from computerized records; analyzed for demographic and covariates	Injury severity, pain, function, and quantities of opioids used	For long-term users total number of medications increased significantly (P=.01) from the first to the fourth quarter; after adjustment for baseline pain, function, and injury severity, the strongest predictor of longer-term opioid prescriptions was total number of medications in the first quarter; receipt of ≥10 mg/day medicine in first quarter more than tripled the odds of receiving opioids long term, and receipt of ≥40 mg/day medicine in first quarter had 6-fold odds of receiving long-term opioids; amount of prescribed opioid received early after injury predicts long-term use	Addressed progression to long-term use according to initial treatment and continuation of same	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Marco et al[57]	2005	Single site; prospective; double blind; randomized controlled trial; concealment method described; ED patients with fractures	Single dose of oxycodone 5 mg/acetaminophen 325 mg schedule II vs hydrocodone 5 mg/acetaminophen 325 mg schedule III	Primary outcomes were numeric pain scores (0-10) at 30 and 60 min	88 subjects evaluated, 73 enrolled, 67 completed ED study period, 35 to oxycodone, 32 to hydrocodone; no baseline differences, no differences in outcomes at 30 min: -0.6 (95% CI -1.8 to 0.5); 60 min -0.5 (95% CI -2.0 to 1.0); adverse effects higher for constipation with hydrocodone (21% vs 0%; (95% CI 3% to 39%)	Small sample size powered to address acute pain during the first 30 to 60 min in the ED; study also assessed adverse effects during a longer period of time; excluded history of alcohol or opioid or other substance abuse; limited time period	II
Palangio et al[58]	2002	Prospective multicenter (18 sites), randomized controlled trial, sequential assignment by computer-generated randomization schedule	Hydrocodone 7.5 mg/ibuprofen 200 mg (schedule III) vs oxycodone 5 mg/acetaminophen 325 mg (schedule II)	Primary outcome was mean daily pain relief score at endpoint (day 8 or day of discontinuation), study period up to 8 days, intention-to-treat analysis	147 subjects enrolled (75 hydrocodone/ibuprofen, 72 oxycodone/acetaminophen), adults with acute or recurrent low back pain requiring opioids, 85% completed study in both groups, mean days to endpoint 6.5 vs 6.9 days, no baseline differences, no differences in pain relief, number of pills, global evaluations, SF-36, pain interference with work, adverse events	Excluded drug or alcohol abuse, concealment methods described	I

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Portenoy et al[59]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic low back pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain in chronic low back pain; adverse effects in 65%; 34% during double-blind phase	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Simpson et al[60]	2007	Randomized, double blind, placebo controlled	Fentanyl buccal tablet for breakthrough pain in chronic pain patients	Pain before treatment and for 2 h after treatment	Fentanyl buccal tablet effective for breakthrough pain; adverse effects in 63%; 22% dropout	Severe selection bias in initial screening; industry sponsored	III for adverse effects
Kalso et al[62]	2004	Systematic review	Randomized trials in chronic noncancer pain comparing potent opioids with placebo	Pain intensity outcomes	15 randomized trials were included; 11 studies compared oral opioids for 4 wk; pain intensity decrease was 30% compared with placebo; only 44% were taking opioids by mo 7 to 24; 80% of patients experienced at least 1 adverse event: constipation (41%), nausea (32%), somnolence (29%)	4-wk duration on average; differing causes of pain; open label in many of the studies; limited power calculations; concealment not maintained in some studies	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Peloso et al[63]	2004	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; 3-mo trial	336 patients randomized; improved mean final pain scores (47 vs 63; $P<.001$), adverse effects: nausea 12%, dizziness 11%, constipation 10%, somnolence 9%	35%-40% dropout rate; pharmaceutical-sponsored research	II
Ruoff et al[64]	2003	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Pain VAS; pain relief rating scale; Short Form Magill Pain Questionnaire SF-36; Roland Disability Questionnaire	318 patients randomized; tramadol improved pain VAS ($P=.15$) and final Pain Relief Rating Scale ($P<.001$); adverse effects: nausea 13%, somnolence 12%, constipation 11%, dizziness 8%	153 of 318 dropped out; pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Schnitzer et al[65]	2000	Prospective, randomized, blinded study	Tramadol/acetaminophen vs placebo; patients with chronic low back pain requiring daily medication for at least 3 mo	Time to discontinuation because of inadequate pain relief; Short Form Magill Pain Questionnaire; Roland Disability Questionnaire	380 patients in open-label phase; 254 entered into blinded phase; time to therapeutic failure was greater in the placebo group ($P<.0001$); other parameters showed improvement; adverse effects: nausea 17%, dizziness 15%, somnolence 14%, headache 12%	The dropout rate was the primary outcome; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Allan et al[66]	2005	Nonblinded, randomized comparison of 2 treatments in patients with chronic low back pain	Transdermal fentanyl vs sustained-release oral morphine; 680 total patients; dose titrated to effect; followed for 13 mo; outpatient setting; not applicable to ED	Pain relief (VAS scale); bowel function (validated questionnaire); quality of life (SF-36); disease, progression (3-point scale), days not working, adverse events all during 13 mo	Comparable pain relief, noninferior, VAS score for fentanyl (56) vs morphine (55); fentanyl had lower constipation rate: fentanyl (31%) vs morphine (48%)	Both groups had half of the participants drop out; vague definition of chronic low back pain; not blinded	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Hale et al[67]	2005	Randomized trial, blinded	Comparison of oxymorphone extended-release vs oxycodone controlled release vs placebo in patients with chronic low back pain who were taking a stable dose of opioids	VAS of pain score 4 h after morning dose; use of breakthrough pain medications; categorical pain intensity, pain intensity, global assessment, adverse events	Opioids were superior to placebo at reducing VAS for pain compared with placebo, oxymorphone (-27), oxycodone (-36); oxymorphone was comparable to oxycodone in pain efficacy and adverse effects; sedation and constipation were more common with opioids (35% vs 29% vs 11%)	Only 22 of 75 patients in the placebo group completed the study; included only patients receiving stable opioids and then randomized to opioids or placebo; baseline characteristics between groups not specified; pharmaceutical-sponsored research	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/ Comments	Class
Furlan et al[68]	2006	Meta-analysis	Study included randomized trials of any opioid for chronic noncancer pain (defined as pain for longer than 6 mo) vs placebo or some other nonopioid treatment	41 randomized studies with 6,019 patients evaluated for effectiveness and adverse effects; most (80%) had nociceptive pain	81% of the studies were believed to be of high quality; dropout rates were 33% in the opioid group and 38% in the placebo group; opioids improved pain and functional outcomes compared with placebo in nociceptive and neuropathic pain; strong opioids were superior to naproxen and nortriptyline for pain relief; weak opioids were not superior; constipation and nausea were the only significant adverse effects observed	Average duration of the study was 5 wk (range 1-16 wk); adequate random patient assignment in only 17 of 41 trials; 90% of trials were pharmaceutical-sponsored research	II

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Holmes et al[69]	2006	Prospective cohort	Convenience sample of patients who were new at a pain clinic; Pain Medication Questionnaire was administered; patients were treated with interdisciplinary treatment and/or medications alone, depending on the results of an initial evaluation	Beck Depression Inventory; Confidential Pain questionnaire; SF-36; Million VAS; Oswestry Disability Questionnaire; Physician Risk Assessment; VAS	271 patients, divided into low-, medium-, and high-score pain medication questionnaire; high-score group was more likely to have a known substance use problem (OR 2.6), request early refills (OR 3.2), or drop out of treatment (OR 2.3)	Only 26% of patients completed the full treatment program; heterogeneous types of pain diagnosis; differing treatment plans	III

Evidentiary Table (continued).

Study	Year	Design	Intervention(s)/Test(s)/Modality	Outcome Measure/Criterion Standard	Results	Limitations/Comments	Class
Jensen et al[70]	2006	Retrospective review of cohort	Patients who were treated and discharged from a pain clinic 10 y ago; medical records were abstracted and questionnaires were sent to willing participants	Demographics, health care utilization, SF-36; Hospital Anxiety and Depression Scale; Coping Strategy Questionnaire; CAGE* test	160 patients; 60% of patients were still taking long-acting opioids; dose escalation was unusual; chronic users had lower health-related quality of life and higher occurrence of depression	160 of 279 possible patients participated; no control group	III

COX-2, cyclooxygenase-2; *ED*, emergency department; *h*, hour; *mg*, milligram; *min*, minute; *mo*, month; *NSAID*, nonsteroidal anti-inflammatory drug; *OR*, odds ratio; *SF-36*, Short-Form Health Survey; *VAS*, visual analog scale; *vs*, versus; *wk*, week; *y*, year.
*CAGE (Cutting down, Annoyed, Guilty, Eye-opener) test is a method of screening for alcoholism.

