Board Meeting of the Virginia Board of Medicine

February 15, 2018
8:30 a.m.

Department of Health Professions

Board of Medicine

Thursday, February 15, 2018 @ 8:30 a.m.
Perimeter Center
9960 Mayland Drive, Suite 201
Board Room 2
Henrico, VA 23233

■ **Public Hearing - Proposed Regulations for Licensure by Endorsement**

■ **Board of Medicine Business Meeting**

Call to Order and Roll Call

PERIMETER CENTER CONFERENCE CENTER
EMERGENCY EVACUATION OF BOARD AND TRAINING ROOMS
(Script to be read at the beginning of each meeting.)

PLEASE LISTEN TO THE FOLLOWING INSTRUCTIONS ABOUT EXITING THESE PREMISES IN THE EVENT OF AN EMERGENCY.

In the event of a fire or other emergency requiring the evacuation of the building, alarms will sound.

When the alarms sound, leave the room immediately. Follow any instructions given by Security staff

Board Room 2

Exit the room using one of the doors at the back of the room. (Point) Upon exiting the room, turn **RIGHT.** Follow the corridor to the emergency exit at the end of the hall.

Upon exiting the building, proceed straight ahead through the parking lot to the fence at the end of the lot. Wait there for further instructions.

You may also exit the room using the side door (**Point**), turn **Right** out the door and make an immediate **Left**. Follow the corridor to the emergency exit at the end of the hall.

Upon exiting the building, proceed straight ahead through the parking lot to the fence at the end of the lot. Wait there for further instructions.

Agenda Item: **Approval of Minutes of the October 26, 2017**

Staff Note: Draft minutes that have been posted on Regulatory Townhall and the Board's website are presented. Review and revise if necessary.

Action: Motion to approve minutes.

---DRAFT UNAPPROVED---

VIRGINIA BOARD OF MEDICINE
FULL BOARD MINUTES

October 26, 2017 | Department of Health Professions | Henrico, VA 23233

CALL TO ORDER: Dr. O'Connor called the meeting of the Board to order at 8:34 a.m.

ROLL CALL: Ms. Opher called the roll. A quorum was established.

MEMBERS PRESENT:
Kevin O'Connor, MD, President
Ray Tuck, DC, Vice-President
Lori Conklin, MD, Secretary-Treasurer
Syed Ali, MD
Barbara Allison-Bryan, MD
Randy Clements, DPM
Alvin Edwards, PhD
David Giammittorio, MD
The Honorable Jasmine Gore
Jane Hickey, JD
Isaac Koziol, MD
Maxine Lee, MD
Wayne Reynolds, DO
David Taminger, MD
Svinder Toor, MD
Kenneth Walker, MD
Martha Wingfield

MEMBERS ABSENT: David Archer, MD

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Executive Director, Discipline
Barbara Matusiak, MD, Medical Review Coordinator
Alan Heaberlin, Deputy Executive Director, Licensing
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
Deirdre Brown, Administrative Assistant
Lisa Hahn, MPA, DHP Chief Deputy Director
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:
Tyler Cox, MSV
Becky Bowers-Lanier, VMA
Maya Hawthorn Gunderson, VMA, Midwifery Advisory

EMERGENCY EGRESS PROCEDURES

Dr. Tuck provided the emergency egress procedures for Conference Room 2.

APPROVAL OF THE JUNE 22, 2017 MINUTES

Dr. Reynolds moved to approve the June 22, 2017 as presented. The motion was seconded and carried unanimously.

ADOPTION OF THE AGENDA

Dr. Edwards moved to accept the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT ON AGENDA ITEM

Maya Hawthorn Gunderson addressed the Board as a member of the Midwifery Advisory Board. She provided comment on Guidance Document 85-28. She said the Advisory Board was requesting the authorization to order ultrasounds and other testing throughout pregnancy. She also spoke to the Advisory Board's request to amend the midwifery regulations to bring them into alignment with NARM. NARM allows a midwifery student up to 10 years of training/experience in order to fulfill the qualifications to sit for its examination.

The floor closed for comment at 8:43 a.m.

INTRODUCTION OF NEW BOARD MEMBER

Dr. O'Connor introduced Ms. Wingfield as the newest board member to the Board of Medicine.

Ms. Wingfield provided a brief overview of her background in community health and stated that she looks forward to working with the Board.

PRESENTATION TO LANA WESTFALL

Dr. O'Connor introduced Lana Westfall from the Office of the Secretary of the Commonwealth.

Dr. Harp presented Ms. Westfall with a plaque that expressed the Board's gratitude for her work in securing Board member and Advisory Board member appointments during this administration.

Ms. Westfall said that it was a joy to be able to attend this meeting, for she was now able to put names with faces. She said she joined the Office of the Secretary of the Commonwealth January 20th almost 4 years ago, so she been instrumental in appointing or reappointing most of the members on the Board of Medicine. She said that all the health regulatory boards were near and dear to her heart, and she has enjoyed working with everyone. She also thanked all the Board members for their service.

Dr. Harp said that the Board was honored to have her in attendance and wanted all to know the great resource and great communicator she has been. Dr. Harp then invited other DHP Executives in attendance to make comments.

Dr. Liz Carter, Executive Director for the Board of Health Professions, stated that Ms. Westfall has been outstanding, and because of her diligence, BHP has a full complement of members. Ms. Carter said that Caroline Juran, Executive Director for the Board of Pharmacy, was unable to attend but echoes the same sentiment.

Lisa Hahn, DHP Deputy Director for the Department of Health Professions, said that Ms. Westfall has been the most responsive, most participatory, and greatest support to our agency, and it was a pleasure working with her.

Corie Tillman-Wolf, Executive Director for Funeral Director and Embalmers, Long-Term Care Administrators, and Physical Therapy, said that she's only been in the Executive Director role for less than a year. Ms. Westfall has made the process of appointments easy and collaborative and thanked her for her dedication.

DHP DIRECTOR'S REPORT

Ms. Hahn reviewed PMP statistics as a measure of the impact of the Commonwealth's strategies related to the opioid crisis. She stated that there had been a dramatic decrease in patients receiving opioid prescriptions since the Board's regulations went into effect.

Ms. Hahn informed the members that DHP has acquired additional space on the first floor. It is anticipated that the agency receptionists, IT department, mail services, and the Business Research and Planning Division will be relocated to the new space in 2018.

Ms. Hahn also explained that Board disciplinary cases that were continued would be handled differently with the Board's statistics in Virginia Performs. The time provided to the respondent for a continuance will no longer be counted against the Board's statistics.

Ms. Hahn reported that videos on probable cause, sanction reference points, conflict of interest, and chairing board meetings/hearings are being developed for new board members.

REPORT OF OFFICERS AND EXECUTIVE DIRECTOR

PRESIDENT'S REPORT

Dr. O'Connor provided a brief report on his attendance at the Tri-Regulator Conference in September. Dr. O'Connor stated that it was a great opportunity to exchange ideas and explore common concerns and potential solutions with professional colleagues. He said that the majority of time was spent on the opioid crisis and its significance to all the professions. It is his belief that the greatest impact will be made by legislation.

He also spoke about his participation in a Legislative hearing regarding the establishment of the Doctor of Medicine Science profession. Those in favor of this effort seek to elevate physician assistants to practice more like primary care physicians. Such individuals would have an expanded scope of practice and less supervision. A Southwest Virginia legislator sees this as a way to increase access to care in rural areas. The school that currently offers this program is in Tennessee. It appeared that the physician assistant community was not supportive of the Doctor of Medical Science profession.

These reports were for information purposes only.

VICE-PRESIDENT'S REPORT

No report.

SECRETARY-TREASURER'S REPORT

No report.

EXECUTIVE DIRECTOR'S REPORT

- Revenue and Expenditures Report

Dr. Harp noted that the Board's cash balance as of September 30, 2017 is $8,727,384.

Dr. Harp reminded the Board members that in order to bring our cash balance in line with the law, the Board voted to reduce its renewal fees in 2014-2016 by 14%. For the 2016-2018 biennium, the Board voted to reduce renewal fees by 20%. Although the current cash balance is less than it was a year ago, the Board will again need to consider a reduction in fees, since next year will be a big revenue year.

Enforcement, Administrative Proceedings (APD), Health Practitioners Monitoring Program (HPMP) Reports

Dr. Harp reviewed the utilization of Enforcement and APD resources and noted that if trends hold true, the Board's usage will be up 7% during the next year. In reviewing the HPMP Monthly Census Report, Dr. Harp stated that the average number of participants remains about 450 with Medicine accounting for 25% of that total.

Laser Hair Removal

Dr. Harp informed the Board members that the General Assembly has tasked the Board with providing clarity in the practice of laser hair removal through regulations. A Regulatory Advisory Panel, chaired by a previous Board of Medicine member, Jane Piness, will be meet November 20, 2017 to define "adequate training" and "supervision" for physicians, nurse practitioners, physician assistants, and other individuals for the practice of laser hair removal.

Dr. Harp then welcomed Martha Wingfield to the Board.

Dr. Harp said that Jennifer and he had received an e-mail from Ms. DeMoss Fonseca expressing gratitude for her time on the Board and her honor of working alongside such dedicated group of professionals.

Dr. O'Connor noted that she will be missed.

These reports were for information only and did not require any action.

COMMITTEE AND ADVISORY BOARD REPORTS

- Committee Appointments and Advisory Board Reports

Dr. Edwards moved to accept the remaining minutes en bloc. The motion was seconded and carried unanimously.

OTHER REPORTS

Assistant Attorney General

Ms. Barrett provided an update on the status of the following cases:

Dr. Zackrison's case has concluded.
Dr. Hagmann's case is still pending.
Dr. Clowdis' case, begun in 2013, is still pending.
Dr. Merchia's case will have a hearing on the merits in early December.
Dr. Garada's case will have a hearing in mid-November.

Board of Health Professions

Dr. Allison-Bryan reported that DHP was in the process of designing a new logo. She has enjoyed being a part of the committee working with VCU on this effort.

She also reported that the Regulatory Research Committee of the Board of Health Professions heard testimony on Certified Anesthesiology Assistants (CAA) and determined not to recommend licensure at this time. Dr. Allison-Bryan also noted that naturopaths may be seeking licensure.

Dr. Lee informed the Board that she was very much involved in bringing the question of licensure for anesthesiology assistants to the Board of Health Professions. She said she believes that CAAs have training equivalent to a physician assistant and nurse practitioner. If licensed to practice to the fullness of their education and training, CAA's could help forestall delays in surgery, delays which can range from inconvenient to life-threatening. A senator that may carry a bill to the General Assembly is well aware that there may be some controversy surrounding this issue. The BHP study was requested in hopes that it would recommend licensure in support of a bill in

the General Assembly. During the public comment period, 150 letters were received in support of licensure, and only 50 opposed it. it was the highest number of comments received by BHP to date. Despite 301 comments in favor of licensure, BHP did not recommend it. Dr. Lee believes that one member repeatedly spoke against licensure and brought forward multiple erroneous comments. She said that not much more can be done at this time, but BHP's action will delay the opportunity to bring this issue to the General Assembly for at least 4 more years.

Dr. O'Connor noted that all the meeting minutes were for information only.

Dr. Edwards asked what BHP saw as an issue with licensure of the CAA profession.

Dr. O'Connor stated that this was outside the Board of Medicine's scope to address.

Dr. Conklin commented that it is not a matter of the training of CAA's or their experience. They want to work to the limits of their training and skills, but are being denied.

Dr. Clements asked if it was reasonable to request BHP to do a workforce study.

Ms. Barrett advised that the Board of Medicine does not have the ability to request a study; BHP gets its study orders from the General Assembly.

Podiatry Report

Dr. Clements had no report.

Chiropractic Report

Dr. Tuck had no report.

Committee of the Joint Boards of Nursing and Medicine

Dr. O'Connor had no report but looks forward to continued service at the Board.

NEW BUSINESS

1. **REGULATORY AND LEGISLATIVE ISSUES**

- Chart of Regulatory Actions

Ms. Yeatts briefly reviewed the Board's regulatory activity and the actions needed to be taken with each.

- Legislative Proposals

Ms. Yeatts presented a list of the legislative proposals for the 2018 General Assembly highlighting:

1. **Clarification for electronic renewal notice** – amends Code sections for the Boards of Funeral Directors and Embalmers, Medicine, and Nursing that require renewal notices to be sent by "mail" to licensees. The amendments will clarify that each board may send such notices electronically.

2. **Addition of Schedule V and naxolone to PMP** – adds naloxone and Schedule V drugs to the definition of covered substances to be included in a Prescription Monitoring Program (PMP) report.

3. **Student exemption for polysomnographic technologists** – amends the Code to provide license exemptions for a student polysomnographic technologist to practice under supervision for a period of up to18 months from the beginning of an educational program, and to practice for up to six months in a traineeship after finishing his/her program.

Proposed Regulatory Action – Nursing/Elimination of Separate License for Prescriptive Authority

Ms. Yeatts advised that the Joint Boards of Nursing and Medicine discussed the elimination of a separate license for prescriptive authority for nurse practitioners. The Code of Virginia does have certain requirements for prescriptive authority but does not mandate a separate license. The Joint Boards' action to implement elimination of the separate license must be accomplished by regulation, beginning with a Notice of Intended Regulatory Action (NOIRA).

Dr. Reynolds moved to adopt the recommendation of the Joint Boards for the adoption of a NOIRA to begin the regulatory process to eliminate a separate prescriptive authority license. The motion was seconded and carried unanimously.

Regulatory Action – Fee Reduction

Ms. Yeatts referred Board members to the letter from Dr. Brown, DHP Director, and supporting documentation for the recommendation of a one-time reduction in renewal fees for the next biennium.

After a brief discussion, Dr. Edwards moved to adopt the amendments to the regulations for reduction of renewal fees for the next biennium by 20%. The motion was seconded and carried unanimously. As noted, the reduction would begin January 2018 and run through December 2020 for all professions licensed by the Board of Medicine.

Regulatory Actions – Licensed Midwives

Ms. Yeatts said that the Advisory Board on Midwifery had noted that midwifery students can perform midwifery tasks under direct and immediate supervision, while enrolled in an accredited midwifery program or during a NARM portfolio pathway, but they can only do so for three years.

Completion of a NARM portfolio can take up to 10 years, if the supervising midwife has a very small practice. NARM will not accept student midwifery experience beyond 10 years.

Therefore, the Advisory has recommended an amendment to 18VAC85-130-45 to synchronize the regulations with NARM, which if approved would be done by fast-track action.

Dr. Edwards moved to adopt changes to 18VAC85-130-45 as recommended by the Advisory Board.

Guidance Document

The Advisory Board on Midwifery recommended an amendment to Guidance Document 85-28 Authority to Order Tests to address the possibility that a midwife may need to order an ultrasound earlier in a pregnancy, not just for a post-date pregnancy.

The document would be amended as follows:

> Under Prenatal Care
>
> Assess and evaluate a ~~post-date~~ pregnancy by monitoring/screening:
> Consult or refer for:
> - Ultrasound
> - Non-stress test
> - Biophysical profile

Dr. Edwards moved to adopt the recommendation of the Advisory Board for the amendment to Guidance Document 85-28. The motion was seconded and carried unanimously.

Adoption of Notice of Intended Regulatory Action (NOIRA) for Physician Assistants

Ms. Yeatts said that the Advisory Board on Physician Assistants is recommending adoption of a NOIRA for the purpose of simplifying and clarifying the definitions of supervision and for more consistency with the Code and everyday practice. The action also adds a provision in the section on Pharmacotherapy for Weight Loss to clarify that a physician assistant can conduct the initial physical examination, review tests, and prescribe drugs, if so stated in the practice agreement.

Dr. Edwards moved to adopt a NOIRA with the substance of the proposed actions as presented. The motion was seconded and carried unanimously.