Appendix A. Literature classification schema.*

Design/Class	Therapy†	Diagnosis‡	Prognosis§
1	Randomized, controlled trial or meta-analysis of randomized trials	Prospective cohort using a criterion standard or meta-analysis of prospective studies	Population prospective cohort or meta-analysis of prospective studies
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)	Case series Case report Other (eg, consensus, review)

*Some designs (eg, surveys) will not fit this schema and should be assessed individually.
†Objective is to measure therapeutic efficacy comparing interventions.
‡Objective is to determine the sensitivity and specificity of diagnostic tests.
§Objective is to predict outcome, including mortality and morbidity.

Appendix B. Approach to downgrading strength of evidence.

	Design/Class		
Downgrading	**1**	**2**	**3**
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

Appendix 2 - Older Adults

Older Adults[17]

The prevalence of pain among older adults has been estimated between 25% and 50%. The prevalence of pain in nursing homes is even higher. Unfortunately, managing pain in older adults is challenging due to: underreporting of symptoms; presence of multiple medical conditions; polypharmacy; declines in liver and kidney function; problems with communication, mobility and safety; and cognitive and functional decline in general.

Acetaminophen is considered the drug of choice for mild-to-moderate pain in older adults because it lacks the gastrointestinal, bleeding, renal toxicities, and cognitive side-effects that have been observed with NSAIDs in older adults (although acetaminophen may pose a risk of liver damage). Opioids must be used with particular caution and clinicians should "start low, go slow" with initial doses and subsequent titration. Clinicians should consult the American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults for further information on the many medications that may not be recommended.

The various challenges of pain management in older adults, only sketched here, suggest that early referral and/or consultation with geriatric specialists or pain specialists may be advisable.

[17] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 3 - Pediatric Patients

Pediatric Patients[18]

Children of all ages deserve compassionate and effective pain treatment. In fact, due to their more robust inflammatory response and immature central inhibitory influences, infants and young children actually may experience greater pain sensations and pain-related distress than adults. Effective pain management in the pediatric population is critical since children and adolescents experience a variety of acute and chronic pain conditions associated with common childhood illnesses and injuries, as well as some painful chronic diseases that typically emerge in childhood such as sickle cell anemia and cystic fibrosis.

The same basic principles of appropriate pain management for adults apply to children and teens, which means that opioids have a place in the treatment armamentarium. Developmental differences, however, can make opioid dosing challenging, especially in the first several months of life. In the first week of a newborn's life, for example, the elimination half-life of morphine is more than twice as long as that in older children and adults, as a result of delayed clearance. For older children, dosing must be adjusted for body weight.

Although a thorough discussion of this topic is not possible in this document, the following are summary recommendations for pain management in children and teens from the American Pain Society and the American Academy of Pediatrics:

- Provide a calm environment for procedures that reduce distress-producing stimulation;
- Use age-appropriate pain assessment tools and techniques;
- Anticipate predictable painful experiences, intervene and monitor accordingly;
- Use a multimodal approach (pharmacologic, cognitive, behavioral and physical) to pain management and use a multidisciplinary approach when possible;
- Involve families and tailor interventions to the individual child; and
- Advocate for the effective use of pain medication for children to ensure compassionate and competent management of their pain.

[18] California Medical Association (Prescribing Opioids: Care amid Controversy, March 2014).

Appendix 4 - Opioid Risk Tool (ORT)

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		[ ]		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk ≥ 8

Appendix 5 - Patient Evaluation and Risk Stratification

Patient Evaluation and Risk Stratification[19]

The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing?.

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R] or the Opioid Risk Tool [ORT]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

[19] Federation of State Medical Boards - Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers.

If possible, the patient evaluation should include information from family members and/or significant others. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community.

Appendix 6 - CAGE-AID

CAGE-AID Questionnaire

CAGE-AID Questionnaire

Patient Name _____ Date of Visit _____

When thinking about drug use, include illegal drug use and the use of prescription drug other than prescribed.

Questions:	YES	NO
1. Have you ever felt that you ought to cut down on your drinking or drug use?	☐	☐
2. Have people annoyed you by criticizing your drinking or drug use?	☐	☐
3. Have you ever felt bad or guilty about your drinking or drug use?	☐	☐
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	☐	☐

Scoring
Regard one or more positive responses to the CAGE-AID as a positive screen.

Psychometric Properties

The CAGE-AID exhibited:	Sensitivity	Specificity
One or more Yes responses	0.79	0.77
Two or more Yes responses	0.70	0.85

(Brown 1995)

Appendix 7 - PHQ-9 Nine Symptom Checklist

PHQ-9 — Nine Symptom Checklist

Patient Name _____ **Date** _____

1. Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.

   a. Little interest or pleasure in doing things
   Not at all **Several days** **More than half the days** **Nearly every day**

   b. Feeling down, depressed, or hopeless
   Not at all **Several days** **More than half the days** **Nearly every day**

   c. Trouble falling asleep, staying asleep, or sleeping too much
   Not at all **Several days** **More than half the days** **Nearly every day**

   d. Feeling tired or having little energy
   Not at all **Several days** **More than half the days** **Nearly every day**

   e. Poor appetite or overeating
   Not at all **Several days** **More than half the days** **Nearly every day**

   f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down
   Not at all **Several days** **More than half the days** **Nearly every day**

   g. Trouble concentrating on things such as reading the newspaper or watching television
   Not at all **Several days** **More than half the days** **Nearly every day**

   h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual
   Not at all **Several days** **More than half the days** **Nearly every day**

   i. Thinking that you would be better off dead or that you want to hurt yourself in some way
   Not at all **Several days** **More than half the days** **Nearly every day**

2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

   Not Difficult at All **Somewhat Difficult** **Very Difficult** **Extremely Difficult**

PHQ-9 — Scoring Tally Sheet

Patient Name _____ **Date** _____

1. **Over the last 2 weeks, how often have you been bothered by any of the following problems? Read each item carefully, and circle your response.**

	Not at all	Several days	More than half the days	Nearly every day
	0	1	2	3
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling asleep, staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down				
g. Trouble concentrating on things such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual				
i. Thinking that you would be better off dead or that you want to hurt yourself in some way				
Totals				

2. **If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**

Not Difficult At All	Somewhat Difficult	Very Difficult	Extremely Difficult
0	1	2	3

How to Score PHQ-9

Scoring Method For Diagnosis

Major Depressive Syndrome is suggested if:

- Of the 9 items, 5 or more are circled as at least "More than half the days"
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Minor Depressive Syndrome is suggested if:

- Of the 9 items, b, c, or d are circled as at least "More than half the days".
- Either item 1a or 1b is positive, that is, at least "More than half the days"

Scoring Method For Planning And Monitoring Treatment

Question One

- To score the first question, tally each response by the number value of each response:

  Not at all = 0

  Several days = 1

  More than half the days = 2

  Nearly every day = 3
- Add the numbers together to total the score.
- Interpret the score by using the guide listed below:

Score	Action
≤4	The score suggests the patient may not need depression treatment.
> 5-14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment.
≥15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment

Question Two

In question two the patient responses can be one of four: not difficult at all, somewhat difficult, very difficult, extremely difficult. The last two responses suggest that the patient's functionality is impaired. After treatment begins, the functional status is again measured to see if the patient is improving.