Comment on the Opioid Regulations

Ms. Yeatts referred to a copy of the Amended Emergency Regulations Governing Prescribing of Opioids and Buprenorphine and two comments from Regulatory Town Hall. She noted that there was no need to respond or take any action. There has been a significant amount of activity in the offices of the Secretary and Governor regarding drug screens that indicate some tweaking of the regulations may be needed. Ms. Yeatts said that the question is whether the Governor will approve the Emergency Proposed Regulations and then allow amendments, or send them back to the Board to amend before publication.

Dr. O'Connor stated that 175 citizens die from opioid overdose in the US everyday.

Dr. Allison-Bryan suggested that providing the graphs to which Ms. Hahn referred at the top of the meeting would be helpful.

Dr. Ali stated that the impetus for the regulations was physicians being too willing to prescribe opioids, and it's the Board's job to protect the citizens of the Commonwealth.

Ms. Deschenes said that we are facing the same issue as in 2007 with drug screens; had these regulations been put in place then, it is possible we would not be facing the epidemic that we see now.

Ms. Gore added that another factor to consider is the economic toll the epidemic takes on localities in terms of law enforcement manpower.

Ms. Barrett stated that, at a recent meeting, attendees were very impressed with what Virginia has done with opioid prescribing.

Dr. Reynolds noted that practitioners will find the reports from PMP useful and be more cognizant of their prescribing habits.

Dr. Lee asked if there are separate regulations for nurse practitioners. Ms. Yeatts advised that the nurse practitioner regulations are essentially identical to Medicine's regulations.

2. BOARD OF MEDICINE BYLAWS

Dr. Harp advised that the Board's Bylaws need to be reviewed periodically for currency and to recommend revision if necessary. As it stands, the changes lie in including the new professions of genetic counselors and behavior analysts to the list under Report of Advisory Boards.

Dr. Clements posed the question of moving the election of officers to the October meeting after appointments have been made.

After a brief discussion, it was determined that there were no advantages to amend the election date.

Dr. Harp said that the Bylaws will be provided two weeks prior to the February Board meeting, and any amendments will be voted on at the meeting.

3. CREDENTIALS COMMITTEE RECOMMENDATION FOR FORM B'S

Dr. O'Connor began by explaining that the recommendations being presented are driven by concerns of applicants who practice telemedicine being able to obtain FORM B's from all hospitals, clinics, and facilities where they had been granted privileges in the last 5 years.

Mr. Heaberlin went on the explain many of the FORM B's received on behalf of these individuals have little information other than the dates of services, and many have been difficult to get. Board staff is requesting the following:

A) FORM B from the chief medical officer of a telemedicine company to suffice instead of requiring a FORM B from all sites of services. Dr. Edwards moved to accept and the motion was seconded and carried unanimously.

B) Extend the exemption of FORM B's from all sites in lieu of a FORM B from the chief medical officer to all specialties practicing telemedicine. Dr. Edwards moved to accept and the motion was seconded and carried unanimously.

C) Require only 2 years of FORM B's if the applicant is in a profession for which the Board receives an NPDB report. Dr. Edwards moved to accept and the motion was seconded and carried unanimously.

D) Accept that all applicants/professions that cannot provide a NPDB report submit 5 years of FORM B's. Dr. Edwards moved to accept and the motion was seconded and carried unanimously.

The question of whether the Board should issue a telemedicine license was raised. Dr. O'Connor advised that the Credentials Committee had discussed the issue and determined it was not within the Board's authority to do so.

LICENSING REPORT

Mr. Heaberlin provided the members with the total number of licenses issued over the last two fiscal years. As of October 17, 2017, there were 69,117 licensees under the Board of Medicine. Medicine and Surgery – 38,116; Osteopathy – 3,371; Chiropractors – 1,757 and Podiatrists – 541; all other professions - 25,332.

DISCIPLINE REPORT

Ms. Deschenes gave a quick update on the status of discipline cases. She anticipates that APD will begin moving cases to the Board as APD has filled some of their vacancies. Cases may be slow in coming until the new adjudication specialists are acclimated to the Board's regulations and processes.

Ms. Deschenes then presented a reinstatement Consent Order for Brandon Jennings Watson, MD.

After a summarization of the findings of fact, Dr. Edwards moved to accept the Consent Order as presented.

Dr. Conklin asked that the entire Consent Order be presented before voting.

Ms. Deschenes explained that the action taken was the result of a mandatory suspension, and no patient harm was involved.

The standing motion was then seconded and carried unanimously.

ANNOUNCEMENTS

Travel vouchers are due by November 23, 2017.

ADJOURNMENT

Dr. O'Connor adjourned the meeting at 10:32 a.m.

Kevin O'Connor, MD
President, Chair

William L. Harp, MD
Executive Director

Colanthia M. Opher
Recording Secretary

Agenda Item: **Director's Report**

Staff Note: None.

Action: Informational presentation. No action required.

Agenda Item: **Report of Officers and Executive Director**

Staff Note:

- President
- Vice-President
- Secretary-Treasurer
- Executive Director

Action: Informational presentation. No action required.

Virginia Department of Health Professions
Cash Balance
As of December 31, 2017

	102- Medicine
Board Cash Balance as June 30, 2017	$ 10,051,272
YTD FY18 Revenue	1,647,703
Less: YTD FY18 Direct and Allocated Expenditures	3,944,143
Board Cash Balance as December 31, 2017	7,754,832

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2017 and Ending December 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
4002400	Fee Revenue				
4002401	Application Fee	515,091.00	964,774.00	449,683.00	53.39%
4002402	Examination Fee	1,410.00	-	(1,410.00)	0.00%
4002406	License & Renewal Fee	1,092,480.00	5,959,129.00	4,866,649.00	18.33%
4002407	Dup. License Certificate Fee	4,240.00	3,375.00	(865.00)	125.63%
4002409	Board Endorsement - Out	6,650.00	49,820.00	43,170.00	13.35%
4002421	Monetary Penalty & Late Fees	25,967.00	94,179.00	68,212.00	27.57%
4002432	Misc. Fee (Bad Check Fee)	175.00	175.00	-	100.00%
	Total Fee Revenue	1,646,013.00	7,071,452.00	5,425,439.00	23.28%
4003000	Sales of Prop. & Commodities				
4003020	Misc. Sales-Dishonored Payments	1,690.00	-	(1,690.00)	0.00%
	Total Sales of Prop. & Commodities	1,690.00	-	(1,690.00)	0.00%
	Total Revenue	1,647,703.00	7,071,452.00	5,423,749.00	23.30%
5011110	Employer Retirement Contrib.	85,403.96	174,066.00	88,662.04	49.06%
5011120	Fed Old-Age Ins- Sal St Emp	37,373.66	88,287.00	50,913.34	42.33%
5011130	Fed Old-Age Ins- Wage Earners	384.85	-	(384.85)	0.00%
5011140	Group Insurance	8,428.19	16,904.00	8,475.81	49.86%
5011150	Medical/Hospitalization Ins.	111,230.87	245,763.00	134,532.13	45.26%
5011160	Retiree Medical/Hospitalizatn	7,522.14	15,226.00	7,703.86	49.40%
5011170	Long term Disability Ins	3,807.61	8,517.00	4,709.39	44.71%
	Total Employee Benefits	254,151.28	548,763.00	294,611.72	46.31%
5011200	Salaries				
5011230	Salaries, Classified	609,237.93	1,290,330.00	681,092.07	47.22%
5011250	Salaries, Overtime	3,508.82	670.00	(2,838.82)	523.70%
	Total Salaries	612,746.75	1,291,000.00	678,253.25	47.46%
5011300	Special Payments				
5011340	Specified Per Diem Payment	4,450.00	21,150.00	16,700.00	21.04%
5011380	Deferred Compnstn Match Pmts	2,966.20	9,298.00	6,331.80	31.90%
	Total Special Payments	7,416.20	30,448.00	23,031.80	24.36%
5011400	Wages				
5011410	Wages, General	5,030.69	-	(5,030.69)	0.00%
	Total Wages	5,030.69	-	(5,030.69)	0.00%
5011530	Short-trm Disability Benefits	24,808.36	-	(24,808.36)	0.00%
	Total Disability Benefits	24,808.36	-	(24,808.36)	0.00%
5011600	Terminatn Personal Svce Costs				
5011620	Salaries, Annual Leave Balanc	68.00	-	(68.00)	0.00%
5011660	Defined Contribution Match - Hy	444.69	-	(444.69)	0.00%
	Total Terminatn Personal Svce Costs	512.69	-	(512.69)	0.00%
5011930	Turnover/Vacancy Benefits		-	-	0.00%
	Total Personal Services	904,665.97	1,870,211.00	965,545.03	48.37%
5012000	Contractual Svs				
5012100	Communication Services				
5012110	Express Services	2,371.06	5,997.00	3,625.94	39.54%
5012130	Messenger Services	125.30	-	(125.30)	0.00%
5012140	Postal Services	21,014.87	66,802.00	45,787.13	31.46%

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2017 and Ending December 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
5012150	Printing Services	1,297.07	3,026.00	1,728.93	42.86%
5012160	Telecommunications Svcs (VITA)	2,253.07	10,500.00	8,246.93	21.46%
5012170	Telecomm. Svcs (Non-State)	585.00	-	(585.00)	0.00%
5012190	Inbound Freight Services	21.56	35.00	13.44	61.60%
	Total Communication Services	27,667.93	86,360.00	58,692.07	32.04%
5012200	Employee Development Services				
5012210	Organization Memberships	6,020.00	7,228.00	1,208.00	83.29%
5012240	Employee Trainng/Workshop/Conf	60.00	4,283.00	4,223.00	1.40%
5012250	Employee Tuition Reimbursement	-	752.00	752.00	0.00%
	Total Employee Development Services	6,080.00	12,263.00	6,183.00	49.58%
5012300	Health Services				
5012360	X-ray and Laboratory Services	-	2,298.00	2,298.00	0.00%
	Total Health Services	-	2,298.00	2,298.00	0.00%
5012400	Mgmnt and Informational Svcs	-			
5012420	Fiscal Services	16,035.27	119,963.00	103,927.73	13.37%
5012440	Management Services	844.80	1,797.00	952.20	47.01%
5012460	Public Infrmtnl & Relatn Svcs	10.00	-	(10.00)	0.00%
5012470	Legal Services	1,855.00	5,579.00	3,724.00	33.25%
	Total Mgmnt and Informational Svcs	18,745.07	127,339.00	108,593.93	14.72%
5012500	Repair and Maintenance Svcs				
5012530	Equipment Repair & Maint Srvc	-	1,705.00	1,705.00	0.00%
	Total Repair and Maintenance Svcs	-	1,705.00	1,705.00	0.00%
5012600	Support Services				
5012630	Clerical Services	83,497.80	189,795.00	106,297.20	43.99%
5012640	Food & Dietary Services	4,330.25	12,698.00	8,367.75	34.10%
5012660	Manual Labor Services	8,057.85	24,912.00	16,854.15	32.35%
5012670	Production Services	53,042.49	153,625.00	100,582.51	34.53%
5012680	Skilled Services	187,399.62	531,779.00	344,379.38	35.24%
	Total Support Services	336,328.01	912,809.00	576,480.99	36.85%
5012700	Technical Services				
5012780	VITA InT Int Cost Goods&Svs	372.41	-	(372.41)	0.00%
	Total Technical Services	372.41	-	(372.41)	0.00%
5012800	Transportation Services				
5012820	Travel, Personal Vehicle	9,678.04	25,626.00	15,947.96	37.77%
5012830	Travel, Public Carriers	933.10	4,170.00	3,236.90	22.38%
5012850	Travel, Subsistence & Lodging	5,827.71	21,524.00	15,696.29	27.08%
5012880	Trvl, Meal Reimb- Not Rprtble	2,586.75	7,407.00	4,820.25	34.92%
	Total Transportation Services	19,025.60	58,727.00	39,701.40	32.40%
	Total Contractual Svs	408,219.02	1,201,501.00	793,281.98	33.98%
5013000	Supplies And Materials				
5013100	Administrative Supplies				
5013120	Office Supplies	4,764.22	14,609.00	9,844.78	32.61%
5013130	Stationery and Forms	-	3,614.00	3,614.00	0.00%
	Total Administrative Supplies	4,764.22	18,223.00	13,458.78	26.14%
5013300	Manufctrng and Merch Supplies				
5013350	Packaging & Shipping Supplies	-	94.00	94.00	0.00%

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2017 and Ending December 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
	Total Manufctrng and Merch Supplies	-	94.00	94.00	0.00%
5013600	Residential Supplies				
5013620	Food and Dietary Supplies	431.33	528.00	96.67	81.69%
5013630	Food Service Supplies	90.71	1,129.00	1,038.29	8.03%
	Total Residential Supplies	522.04	1,657.00	1,134.96	31.51%
5013700	Specific Use Supplies				
5013730	Computer Operating Supplies	-	166.00	166.00	0.00%
	Total Specific Use Supplies	-	166.00	166.00	0.00%
	Total Supplies And Materials	5,286.26	20,140.00	14,853.74	26.25%
5014000	Transfer Payments				
5014100	Awards, Contrib., and Claims				
5014130	Premiums	448.00	-	(448.00)	0.00%
	Total Awards, Contrib., and Claims	448.00	-	(448.00)	0.00%
	Total Transfer Payments	448.00	-	(448.00)	0.00%
5015000	Continuous Charges				
5015100	Insurance-Fixed Assets				
5015160	Property Insurance	-	485.00	485.00	0.00%
	Total Insurance-Fixed Assets	-	485.00	485.00	0.00%
5015300	Operating Lease Payments				
5015340	Equipment Rentals	3,521.75	7,200.00	3,678.25	48.91%
5015350	Building Rentals	215.84	-	(215.84)	0.00%
5015360	Land Rentals	-	100.00	100.00	0.00%
5015390	Building Rentals - Non State	63,677.14	150,699.00	87,021.86	42.25%
	Total Operating Lease Payments	67,414.73	157,999.00	90,584.27	42.67%
5015500	Insurance-Operations				
5015510	General Liability Insurance	-	1,828.00	1,828.00	0.00%
5015540	Surety Bonds	-	108.00	108.00	0.00%
	Total Insurance-Operations	-	1,936.00	1,936.00	0.00%
	Total Continuous Charges	67,414.73	160,420.00	93,005.27	42.02%
5022000	Equipment				
5022100	Computer Hrdware & Sftware				
5022170	Other Computer Equipment	2,331.71	-	(2,331.71)	0.00%
	Total Computer Hrdware & Sftware	2,331.71	-	(2,331.71)	0.00%
5022200	Educational & Cultural Equip				
5022240	Reference Equipment	96.00	829.00	733.00	11.58%
	Total Educational & Cultural Equip	96.00	829.00	733.00	11.58%
5022600	Office Equipment				
5022610	Office Appurtenances	-	125.00	125.00	0.00%
5022620	Office Furniture	-	1,857.00	1,857.00	0.00%
5022630	Office Incidentals	855.65	-	(855.65)	0.00%
5022640	Office Machines	-	1,250.00	1,250.00	0.00%
5022680	Office Equipment Improvements	-	17.00	17.00	0.00%
	Total Office Equipment	855.65	3,249.00	2,393.35	26.34%
	Total Equipment	3,283.36	4,078.00	794.64	80.51%
	Total Expenditures	1,389,317.34	3,256,350.00	1,867,032.66	42.66%

Virginia Department of Health Professions
Revenue and Expenditures Summary
Department 10200 - Medicine
For the Period Beginning July 1, 2017 and Ending December 31, 2017