Appendix 8 - SOAPP®-R

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is NOT intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

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Scoring Instructions for the SOAPP®-R

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is 2.5 times (2.53 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	2.53	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater)*

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician' care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21)*

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

**Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9)*

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

**Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Appendix 9 - Pain Intensity and Interference (pain scale)

Pain Intensity and Interference (pain scale)[20]

Pain intensity and interference

In the last month, on average, how would you rate your pain? Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"? [*That is, your usual pain at times you were in pain.*]

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10

In the last month, how much has pain interfered with your daily activities? Use a scale from 0 to 10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

Interpretation of the Two Item Graded Chronic Pain Scale – This two item version of the Graded Chronic Pain Scale is intended for brief and simple assessment of pain severity in primary care settings. Based on prior research, the interpretation of scores on these items is as follows:

Pain Rating Item	Mild	Moderate	Severe
Average/Usual Pain Intensity	1–4	5–6	7–10
Pain-related interference with activities	1–3	4–6	7–10

Although pain intensity and pain-related interference with activities are highly correlated and tend to change together, it is recommended that change over time be tracked for pain intensity and pain-related interference with activities separately when using these two items.

For an individual patient, a reduction in pain intensity and improvement in pain-related interference with activities of two points is considered moderate but clinically significant improvement.

Similar pain ratings have been widely used in the Brief Pain Inventory, the Multidimensional Pain Inventory, and the Pain Severity Scale of the SF-12.

There is extensive research on the reliability, validity and responsiveness to change of these pain severity ratings, which is summarized in the following reference:

Von Korff M. Chronic Pain Assessment in Epidemiologic and Health Services Research: Empirical Bases and New Directions. Handbook of Pain Assessment: Third Edition. Dennis C. Turk and Ronald Melzack, Editors. Guilford Press, New York., In press

[20] Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy (Washington State Agency Medical Directors' Group)

Appendix 10 - Therapeutic Options for Pain Management

Therapeutic Options for Pain Management[21]

In treating pain, clinicians can avail themselves of five basic modalities of pain-management tools:

1. Cognitive-behavioral approaches
2. Rehabilitative approaches
3. Complementary and alternative therapies
4. Interventional approaches
5. Pharmacotherapy

Not all of these options are necessary or appropriate for every patient, but clinical guidelines suggest that all options should be considered every time a health care provider decides to treat a patient with chronic pain. These options can be used alone or in combinations to maximize pain control and functional gains. Only one of these options involves medications and opioids are only one of many types of medications with potential analgesic utility. Which options are used in a given patient depends on factors such as the type of pain, the duration and severity of pain, patient preferences, co-occurring disease states or illnesses, patient life expectancy, cost and the local availability of the treatment option.

Cognitive-behavioral Approaches

The brain plays a vitally important role in pain perception and in recovery from injury, illness or other conditions involving pain. Psychological therapies of all kinds, therefore, may be a key element in pain management. At the most basic level, such therapy involves patient education about disease states, treatment options or interventions, and methods of assessing and managing pain. Cognitive therapy techniques may help patients monitor and evaluate negative or inaccurate thoughts and beliefs about their pain. For example, some patients engage in an exaggeration of their condition called "catastrophizing" or they may have an overly passive attitude toward their recovery which leads them to inappropriately expect a physician to "fix" their pain with little or no work or responsibility on their part. Another way to frame this is to assess whether a patient has an internal or external "locus of control" relative to their pain. Someone with an external locus of control attributes the cause/relief of pain to external causes and they expect that the relief comes from someone else. Someone with an internal locus of control believes that they are responsible for their own well being; they own the experience of pain and recognize they have the ability and obligation to undertake remediation, with the help of others.

Some chronic pain patients have a strong external locus of control, and successful management of their pain hinges, in part, on the use of cognitive or other types of

[21] California Medical Association (Prescribing Opioids: Care amid Controversy March 2014)

therapy to shift the locus from external to internal. Individual, group or family psychotherapy may be extremely helpful for addressing this and other psychological issues, depending on the specific needs of a patient.

In general, psychological interventions may be best suited for patients who express interest in such approaches, who feel anxious or fearful about their condition, or whose personal relationships are suffering as a result of chronic or recurrent pain. Unfortunately, the use of psychological approaches to pain management can be hampered by such barriers as provider time constraints, unsupportive provider reimbursement policies, lack of access to skilled and trained providers, or a lack of awareness on the part of patients and/or physicians about the utility of such approaches for improving pain relief and overall function.

Rehabilitative Approaches

In addition to relieving pain, a range of rehabilitative therapies can improve physical function, alter physiological responses to pain and help reduce fear and anxiety. Treatments used in physical rehabilitation include exercises to improve strength, endurance, and flexibility; gait and posture training; stretching; and education about ergonomics and body mechanics. Exercise programs that incorporate Tai Chi, swimming, yoga or core-training may also be useful. Other noninvasive physical treatments for pain include thermotherapy (application of heat), cryotherapy (application of cold), counter-irritation and electroanalgesia (e.g., transcutaneous electrical stimulation). Other types of rehabilitative therapies, such as occupational and social therapies, may be valuable for selected patients.

Complementary and Alternative Therapies

Complementary and alternative therapies (CAT) of various types are used by many patients in pain, both at home and in comprehensive pain clinics, hospitals or other facilities.27 These therapies seek to reduce pain, induce relaxation and enhance a sense of control over the pain or the underlying disease. Meditation, acupuncture, relaxation, imagery, biofeedback and hypnosis are some of the therapies shown to be potentially helpful to some patients. CAT therapies can be combined with other pain treatment modalities and generally have few, if any, risks or attendant adverse effects. Such therapies can be an important and effective component of an integrated program of pain management.

Interventional Approaches

Although beyond the scope of this paper, a wide range of surgical and other interventional approaches to pain management exist, including trigger point injections, epidural injections, facet blocks, spinal cord stimulators, laminectomy, spinal fusion, deep brain implants and neuro-augmentative or neuroablative surgeries. Many of these approaches involve some significant risks, which must be weighed carefully against the potential benefits of the therapy.

Pharmacotherapy

Many types of medications can be used to alleviate pain, some that act directly on pain signals or receptors, and others that contribute indirectly to either reduce pain or improve function. For patients with persistent pain, medications may be used concurrently in an effort to target various aspects of the pain experience.

NSAIDs and Acetaminophen

Non-steroidal anti-inflammatory drugs (NSAIDs), which include aspirin and other salicylic acid derivatives, and acetaminophen, are categorized as non-opioid pain relievers. They are used in the management of both acute and chronic pain such as that arising from injury, arthritis, dental procedures, swelling or surgical procedures. Although they are weaker analgesics than opioids, acetaminophen and NSAIDs do not produce tolerance, physical dependence or addiction. Acetaminophen and NSAIDs are also frequently added to an opioid regimen for their opioid-sparing effect. Since non-opioids and opioids relieve pain via different mechanisms, combination therapy can provide improved relief with fewer side effects.

These agents are not without risk, however. Adverse effects of NSAIDs as a class include gastrointestinal problems (e.g., stomach upset, ulcers, perforation, bleeding, liver dysfunction), bleeding (i.e., antiplatelet effects), kidney dysfunction, hypersensitivity reactions and cardiovascular concerns, particularly in the elderly. The threshold dose for acetaminophen liver toxicity has not been established, although the FDA recommends that the total adult daily dose should not exceed 4,000 mg in patients without liver disease (although the ceiling may be lower for older adults).

In 2009, the FDA required manufacturers of products containing acetaminophen to revise their product labeling to include warnings of the risk of severe liver damage associated with its use. In 2014, new FDA rules went into effect that set a maximum limit of 325 mg of acetaminophen in prescription combination products (e.g. Vicodin and Percocet) in an attempt to limit liver damage and other ill effects from the use of these products. Of note, aspirin (> 325 mg/d), ibuprofen, ketoprofen, naproxen and other non-cyclooxygenase-selective NSAIDs, are listed as "potentially inappropriate medications" for use in older adults in the American Geriatrics Society 2012 Beers Criteria because of the range of adverse effects they can have at higher doses.

Nonetheless, with careful monitoring, and in selected patients, NSAIDs and acetaminophen can be safe and effective for long-term management of persistent pain.

Opioids

Opioids can be effective pain relievers because, at a molecular level, they resemble compounds, such as endorphins, which are produced naturally in the human central nervous system. Opioid analgesics work by binding to one or more of the three major types of opioid receptors in the brain and body: mu, kappa and delta receptors. The

most common opioid pain medications are called "mu agonists" because they bind to and activate mu opioid receptors. The binding of mu agonist opioids to receptors in various body regions results in both therapeutic effects (such as pain relief) and side effects (such as constipation).

Physical tolerance develops for some effects of opioids, but not others. For example, tolerance develops to respiratory suppressant effects within 5-7 days of continuous use, whereas tolerance to constipating effects is unlikely to occur. Tolerance to analgesia may develop early, requiring an escalation of dose, but tolerance may lessen once an effective dose is identified and administered regularly, as long as the associated pathology or condition remains stable.

Opioids, as a class, comprise many specific agents available in a wide range of formulations and routes of administration. Short-acting, orally-administered opioids typically have rapid onset of action (10-60 minutes) and a relatively short duration of action (2-4 hours). They are typically used for acute or intermittent pain, or breakthrough pain that occurs against a background of persistent low-level pain. Extended-release/long-acting (ER/LA) opioids have a relatively slow onset of action (typically between 30 and 90 minutes) and a relatively long duration of action (4 to 72 hours). The FDA states that such drugs are "indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

These agents achieve their extended activity in various ways. Some have intrinsic pharmacokinetic properties that make their effects more enduring than short-acting opioids, while others are modified to slow their absorption or to slow the release of the active ingredient. A given patient might be appropriate for ER/LA therapy only, short-acting only or a combination of an ER/LA opioid with a short-acting opioid. Note that patients may respond in very different ways to any given medication or combination of medications. One size does not fit all, and treatment is best optimized by titrating a given regimen on an individual basis. Combination products that join an opioid with a non-opioid analgesic entail the risk of increasing adverse effects from the non-opioid co-analgesic as doses are escalated, even if an increase of the opioid dose is appropriate.

In response to concerns about opioid misuse and abuse, abuse-deterrent and tamper-resistant opioid formulations have been developed. One class of deterrent formulation incorporates an opioid antagonist into a separate compartment within a capsule; crushing the capsule releases the antagonist and neutralizes the opioid effect. Another strategy is to modify the physical structure of
tablets or incorporate compounds that make it difficult or impossible to liquefy, concentrate, or otherwise transform the tablets. Although abuse-deterrent opioid formulations do not prevent users from simply consuming too much of a medication, they may help reduce the public health burden of prescription opioid abuse.

Patients who receive opioids on a long-term basis to treat pain are considered to be receiving long-term opioid analgesic therapy, which is differentiated from opioid use by

patients who have an established opioid use disorder who use an opioid (e.g. methadone) as part of their treatment program.

Potential Adverse Effects of Opioids

Although opioid analgesics (of all formulations) may provide effective relief from moderate-to-severe pain, they also entail the following significant risks:

- Overdose
- Misuse and diversion
- Addiction
- Physical dependence and tolerance
- Potentially grave interactions with other medications or substances
- Death

At the heart of much of the current controversy over the use of opioid analgesics for chronic pain are beliefs about the degree to which these pain medications are potentially addicting. Unfortunately, it is difficult to quantify the degree of addictive risk associated with opioid analgesics, either for an individual patient or the population of pain patients in general.

In this context, it is critical to differentiate addiction from tolerance and physical dependence which are common physiological responses to a wide range of medications and even to widely-consumed non-prescription drugs (e.g. caffeine). Physical dependence and tolerance alone are not synonymous with addiction. Addiction is a complex disease state that severely impairs health and overall functioning. Opioid analgesics may, indeed, be addicting, but they share this potential with a wide range of other drugs such as sedatives, alcohol, tobacco, stimulants and anti-anxiety medications.

Rigorous, long-term studies of both the potential effectiveness and potential addictive risks of opioid analgesics for patients who do not have co-existing substance-use disorders have not been conducted. The few surveys conducted in community practice settings estimate rates of prescription opioid abuse of between 4% to 26%. A 2011 study of a random sample of 705 patients undergoing long-term opioid therapy for non-cancer pain found a lifetime prevalence rate of opioid-use disorder of 35%.41 The variability in results reflect differences in opioid treatment duration, the short-term nature of most studies and disparate study populations and measures used to assess abuse or addiction. Although precise quantification of the risks of abuse and addiction among patients prescribed opioids is not currently possible, the risks are large enough to underscore the importance of stratifying patients by risk and providing proper monitoring and screening when using opioid analgesic therapy.

Particular caution should be exercised when prescribing opioids to patients with conditions that may be complicated by adverse effects from opioids, including chronic obstructive pulmonary disease (COPD), congestive heart failure, sleep apnea, current

or past alcohol or substance misuse, mental illness, advanced age or patients with a history of kidney or liver dysfunction.

In addition, opioids generally should not be combined with other respiratory depressants, such as alcohol or sedative-hypnotics (benzodiazepines or barbiturates) unless these agents have been demonstrated to provide important clinical benefits, since unexpected opioid fatalities can occur in these combination situations at relatively low opioid doses.

In addition to the potential risks just described, opioids may induce a wide range of side effects including respiratory depression, sedation, mental clouding or confusion, hypogonadism, nausea, vomiting, constipation, itching and urinary retention. With the exception of constipation and hypogonadism, many of these side effects tend to diminish with time. Constipation requires prophylaxis that is prescribed at the time of treatment initiation and modified as needed in response to frequent monitoring. With the exception of constipation, uncomfortable or unpleasant side effects may potentially be reduced by switching to another opioid or route of administration (such side effects may also be alleviated with adjunctive medications). Although constipation is rarely a limiting side effect, other side effects may be intolerable. Because it is impossible to predict which side effects a patient may experience, it is appropriate to inquire about them on a regular basis.

Patients should be fully informed about the risk of respiratory depression with opioids, signs of respiratory depression and about steps to take in an emergency. Patients and their caregivers should be counseled to immediately call 911 or an emergency service if they observe any of these warning signs.

As of January 2014, a California physician may issue standing orders for the distribution of an opioid antagonist to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose. A physician may also issue a standing order for the administration of an opioid antagonist to a person at risk of an opioid-related overdose to a family member, friend, or other person in a position to assist a person experiencing or reasonably suspected of experiencing an opioid overdose.

The potential of adverse effects and the lack of data about the addictive risks posed by opioids do not mean these medications should not be used. Common clinical experience and extensive literature document that some patients benefit from the use of opioids on a short or long term basis. Existing guidelines from many sources, including physician specialty societies (American Academy of Pain Medicine, The American Pain Society), various states (Washington, Colorado, Utah), other countries (Canada) and federal agencies (Department of Defense, Veterans Administration), reflect this potential clinical utility.

Recommendations from authoritative consensus documents have been summarized in concise, user-friendly formats such as: Responsible Opiate Prescribing: A Clinician's

Guide for the Federation of State Medical Boards; the 2013 Washington State Labor and Industries Guideline for Prescribing Opioids to Treat Pain in Injured Workers; and the Agency Medical Directors' Group 2010 Opioid Dosing Guideline for Chronic Non-Cancer Pain.

Methadone

Particular care must be taken when prescribing methadone. Although known primarily as a drug used to help patients recovering from heroin addiction, methadone can be an effective opioid treatment for some pain conditions. Methadone is a focus of current debate because it is frequently involved in unintentional overdose deaths. These deaths have escalated as methadone has increasingly been used to treat chronic pain.

Methadone must be prescribed even more cautiously than other opioids and with full knowledge of its highly variable pharmacokinetics and pharmacodynamics. Of critical importance is the fact that methadone's analgesic half-life is much shorter than its elimination half-life. This can lead to an accumulation of the drug in the body. In addition, methadone is metabolized by a different group of liver enzymes than most other opioids, which can lead to unexpected drug interactions.

When rotating from another opioid to methadone, extreme caution must be used when referring to equianalgesic conversion tables. Consensus recommendations suggest a 75 to 90% decrement in the equianalgesic dose from conventional conversion tables when a switch is made from another opioid to methadone.

Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of mixing unauthorized substances, especially alcohol and other sedatives, with their medication. This should be explicitly stated in any controlled substance agreement that the patient receives, reads and signs before the initiation of treatment [...].

Although uncommon, potentially lethal cardiac arrhythmias can be induced by methadone. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to a history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease or cardiac risk factors or is taking agents that may interact with methadone. In addition, it is important that an ECG be repeated periodically, because QT interval prolongation has been demonstrated to be a function of methadone blood levels and/or in response to a variety of other medications.