Account Number	Account Description	Amount	Budget	Amount Under/(Over) Budget	% of Budget
	Allocated Expenditures				
30100	Data Center	482,980.99	1,166,281.99	683,301.00	41.41%
30200	Human Resources	58,967.56	151,485.99	92,518.43	38.93%
30300	Finance	200,401.28	344,585.29	144,184.02	58.16%
30400	Director's Office	88,890.31	174,226.85	85,336.54	51.02%
30500	Enforcement	1,017,715.59	1,868,566.85	850,851.26	54.47%
30600	Administrative Proceedings	461,269.31	950,901.92	489,632.62	48.51%
30700	Impaired Practitioners	14,757.51	27,276.37	12,518.85	54.10%
30800	Attorney General	90,762.32	181,524.64	90,762.32	50.00%
30900	Board of Health Professions	47,822.08	98,974.10	51,152.01	48.32%
31100	Maintenance and Repairs	-	3,379.12	3,379.12	0.00%
31300	Emp. Recognition Program	-	2,435.73	2,435.73	0.00%
31400	Conference Center	46,072.56	47,116.09	1,043.53	97.79%
31500	Pgm Devlpmnt & Implmentn	45,186.20	97,155.57	51,969.38	46.51%
	Total Allocated Expenditures	2,554,825.71	5,113,910.50	2,559,084.79	49.96%
	Net Revenue in Excess (Shortfall) of Expenditures	$ (2,296,440.05)	$ (1,298,808.50)	$ 997,631.55	176.81%

HPMP Monthly Census Report

Active Cases January 31, 2018

Board	Board Participants	License	Count of ID	% with this license
Nursing	269	LPN	33	7.6
Nursing	269	RN	220	50.8
Nursing	269	LNP	16	3.7
			269	**62.1**
Nursing	5	CNA	**5**	**1.2**
Medicine	111	DO	9	2.1
Medicine	111	Intern/Resident	6	1.4
Medicine	111	MD	75	17.3
Medicine	111	PA	7	1.6
Medicine	111	Lic Rad Tech	2	0.5
Medicine	111	DC	3	0.7
Medicine	111	OT	3	0.7
Medicine	111	RT	4	0.9
Medicine	111	DPM	1	0.2
Medicine	111	LBA	1	0.2
			111	**25.6**
Pharmacy	16	Pharmacist	**16**	**3.7**
Dentistry	15	DDS	10	2.3
Dentistry	15	DMD	1	0.2
Dentistry	15	RDH	4	0.9
			15	**3.5**
Social Work	4	LCSW	**4**	**0.9**
Psychology	3	LCP	2	0.5
	3	SOTP	1	0.2
			3	**0.7**
Counseling	1	LPC	**1**	**0.2**
Funeral Directors and Embalmers	1	FSL	**1**	**0.2**
Optometry	2	OD	**2**	**0.5**
Veterinary Medicine	1	DVM	**1**	**0.2**
Audiology & Speech-Language Path	1	SLP	**1**	**0.2**
Physical Therapy	4	PT	1	0.2
Physical Therapy	4	PTA	3	0.7
			4	**0.9**
TOTALS			**433.0**	**100.0**

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times: Quarterly Performance Measurement, Q2 2014 - Q2 2018

David E. Brown, D.C.
Director

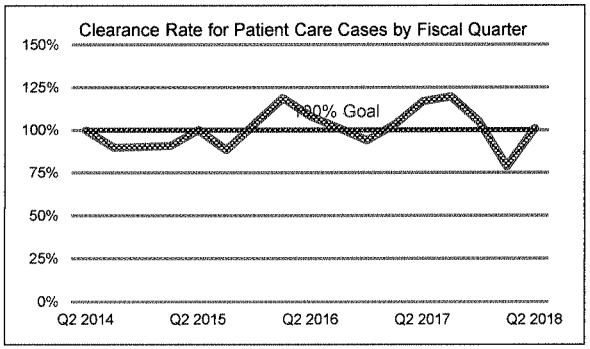
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."
DHP Mission Statement

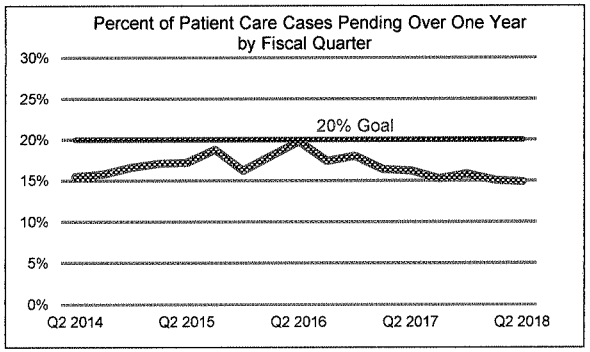
In order to uphold its mission relating to discipline, DHP continually assesses and reports on performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. These three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload; Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days the case was in the continuance activity.

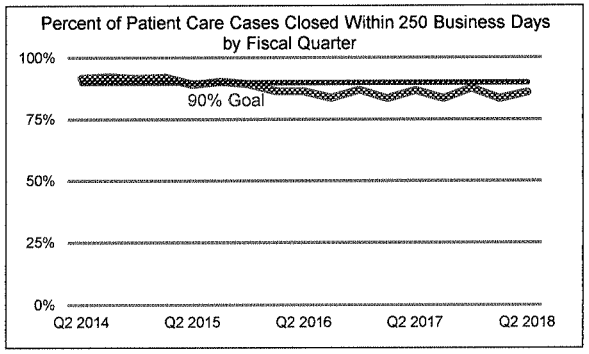
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct. The current quarter's clearance rate is **101%**, with **955** patient care cases received and **965** closed.

Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 250 business days at no more than 20%. The current quarter shows **15%** patient care cases pending over 250 business days with **2689** patient care cases pending and **400** pending over 250 business days.

Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 250 business days. The current quarter shows **86%** percent of patient care cases being resolved within 250 business days with **965** cases closed and **830** closed within 250 business days.







Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

In order to uphold its mission relating to discipline, DHP continually assesses i

Clearance Rate

Age of Pending Caseload

(percent of cases pending over one year)

Percent Closed in 250 Business Days

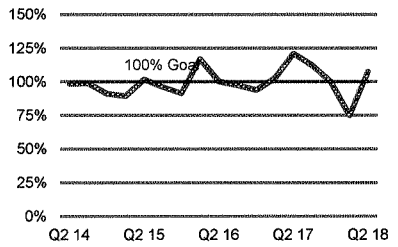
Nursing - In Q2 2018, the clearance rate was **108%**, the Pending Caseload older than 250 business days was **11%** and the percent closed within 250 business days was **80%**

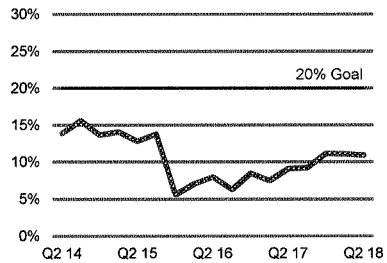
Q1 2018 Caseloads:

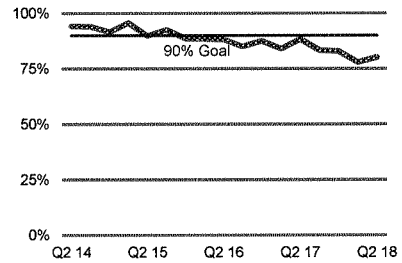
Received = **382** , Closed = **411**

Pending over 250 days = **143**

Closed within 250 days = **330**







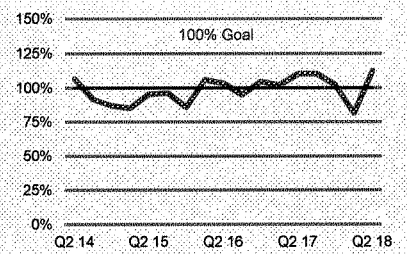
Nurses - In Q2 2018, the clearance rate was **113%**, the Pending Caseload older than 250 business days was **13%** and the percent closed within 250 business days was **81%**.

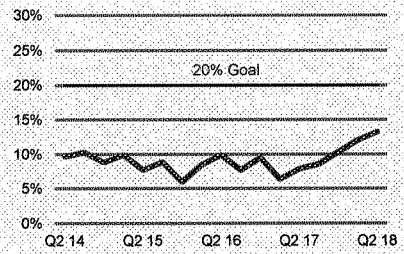
Q1 2018 Caseloads:

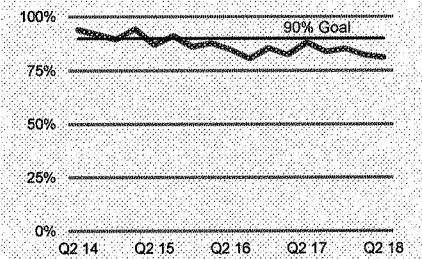
Received = **280** , Closed = **315**

Pending over 250 days = **120**

Closed within 250 days = **256**







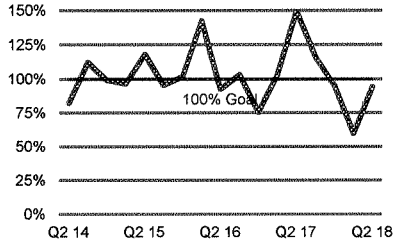
CNA - In Q2 2018, the clearance rate was **94%**, the Pending Caseload older than 250 business days was **6%** and the percent closed within 250 business days was **77%**.