Adjuvant Pain Medications

Although opioid medications are powerful pain relievers, in the treatment of neuropathic pain and some other centralized pain disorders such as fibromyalgia, they are of limited effectiveness and are not preferred. Other

classes of medications, however, may provide relief for pain types or conditions that do not respond well to opioids. Some of these adjuvant medications exert a direct analgesic effect mediated by non-opioid receptors centrally or peripherally. Others have no direct analgesic qualities but may provide pain relief indirectly via central or peripheral affects.

Commonly-used non-opioid adjuvant analgesics include antiepileptic drugs (AEDs), tricyclic antidepressants (TCAs) and local anesthetics (LAs). AEDs, such as gabapentin and pregabalin, are used to treat neuropathic pain, especially shooting, stabbing or knife-like pain from peripheral nerve syndromes.TCAs and some newer types of antidepressants may be valuable in treating a variety of types of chronic and neuropathic pain, including post-herpetic neuralgia and diabetic neuropathy. LAs are used to manage both acute and chronic pain. Topical application provides localized analgesia for painful procedures or conditions with minimal systemic absorption or side effects. Topical Las are also used to treat neuropathic pain. Epidural blocks with LAs, with or without opioids, play an important role in managing postoperative and obstetrical pain.

Non-Opiod Pain Management Tool by Jeremy Biggs MD MSPH

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to Initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 6	Within 7-10 days of injury	All ages	Life long	Consider co morbities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat 2, 4, 6, 7	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day 1, 2, 4, 6, 8, 9	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy 4, 6, 10, 11	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs 2, 4, 6, 9, 12	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers 4, 9, 13	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School 14, 15	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol 2	After initial acetaminophen trail	Adults	Can be long term	Consider co morbidities
	Manipulation 1, 4, 6, 16, 17, 18, 19	Most effective when used for pain <6 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
Back Pain >4 weeks	Directed Exercise Program 1, 2, 3, 4, 5, 8, 18, 19	Immediately	Adults	Life Long	Consider co morbidities
	Yoga exercises (viniyoga) 20	Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
	Controlled Weight Loss 2	Immediately	Adults	Life Long	Consider co morbidities
	Acetaminophen up to 4 g/day 1, 2, 4, 8	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 4, 12	Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21) Some	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors

		evidence that it is superior at pain control. (22)			
	Muscle Relaxers 4, 13	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and no CV risk factors	Adults with no CV risk factors	Short term	Consider co morbidities, no CV risk factors
	Back School 14, 15, 18	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
	Tricyclic antidepressants 9, 23	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Have significant side effects profile, consider co morbidities
	Tramadol/acetaminophen 2	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol 2	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
	Injections, epidural/facet joints 24, 25	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
	Physical Therapy 10, 11	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
	Message Therapy 26, 27, 28	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
	Neuroreflexotherapy 29	Only in Chronic LBP	Adults	Undetermined	Preliminarily this has shown some effect. Requires lengthy training of practitioner to be considered effective
Neck Pain	Directed Exercise Program 1, 2, 3, 6, 30	Within 7-10 days of injury	All ages	Life long	Consider co morbidities, can add mechanical manipulation to an exercise program
	Acetaminophen 4g/day maximum 2, 6, 31	Immediately	Adults	Can be long term	Consider co morbidities

	NSAIDs 6, 12, 31	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Physical Therapy 6	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities
	Manipulation 6	Once more conservative measures fail	Adults	Best when combined with exercise	Consider co morbidites, rare instances of CVA
	IV methylprednisolone 31	Within 8 hours of injury for acute whiplash	Adults	One time treatment	Any contraindications to IV steroids.
	IM Lidocaine 31	Chronic neck pain with arm symptoms	Adults	Only a few treatments indicated	Consider co morbidities
	Muscle Relaxers 31	Immediately	Adults	Short term	Consider co morbidities
	Acupuncture 32	After failing exercise and/or acetaminophen/NSAIDs	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
Headache	Directed exercise program 33	Immediately	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
	Acetaminophen 4g/day maximum 34	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
	NSAIDS 12, 35, 36	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
	Triptans 36, 37	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Beneficial for migraine headaches. IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
	Excedrin 36	Immediately	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
	Amitriptyline 35	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness
	Antidepressants (other TCAs, SNRIs, SSRIs) 38, 39	After failing conservative therapy	Adults	Migraine, tension, and mixed. Studies lasted 4-27 weeks	Independent of depression, SSRI least effective
	Antiemetics 36	With migraine associated nausea	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
	Anticonvulsants 40	After failing other therapies, for prevention	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
	NSAIDS combined with metoclopromide 41	After failing acetaminophen	Adults	Migraine	Consider co morbidities, metoclopromide can cause dystonia. NNT 3.5
	DHE IM/SC/IV 36	After failing more conservative therapies	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
	Isometheptene 36	After failing more conservative	Adults	Found effective for mild-	Consider co morbidities

		therapies		moderate migraine	
	Normal barometric oxygen therapy 42	Immediately	Adults	For use in Cluster Headaches	Unknown
	TENS 35	Immediately	Adults	Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Manipulation 35	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	Acupuncture 43	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
Osteoarthritis	Directed Exercise Program1, 2, 3, 6, 44	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss 2	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 4g/day maximum 2, 8	Immediately first line	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 12	Immediately	Younger adults, without any CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Non-acetylated salicylates 2	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Topical capsaicin 2	Immediately	Adults	Short term	Consider co morbidities
	Intra-articular steroid injection 2, 45	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	Cox-2 Inhibitors 1, 2	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Diacerein 46, 47	After failing other therapies	Adults	Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief
Acute Sports Injury	Ice/Heat 2	Immediately for first 1-4 days	All ages	For first 1-4 days	Instruct on timing to not cause tissue damage
	Acetaminophen 4g/day maximum 2	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs 2, 12	Immediately, recommended to try acetaminophen first	Adults	Short term	Consider co morbidities
Neuropathic Pain	Acetaminophen 4g/day maximum 48	Immediately	Adults	Can be long term	Consider co morbidities
	Anticonvulsants 49, 50	After failing acetaminophen	Adults	Can be long term	Have a side effect profile that must be monitored. Carbamezapine and gabapentin found to most effective, some showing crabamezapine to be more

					effective with lower NNT and higher NNH
	Systemic administration of local anesthetics 51	After failing acetaminophen	Adults	Undetermined	Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressantsv34, 52	After failing acetaminophen.	Adults	Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies	Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain	Anticonvulsants 49	Immediately	Adults	While symptoms last	Can cause drowsiness
Fibromyalgia	Supervised Aerobic/Strength training exercise 53, 54, 55	Immediately, for at least 20 minutes a day 3 times a week	All ages	Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.	Consider co morbidities
	Cognitive Behavioral Therapy 54, 56	Immediately	Adults	Data showed results from 6-30 months	Works best as a multidisciplinary approach
	Amitriptyline 54, 57, 58	Immediately	Adults	While beneficial	Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine 54, 57	Typically is after exercise, acetaminophen and amitriptyline	Adults	While beneficial	Significant side effects
	Acupuncture 54, 59, 60	After exercise and amitriptyline	Adults	While beneficial	Mild/weak evidence
	Deep tissue message 54	Immediately	Adults	While beneficial	Mild/weak evidence
	Fluoxetine 54	Typically start with exercise, acetaminophen, and amitriptyline first	Adults	While beneficial	Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): 54	Immediately	Adults	While beneficial	Weaker evidence than previous medications
	Gabapentin 61	Immediately	Audlts	While beneficial, studied over a 12 week period	Consider co morbidities
	Pregabalin 54, 62, 63	Immediately	Adults	While beneficial	Still under investigation, one study showing positive results
Dental Pain	Acetaminophen 64, 65	Immediately	All ages	As needed	Consider co morbidities
	NSAIDs 65	Immediately	Adults	As needed	Consider co morbidities
	Acupuncture 57, 66	Immediately postop	Adults	1-4 sessions	
Pelvic Pain (dysmenorrheal)	Directed exercise program 67	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 68	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	NSAIDs 68, 69	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	Oral contraceptives 70	Immediately	Adults/Adolescents	While beneficial	Consider co morbidities, can be traditional or extended continuous cycle
	Acupuncture 71	Immediately	Adults	10 visits over 3 months	Consider co morbidities
	Chinese herbal medication 72	After other interventions	Adults	While beneficial	Not all interactions known

					with other medications
Pelvic Pain (chronic pelvic pain)	Directed exercise program 73	Immediately	All ages	Life long	Consider co morbidities
	Medroxyprogesterone acetate 73	Immediately	Adults	Not found to be effected after 9 months	Consider co morbidities
	Goserelin 73	After failing more conservative therapies	Adults	As long as beneficial, cannot be taken longer than six months	Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol 74	After failing conservative therapy	Adults	For up to 6 months	Consider co morbidities, extensive side effects
	OCPs 75	Immediately	Adults	While beneficial	Consider co morbidities
	Goserelin 75	After failing more conservative therapies	Adults	While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects

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Appendix 12 – Suggested Language on Naloxone for Pain Management Agreement

- I understand that "overdose" is a risk of opioid therapy which can lead to death. I understand and can recognize the signs and symptoms of overdose including respiratory depression.