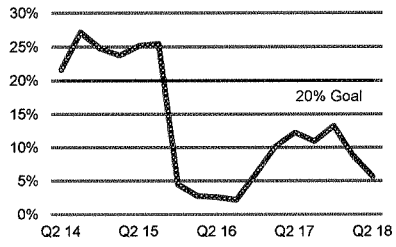
Q1 2018 Caseloads:

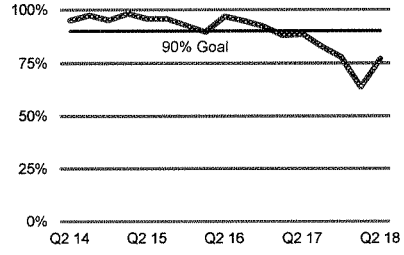
Received= **102** , Closed = **96**

Pending over 250 days = **23**

Closed within 250 days = **74**







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

In order to uphold its mission relating to discipline, DHP continually assesses i

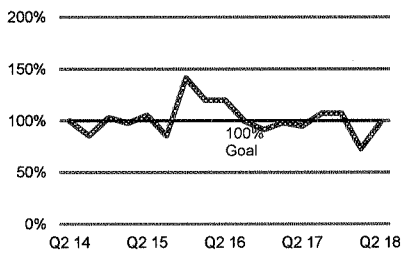
Clearance Rate

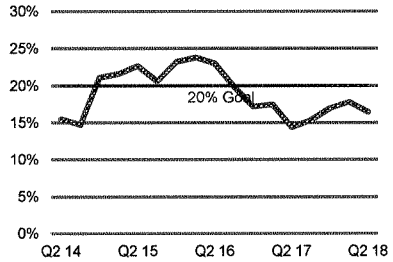
Age of Pending Caseload
(percent of cases pending over one year)

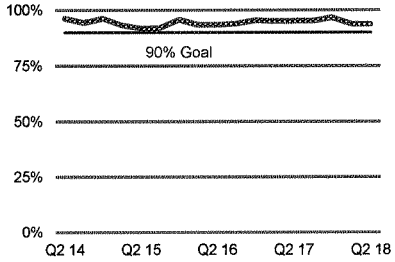
Percent Closed in 250 Business Days

Medicine - In Q2 2018, the clearance rate was **98%**, the Pending Caseload older than 250 business days was **16%** and the percent closed within 250 business days was **94%**.

Q1 2018 Caseloads:
Received = **341** , Closed = **335**
Pending over 250 days = **112**
Closed within 250 days = **314**

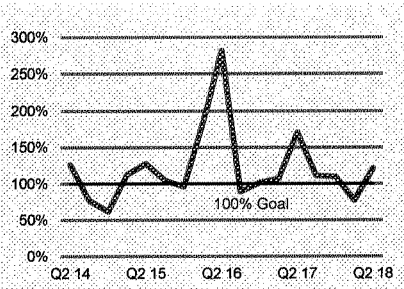


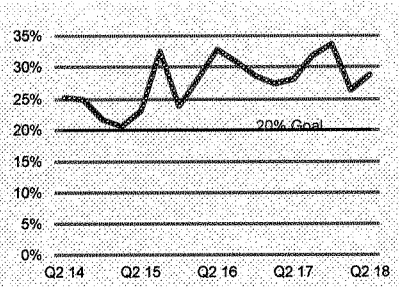


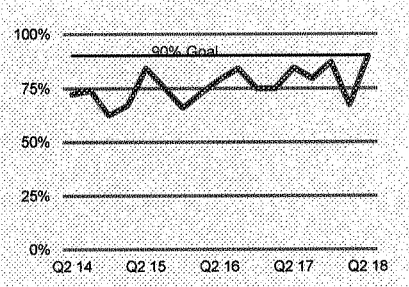


Dentistry - In Q2 2018, the clearance rate was **122%**, the Pending Caseload older than 250 business days was **29%** and the percent closed within 250 business days was **90%**.

Q1 2018 Caseloads:
Received= **64**, Closed = **78**
Pending over 250 days = **51**
Closed within 250 days = **70**

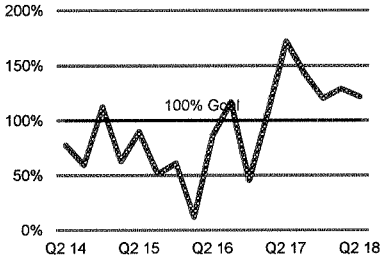


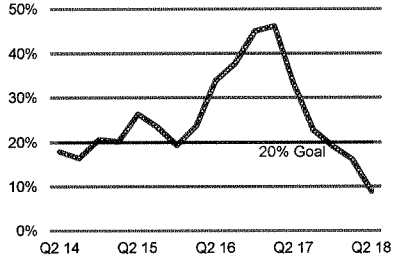


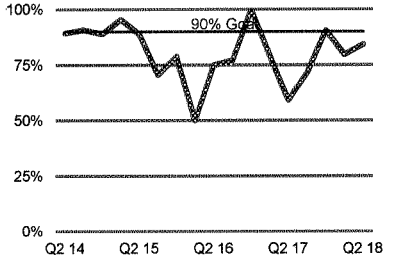


Pharmacy - In Q2 2018, the clearance rate was **121%**, the Pending Caseload older than 250 business days was **9%** and the percent closed within 250 business days was **84%**.

Q1 2018 Caseloads:
Received = **42** , Closed = **51**
Pending over 250 days = **9**
Closed within 250 days = **43**







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Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

In order to uphold its mission relating to discipline, DHP continually assesses :

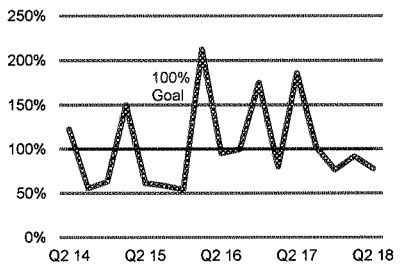
Clearance Rate

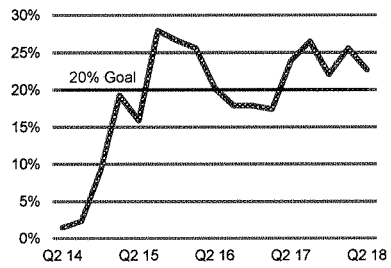
Age of Pending Caseload
(percent of cases pending over one year)

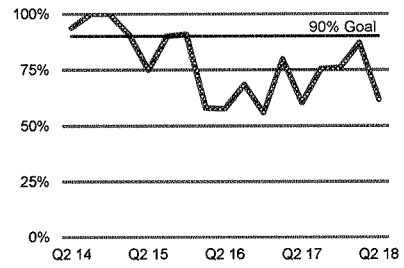
Percent Closed in 250 Business Days

Veterinary Medicine - In Q2 2018, the clearance rate was **78%** the Pending Caseload older 250 business days was **23%** and the percent closed within 250 business days was **62%**.

Q1 2018 Caseloads:
Received = **27** , Closed = **21**
Pending over 250 days = **32**
Closed within 250 days = **13**

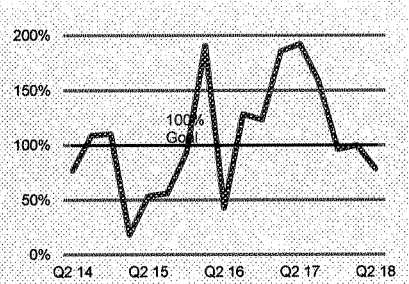


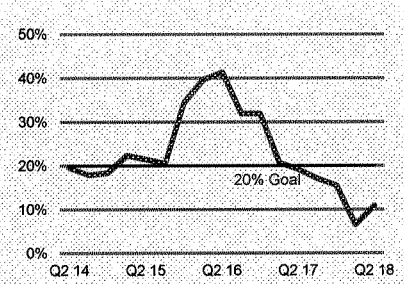


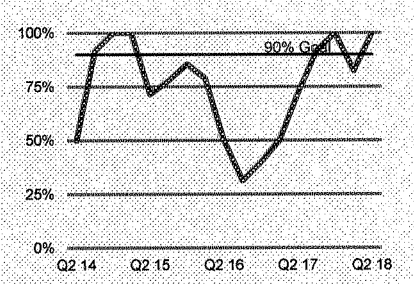


Counseling - In Q2 2018, the clearance rate was **78%**, the Pending Caseload older than 250 business days was **11%** and the percent closed within 250 business days was **100%**.

Q1 2018 Caseloads:
Received = **23** , Closed = **18**
Pending over 250 days = **6**
Closed within 250 days = **18**

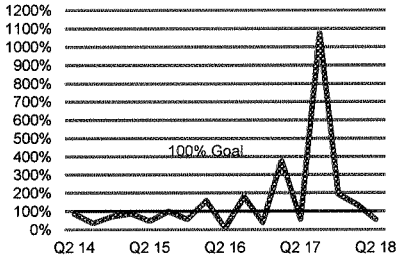


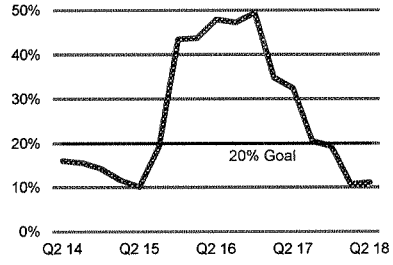


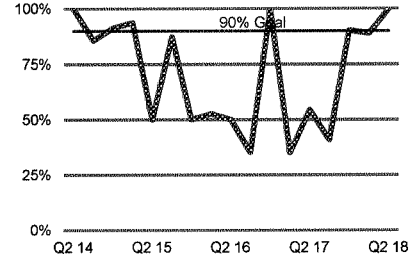


Social Work - In Q2 2018, the clearance rate was **56%**, the Pending Caseload older than 250 business days was **11%** and the percent closed within 250 business days was **100%**.

Q1 2018 Caseloads:
Received = **18** , Closed = **10**
Pending over 250 days = **4**
Closed within 250 days = **10**







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

In order to uphold its mission relating to discipline, DHP continually assesses i

Psychology - In Q2 2018, the clearance rate was **127%**, the Pending Caseload older than 250 business days was **19%** and the percent closed within 250 business days was **79%**.

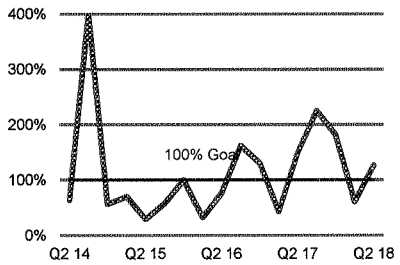
Q1 2018 Caseloads:

Received = **15** , Closed = **18**

Pending over 250 days = **6**

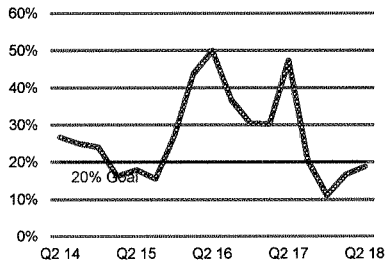
Closed within 250 days = **15**

Clearance Rate

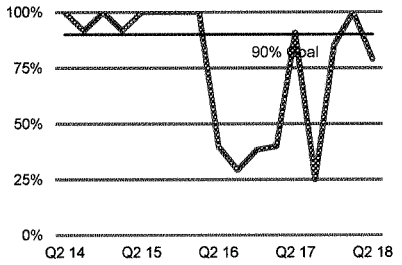


Age of Pending Caseload

(percent of cases pending over one year)



Percent Closed in 250 Business Days



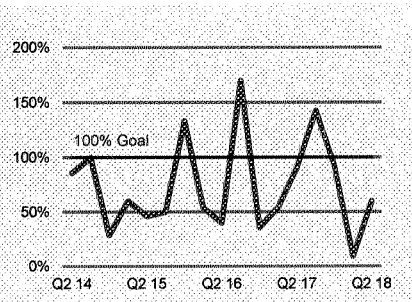
Long-Term Care - In Q2 2018, the clearance rate was **60%**, the Pending Caseload older than 250 business days was **29%** and the percent closed within 250 business days was **33%**.

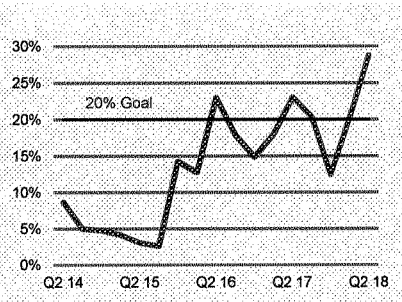
Q1 2018 Caseloads:

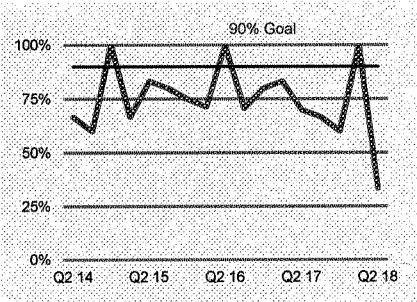
Received = **10** , Closed = **6**

Pending over 250 days = **19**

Closed within 250 days = **2**







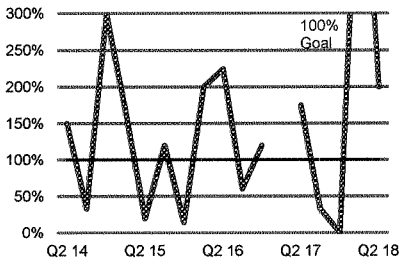
Optometry - In Q2 2018, the clearance rate was **200%**, the Pending Caseload older than 250 business days was **33%** and the percent closed within 250 business days was **50%**.

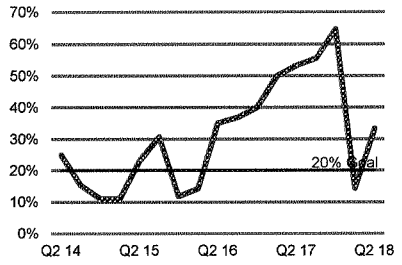
Q1 2018 Caseloads:

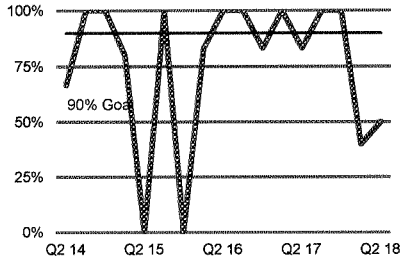
Received = **1** , Closed = **2**

Pending over 250 days = **2**

Closed within 250 days = **1**







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Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

In order to uphold its mission relating to discipline, DHP continually assesses a

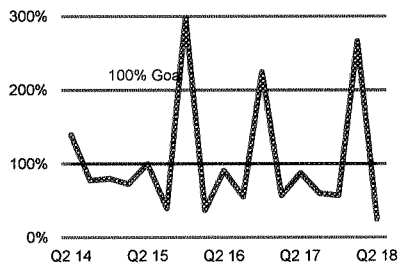
Clearance Rate

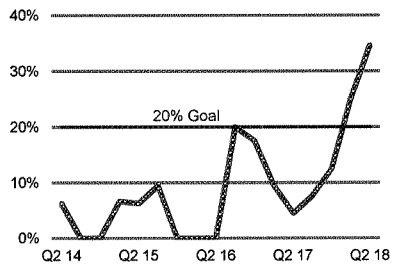
Age of Pending Caseload
(percent of cases pending over one year)

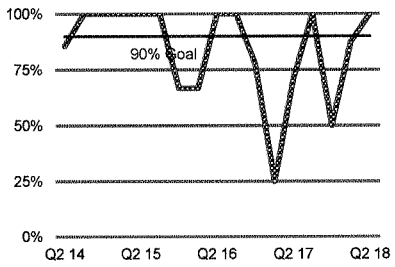
Percent Closed in 250 Business Days

Physical Therapy - In Q2 2018, the clearance rate was **25%**, the Pending Caseload older than 250 business days was **35%** and the percent closed within 250 business days was **100%**.