- I understand that I will be prescribed naloxone because overdose is a risk of opioid therapy. I understand that naloxone is a drug that can reverse opioid overdose. I understand when and how to use naloxone.
  - I understand it is strongly encouraged to share information about naloxone with my family and friends.
  - I understand it is strongly encouraged to teach family and friends how to respond to an overdose.

PATIENT PAIN MEDICATION AGREEMENT AND CONSENT

This agreement is important for you:

- *You will have a safe and controlled pain treatment plan.*
- *Your medicines have a high potential for abuse. They can be dangerous if used in the wrong way. You need to understand the risks that come from use of pain medicines.*

Please read and make sure you understand each statement here. Here are rules about refills and health risks. Here are also reasons for stopping your pain control treatment.

I WILL:

- ☐ I will only get my pain medicine from this clinic during scheduled appointments.
- ☐ I will take my pain medicine the way that my healthcare provider has ordered.
- ☐ I will be honest with all my healthcare providers if I am using street drugs.
- ☐ I will be honest about all the medicine I use. This includes medicine from stores and herbal medicines.
- ☐ I will be honest about my full health history.
- ☐ I will tell my healthcare provider if I go to an emergency room for any reasons.
- ☐ If I get pain medicine from an emergency room, I will tell my healthcare provider.
- ☐ I will call this office if I am prescribed any new medicine.
- ☐ I will call this office if I have a reaction to any medicine.
- ☐ I will tell all other healthcare providers that I have a pain medication agreement.
- ☐ I will tell the emergency room people that I have a pain medication agreement.
- ☐ I will take drug tests and other tests when I am told to do so.
- ☐ I will go to office visits when I am told to do so.
- ☐ I will go to physical therapy when I am told to do so.
- ☐ I will go to counseling when I am told to do so.
- ☐ I will follow directions for all treatment.
- ☐ I will show up on time for all appointments.
- ☐ I will make an appointment for refills before I run out of medicine.
- ☐ I will tell my health provider if I will be out of town so that I can get my refills.
- ☐ I will get past health records from other offices when needed.
- ☐ I will deliver these records by hand if needed. I will do this within one month of being asked. I will pay for these records if needed.
- ☐ I will give permission to this clinic to talk about my treatment with pharmacies, doctors, nurses, and others who are helping me.
- ☐ I will give permission to any healthcare provider to get information from this clinic about my health and my pain treatment.
- ☐ I will take responsibility if I overdose myself accidentally or on purpose.
- ☐ I will tell my healthcare provider if I plan to become pregnant.
- ☐ I will tell my healthcare provider if I am pregnant while I am taking pain medicine.
- ☐ I will only take this medicine the way I was told to take it.

CONTINUED ON NEXT PAGE

I WILL NOT:

- ☐ I will not share or sell, or trade any of my medicine.
- ☐ I will not drink alcohol or take street drugs while I am taking pain medicine.
- ☐ I know that I cannot call the office to have my medicine refilled over the phone.
- ☐ I will not go to the emergency room or other doctors for more pain medicine or other drugs.
- ☐ I know that when I drive a car, I must be fully alert. I know that when I use machines, I must also be fully alert. Pain medicines can make me less alert. When I am taking pain medicines, I need to be sure that I am alert. I need to be sure that it is safe for me to drive a car or use a machine.
- ☐ I will not stand in high places or do anything to hurt others after I have taken pain medicine.
- ☐ I will not leave my medicine where it can be stolen or where others can take it.
- ☐ I will not leave my medicine where children can find it.
- ☐ I will not suddenly stop taking my medicine. I know that if I do this, I can have withdrawals.

WHEN USING A PHARMACY, I WILL:

- ☐ I will use the same pharmacy for all my medicines. This is the pharmacy that I have picked: _____
- ☐ I will not ask for early refills or more pain medicine, even if I lose my medicine.

I KNOW THAT

- ☐ Pain management may include other treatment. Some treatment may not include medicine.
- ☐ Pain medicine will probably not get rid of all of my pain. Pain medicine can reduce my pain so that I can do more and have a better life.
- ☐ Part of my treatment is to reduce my need for pain medicine.
- ☐ If the pain medicines work, I will continue to use them. If the pain medicine does not help me, it will be stopped.
- ☐ My medicines will not be replaced if any of these things happen: Medicine is lost. Medicine gets wet. Medicine is destroyed
- ☐ If my medicine is stolen, I might be able to get more medicine if I get a report from the police about the medicine being stolen.
- ☐ Any of my healthcare providers can find out from the California Prescription Drug Monitoring Program about any other medicines I get from any other pharmacy in California. This is called a CURES report.
- ☐ My healthcare provider may contact the drug enforcement agency, if I try to get other doctors to give me pain medicine.
- ☐ Healthcare providers may contact the drug enforcement agency if I am not honest about how I take pain medicine.
- ☐ My doctor and my clinic will help with any investigation if I am suspected of prescription drug abuse.
- ☐ I may be sent somewhere else for drug abuse or addiction help if I need it.
- ☐ Pain medicine can be addictive. This means that my body may need more and more pain medicine or that it can be hard for me to stop taking this medicine.
- ☐ If I suddenly stop using the medicine, I can get withdrawals.
- ☐ If I use too much pain medicine, I can end up with health problems. I could die.
- ☐ If I mix medicines, I could also end up with health problems. I could die.
- ☐ Here are some things that could go wrong if I use too much medicine or mix medicines:

Overdose	Addiction	Constipation	Vomiting	Sleepiness
Slower reflexes	Nausea	Difficulty with urination	Confusion	Itching
Problems with sex	Dry mouth	Depression	Trouble breathing	Death

CAUSE FOR DISMISSAL FROM THIS CLINIC

- ☐ I know that the pain medicines may be stopped if I break any part of this contract.

My signature below means that I have read this contract. I am signing this to say that I understand all of this contract.

Patient Name _____ Doctor Name _____

Patient Signature _____ Doctor Signature _____

Date: _____

Appendix 14 – Suggested Treatment Plan Using Prescription Opioids

Treatment Plan Using Prescription Opioids

Patient name: _____

Prescriber name: _____

THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.

I (patient) understand the following (initial each):

____ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: _____

____ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: _____

____ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

____ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

____ There is a small risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

I agree to the following (initial each):

_____ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

_____ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

_____ I agree not to share, sell, or in any way provide my medication to any other person.

_____ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

_____ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

_____ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

_____ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

_____ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

_____ _____

Patient Signature Date

_____ _____

Prescriber Signature Date

Appendix 15 – Suggested Strategies for Tapering and Weaning

Strategies for Tapering & Weaning

Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation ("You are indifferent to my suffering")
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

Washington State Agency Medical Directors' Group, 2007

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TOOLS

VETERINARY MEDICAL BOARD - 0777
BUDGET REPORT
FY 2015-16 EXPENDITURE PROJECTION
Nov-2015

OBJECT DESCRIPTION	FY 2014-15 ACTUAL EXPENDITURES (MONTH 13)	FY 2014-15 PRIOR YEAR EXPENDITURES 11/30/2014	FY 2015-16 BUDGET STONE 2015-16	FY 2015-16 CURRENT YEAR EXPENDITURES 11/30/2015	FY 2015-16 PERCENT SPENT	FY 2015-16 PROJECTIONS TO YEAR END	FY 2015-16 UNENCUMBERED BALANCE
PERSONNEL SERVICES							
Salary & Wages (Staff)	798,937	208,908	**1,138,000**	425,827	37%	1,021,985	116,015
Statutory Exempt (EO)	88,428	35,075	**82,000**	37,765	46%	90,636	(8,636)
Temp Help Reg (Seasonals)	6,195	44,535	**33,000**				33,000
BL 12-03 Blanket							
Temp Help (Exam Proctors)							
Board Member Per Diem	3,100	2,800	**14,000**	1,000	7%	3,000	11,000
Committee Members (DEC)	600	900	**11,000**				11,000
Overtime	11,352	4,209		33		99	
Staff Benefits	483,685	127,742	**664,000**	250,219	38%	600,526	63,474
TOTALS, PERSONNEL SVC	**1,392,297**	**424,169**	**1,942,000**	**714,844**	**37%**	**1,716,245**	**225,854**
OPERATING EXPENSE AND EQUIPMENT							
General Expense	48,591	8,527	**31,000**	16,604	54%	39,850	(8,850)
Fingerprint Reports	1,040	147	**6,000**	59	1%	142	
Minor Equipment	23,152	8,810		6,919		16,606	
Printing	9,361	3,942	**20,000**	4,881	24%	11,714	8,286
Communication	4,477	1,495	**21,000**	1,136	5%	2,726	18,274
Postage	35,263	14,026	**28,000**	11,206	40%	26,894	1,106
Insurance							
Travel In State	49,487	15,034	**148,000**	28,426	19%	68,222	79,778
Travel, Out-of-State							
Training	816	430	**20,000**	4,779			20,000
Facilities Operations	112,440	94,746	**102,000**	111,462	109%	102,000	0
Utilities							
C & P Services - Interdept.	109,000						
C & P Services - External	147,068	69,468	**106,000**	53,712	51%	106,000	0
HSP Inspection Pgm				28,712		175,000	
DEPARTMENTAL SERVICES:							
Departmental Pro Rata	334,011	110,684	**458,000**	226,000	49%	458,000	0
Admin/Exec	148,320	64,494	**287,000**	140,000	49%	287,000	0
Interagency Services			**50,000**			50,000	0
IA w/ OPES	40,573			45,226		45,226	(45,226)
DOI-ProRata Internal	3,616	2,068	**7,000**	3,500	50%	7,000	0
Public Affairs Office	4,227	2,908	**9,000**	4,500	50%	9,000	0
PCSD Pro Rata	5,001	2,474	**10,000**	5,000	50%	10,000	0
INTERAGENCY SERVICES:							
Consolidated Data Center	1,249	878	**10,000**	769	8%	10,000	0
DP Maintenance & Supply	7,368		**5,000**	4,559	91%	5,000	0
Central Admin Svc-ProRata	141,779	55,146	**157,000**	78,700	50%	157,000	0
EXAM EXPENSES:							0
Exam Supplies			**1,000**				1,000
Exam Freight							
Exam Site Rental			**5,000**				5,000
C/P Svcs-External Expert Administrative	48,502	46,420		23,116		69,348	
C/P Svcs-External Expert Examiners	318		**31,000**	27,558	89%	82,674	(51,674)
C/P Svcs-External Subject Matter	38,503						
ENFORCEMENT:							
Attorney General	488,690	150,525	**460,000**	229,500	50%	550,800	(90,800)
Office Admin. Hearings	132,145	15,226	**59,000**	25,103	43%	60,247	(1,247)
Court Reporters	4,834	84		1,139		2,734	
Evidence/Witness Fees (In-House Consult.)	135,197	31,767	**163,000**	38,219	23%	91,726	71,274
DOI - Investigations	627,679	176,730	**628,000**	305,000	49%	628,000	0
Major Equipment							
Special Items of Expense		24					0
Other (Vehicle Operations)			**3,000**				3,000
TOTALS, OE&E	**2,702,707**	**876,053**	**2,825,000**	**1,425,785**	**50%**	**3,072,909**	**9,920**
TOTAL EXPENSE	**4,095,004**	**1,300,222**	**4,767,000**	**2,140,629**	**45%**	**4,789,154**	**235,774**
Sched. Reimb. - External/Private	(3,575)	(490)					
Sched. Reimb. - Fingerprints			**(11,000)**			**(11,000)**	
Sched. Reimb. - Other			**(15,000)**			**(15,000)**	
Unsched. Reimb. - Other	(142,931)	(25,460)					
NET APPROPRIATION	**3,948,498**	**1,274,272**	**4,741,000**	**2,140,629**	**45%**	**4,763,154**	**235,774**
						SURPLUS/(DEFICIT):	**5.0%**

Veterinary Medical Board
Summary of Expenditures - 2015/2016

Line Item	Appropriation	Summary of Expenses
Personal Services:		
Salary & Wages (Staff)	1,108,685	Board staff salaries
Statutory Exempt (EO)	81,732	Executive Officer salary
Temp Help Reg (Seasonals)	33,000	Wages for temporary help such as a permanent-intermittent employees, students, seasonal employees, etc.
Temp Help Reg (Exam Proctors)	0	Examination Proctors
Board Member Per Diem	14,108	Board members' per-diem
Committee Members (DEC)	10,400	Committee members' per-diem
Overtime	0	Staff Overtime
Staff Benefits	631,921	OASDI, Dental, health, retirement, life, vision, Medicare
Total Personal Services	**1,879,846**	
Operating Expenses & Equipment:		
General Expense	30,757	Office supplies, freight
Fingerprint Reports	6,259	Fingerprint expenses – reimbursed by candidate
Minor Equipment	22,000	Equipment less than $5K per unit
Printing	19,566	Printed forms, office copier, copying service
Communications	20,909	Phones, cellular phones
Postage	28,149	Stamps, DCA and EDD facility mailed postage
Insurance	0	Insurance coverage for department owned vehicles.
Travel In-State	148,423	Board, Committee, and Staff Air, car, bus, taxi, incidentals, service fees
Travel Out-of-State	0	Same as above - out-of-State
Training	20,297	Registration fees, subscriptions
Facilities Operations	102,456	Rent, storage, security
Utilities	0	Electricity, Natural Gas (P.G.& E.), water, sewer, and regular waste removal service.
C&P Services Interdept.	0	Services provided by other state agencies or Interagency Agreement within the Department of Consumer Affairs.
C&P Services External	76,889	Outside DCA contracts - includes MAXIMUS
Departmental Services		
Departmental Prorata	342,549	DCA Svcs: Info systems, Administrative Svcs (HR, Accounting, Budgets, etc.), Legal, Publications, Public Affairs
Admin/Exec	148,089	Pro-rata assessments to support DCA Administrative Services
Interagency Services	49,915	Services provided to one board by another board within the Department
IA w/OPES	0	Services provided by OPES to Board
DOI-Pro Rata Internal	4,597	Services provided by Division of Investigation Pro Rata
Public Affairs Office	4,527	Services provided by DCA Public Affairs
CCED	4,860	Pro-rata Consumer and Community Empowerment Division
Interagency Services		
Consolidated Data Centers	10,535	CAS/Teale Data Center
DP Maintenance & Supply	4,647	Data processing supplies and maintenance
Central Admin Svs-Pro Rata	141,779	State services pro-rata (DGS, DOF, etc)
Exam Expenses		
Exam supplies	557	Examination materials, supplies not covered by contract
Exam freight	0	Freight, shipping and storage of examination material
Exam site rental	5,399	Facility rental charge for vet exams administration
Expert Examiners (SME)	30,699	Subject matter experts for item writing, review and Angoff workshops VET and RVT
C/P Svcs-External Expert Administrative	0	National exam contracts - includes PSI contract
C/P Svcs-External Expert Examiners	0	Wages for services provided by expert examiners in the oral/ written examination process
C/P Svcs-External Subject Matter	0	Services provided by subject matter experts in the oral/written examination process
Enforcement		
Attorney General	460,176	Office of the Attorney General/DAG legal services
Office of Admin Hearings	59,253	Office of Administrative Hearings, Admin. Law Judge and court reporter services
Court Reporters	0	
Evidence/Witness Fees	163,297	Expert Witness and In-house Consultants enforcement case review
Div of Investigation	645,027	DCA Division of Investigation services
Major Equipment	66,000	Equipment more than $5k per unit
Special Items of Expense		
Vehicle Operations	2,580	Leasing & maintenance of State vehicle (CPEI BCP)
Total OE&E	**2,620,191**	
Total Personal Services (above)	**1,879,846**	
Totals, Expenditures	**4,500,037**	
Sched. Reimb. - External		Reimbursements for OIS Public Sales
Sched. Reimb. - Fingerprints	(11,000)	Reimbursements for assessment of fingerprint processing fees
Sched. Reimb. - Other	(15,000)	Reimbursements from private individuals, firms, institutions or corporations
Net Appropriation	**4,474,037**	

VMB Agenda Item #17 (C) –

Enforcement Report

HAND CARRY

Administration/Examination/Licensing Report

Prepared by Ethan Mathes **January 2016**

BreEZe

The BreEZe database system consists of two main components, Versa Regulation and Versa Online. Versa Regulation is the back-office component of the BreEZe database system and is utilized for internal processes that guide an initial application through licensure. Versa Online is the front facing component of the BreEZe database system and is used by external customers for online activities such as submitting a complaint, checking the status of a complaint, applying for examination eligibility, applying for licensure, renewing a license, updating an address of record, etc.

Major components of BreEZe system configuration and testing include:

- *Configuration Interviews* – Staff meets with Iron Data and Accenture personnel to review examination, licensing and enforcement business processes as well as reviews and creates the BreEZe online interface. *[Completed]*
- *Data Conversion/Validation* – Staff reviews existing application, licensee, and enforcement databases for data errors and outdated data records as well as reviews data converted from legacy databases to the BreEZe database. *[Ongoing]*
- C*orrespondence Conversion* – Staff reviews existing correspondence to be converted to the BreEZe noticing system. *[Ongoing]*
- *License Renewal Conversion* – Staff reviews and updates license renewals to the new BreEZe renewal template. *[Completed]*
- *Script Writing and User Acceptance Testing* – Staff outline and test assorted Versa Regulation and Online interfaces and data entry scenarios in order to assess the functionality of the BreEZe database system. *[Completed]*
- *Organizational Change Management* – Staff is guided through the process of planning for organizational change and the As-Is versus To-Be work processes entailed as part of that change. *[Ongoing]*

Board staff continues to be heavily impacted by BreEZe activities and are working on various components of the rollout leading up to “Go-Live” of the BreEZe system. Preparation activities include BreEZe system training for all staff and continuation of Organizational Change Management training.

Board staff has also begun work on various components of BreEZe outreach including updating Board forms and the website as well as interfacing with various interested parties, professional organizations and schools. Department Director Awet Kidane met with CVMA and CaRVTA representatives on November 19, 2015; Board staff will also present at the CVMA meeting on January 23, 2016 to provide an overview of the BreEZe system.

Update [January 2016] – The Board (and BreEZe system as a whole) successfully exited user acceptance testing in late-December. With successful completion of UAT and data conversion activities the project continues towards system go-live on January 19, 2016.

Applications

Applications Received		
	Jan. 2014 - Dec. 2014	*Jan. 2015 - Dec. 2015*
Veterinarian Apps. Received	617	598
Veterinary Tech. Apps. Received	749	735
Veterinary Premise Apps. Received	371	267

Examinations

CALIFORNIA STATE BOARD EXAMINATION			
November 2014 – April 2015		May 2015 – October 2015	
Candidates	Pass Pct.	Candidates	Pass Pct.
573	95%	288	83%

NORTH AMERICAN VETERINARY LICENSING EXAMINATION			
April 2015		Nov./Dec. 2015	
Candidates	Pass Pct.	Candidates	Pass Pct.
92	66%	TBD	TBD

CALIFORNIA VETERINARY TECHNICIAN LAW EXAMINATION					
Jul. – Dec. 2014		Jan. – Jun. 2015		Jul. – Dec. 2015*	
Candidates	Pass Pct.	Candidates	Pass Pct.	Candidates	Pass Pct.
331	62%	358	96%	366	94%
**partial year to date*					

VETERINARY TECHNICIAN NATIONAL EXAMINATION					
Jul./Aug. 2014		Mar./Apr. 2015		Nov./Dec. 2015	
Candidates	Pass Pct.	Candidates	Pass Pct.	Candidates	Pass Pct.
312	70%	255	59%	420	59%

Licensing

Licensees	
as of December 2015	
Veterinarian Licenses*/**	17,048/12,086
Veterinarian Licenses – California**	9,548
Veterinarian – Internship**	29
Veterinarian – Reciprocity**	31
Registered Veterinary Technician Licenses*/**	10,125/6424
Registered Veterinary Technician Licenses – California**	5,982
Premise Permits**	3636
Premise Permits – Exempt**	83
**includes delinquent, inactive, and clear licensees; **clear licensees*	

Licenses Issued		
as of December 2015		
	Jan. 2014 - Dec. 2014	*Jan. 2015 - Dec. 2015*
Veterinarian	521	595
Reciprocity	46	550
Intern	21	30
Registered Veterinary Technician	442	52
Premises	371	267

Examination Development and Workshops

Examination Development Workshops include Item Writing, Item Review, Examination Construction, and Pass Score Setting. Workshops have concluded for the year with the next Workshops scheduled for Summer 2016.

Diversion Program

The next Diversion Evaluation Committee (DEC) meeting is scheduled for February 1, 2016. There is currently one public member vacancy on the five-member DEC, the Board has received an application for the vacancy and they will come before the Board at the April 2016 meeting.

There are currently seven participants in the Diversion Program with one participant undergoing successful transition out of the Program.

MAXIMUS is rolling out a new version of its online MAX-CMS 2.0 portal that will enable both Diversion Program Managers (DPM) and DEC members to confidentially review Program participant's files through the online portal. DPMs and DEC members will be trained on the new MAX-CMS 2.0 portal in the coming months.

Hospital Inspection Report
Prepared by Patty Rodriguez **January 2016**

Hospital Inspection Workload Update (as of 12/31/15)

- Assigned: 364 Routine/ 24 Complaint/Probation Related: 388 Total Inspections Assigned
- Completed: 138 Routine/ 22 Complaint/Probation Related: 160 Total Inspection Completed
- Complaint/Probation Related Requests Pending Assignment: 27 Requests from Enforcement
- Inspections Awaiting Assignment for FY 2015/16: 312
- Anticipated Expenditures for FY 2015/16: $180,000

Program Updates: FY 2015/16 began with 16 Inspectors however, we lost one inspector to professional obligations and two of our inspectors will be joining the Board as In-House Consultants thus limiting their time for field inspections. In spite of these setbacks, we remain optimistic to reach our mandated goal of inspecting 20% of veterinary facilities, roughly 700 inspections. Staff has already worked through the FY 2014-15 backlog of inspection reevaluations.

The Premises Permit licensing function recently transferred to the Hospital Inspection Program in order to streamline the entire process from the permit application, to renewal to facility inspection.

Inspection Compliance Rate: The inspection compliance rate is approximately 35-40% thirty days after the inspection. Despite providing a thorough review of the detailed inspection report with staff and/or the managing licensee, hospitals either fail to document corrections or submit inadequate documentation to the Inspector. At that point, the Inspector submits inspection paperwork to the office, where the staff enters all inspection information in to the database (date of inspection, corrections ordered, due dates, etc.). Inspection reports are reevaluated in order of inspection date and a preliminary letter is sent to address areas that remain deficient. Managing licensees are given ten days from the date of receipt of the preliminary letter to submit additional corrections. This generates additional communication with hospital staff in an effort to reach compliance.

After this process, we see the compliance rate jump to over 90%. Failure to comply following the preliminary letter results in a citation and fine.

Inspectors are getting a firm grasp on Board expectations resulting in thorough inspection process overall.

Staffing: Kristina Kennedy started with the Hospital Inspection Program in December. Ms. Kennedy comes to us from the Health Benefit Exchange where she worked with insurance providers with the Covered California program. She will be handling the Premises Permit licensing functions as well as cross-training with the Inspection program.

We are losing a valuable member of the Hospital Inspection Program on January 8 when Kellie Flores leaves the Board for a promotion at the Board of Optometry. We wish Ms. Flores all the best and thank her for her tremendous contributions to the program. We will begin recruiting for this vacancy as soon as possible.

Looking Ahead: The remaining inspection staff is facing more than triple the workload, in addition to the Premises Permit licensing function, which will be a challenge given current staffing.