Q1 2018 Caseloads:
Received = **8** , Closed = **2**
Pending over 250 days = **9**
Closed within 250 days = **2**

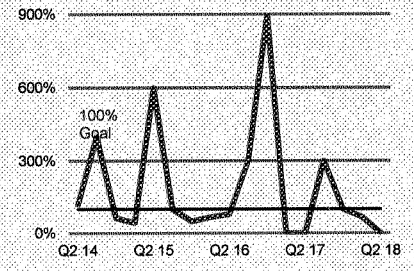


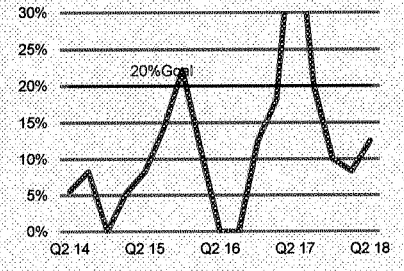


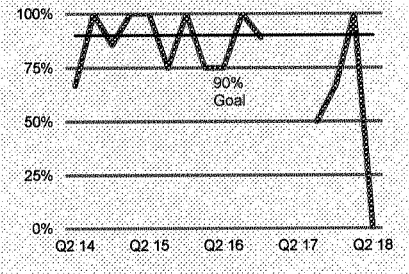


Funeral - In Q2 2018, the clearance rate was **0%**, the Pending Caseload older than 250 business days was **13%** and the percent closed within 250 business was **N/A**

Q1 2018 Caseloads:
Received = **4** , Closed = **0**
Pending over 250 days = **2**
Closed within 250 days = **0**

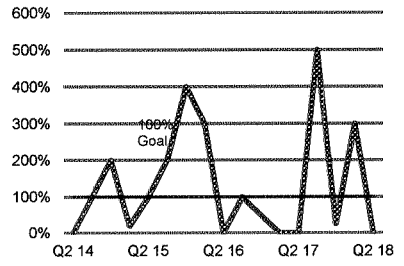


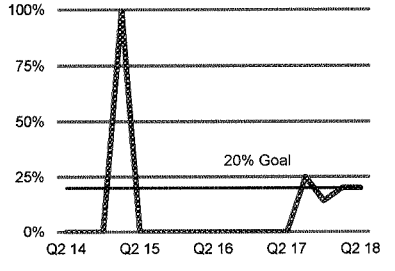


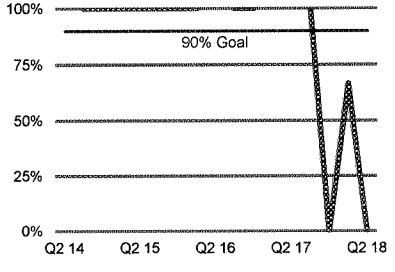


Audiology - In Q2 2018, the clearance rate was **0%**, the Pending Caseload older than 250 business days was **20%** and the percent closed within 250 business days was **N/A**

Q1 2018 Caseloads:
Received = **4** , Closed = **0**
Pending over 250 days = **2**
Closed within 250 days = **0**







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Morton, Colanthia D. (DHP)

From: Harp, William L. (DHP)
Sent: Tuesday, January 23, 2018 9:35 AM
To: Morton, Colanthia D. (DHP)
Subject: FW: Congratulations!

Importance: High

Perhaps for my report at the Board meeting

From: Pamela Huffman (FSMB) [mailto:phuffman@fsmb.org]
Sent: Monday, January 22, 2018 10:45 PM
To: Kenneth Walker <kjwalk@gmail.com>
Cc: Kevin O'Connor, MD <vonconnor@aol.com>; Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Congratulations!
Importance: High

Dear Dr. Walker:

It is my pleasure to inform you that the FSMB Nominating Committee met on Friday, January 19th and approved your nomination for the FSMB Nominating Committee! Please let me know by Monday, January 29th if you accept this nomination so that we may add you to the Committee's 2018 roster of candidates.

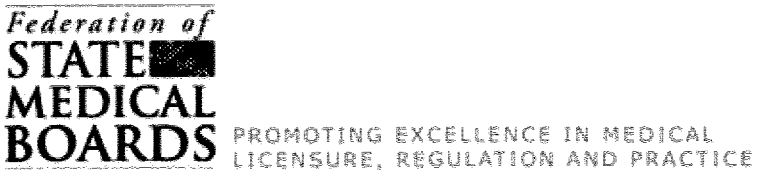
Upon receipt of all candidate acceptances, a report will be drafted and sent to the membership announcing the names of the candidates. In February, I will also send you and the rest of the candidate's information on preparing for the April elections.

Congratulations on your nomination! I look forward to hearing from you soon.

Warmest regards,
Pam

Pamela Huffman
Governance Support Associate
Leadership Services

Federation of State Medical Boards
400 Fuller Wiser Road | Suite 300 | Euless, TX 76039
817-868-4060 direct | 817-868-4258 fax
phuffman@fsmb.org| www.fsmb.org



Agenda Item: **Committee and Advisory Board Reports**

Staff Note: Please note Committee assignments and minutes of meetings since October 26, 2017.

Action: Motion to accept minutes as reports to the Board.

VIRGINIA BOARD OF MEDICINE

Committee Appointments

2017-2018

EXECUTIVE COMMITTEE (8)
Kevin O'Connor MD, President, Chair
Syed Salman Ali, MD
Randy Clements, DPM
Lori Conklin, MD, Secretary/Treasurer
Alvin Edwards, PhD
Jane Hickey, JD
Maxine Lee, MD
Ray Tuck, DC, Vice-President

LEGISLATIVE COMMITTEE (7)
Ray Tuck, Jr., DC, Vice-President, Chair
Barbara Allison-Bryan, MD
David Giammittorio, MD
Jane Hickey, JD
Isaac Koziol, MD
David Taminger, MD
Svinder Toor, MD

CREDENTIALS COMMITTEE (9)
Kenneth Walker, MD, Chair
David Archer, MD
Jane Hickey, JD
James Jenkins, RN
Isaac Koziol, MD
Jacob Miller, DO
David Taminger, MD
Svinder Toor, MD
Martha Wingfield

FINANCE COMMITTEE
Kevin O'Connor, MD, President
Ray Tuck, Jr., DC, Vice-President
Lori Conklin, MD - Secretary/Treasurer

BOARD BRIEFS COMMITTEE
William L. Harp, M.D., Ex Officio

CHIROPRACTIC COMMITTEE
Ray Tuck, Jr., DC - Secretary/Treasurer

BOARD OF HEALTH PROFESSIONS
Barbara Allison-Bryan, MD

COMMITTEE OF THE JOINT BOARDS OF NURSING AND MEDICINE
Lori Conklin, MD
Kevin O'Connor, MD
Kenneth Walker, MD

--- DRAFT UNAPPROVED --

VIRGINIA BOARD OF MEDICINE

EXECUTIVE COMMITTEE MINUTES

Friday, December 1, 2017 Department of Health Professions Henrico, VA

PUBLIC HEARING

Dr. O'Connor opened the floor at 8:34 a.m. for comments on the Proposed Regulations on the Prescribing of Opioids. Dr. O'Connor stated that the final regulations will be adopted by the Full Board on February 15, 2018.

Dr. O'Connor acknowledged the written comment submission from William O'Keefe. In his letter, Mr. O'Keefe urges the Board not to treat all classes of opioids the same and to place greater reliance on the existing monitoring system to track potential overprescribing.

George Carter, Administrator of the Statewide Sickle Cell Chapters of Virginia, Inc. addressed the Committee and expressed his concerns about the adverse effects the opioid laws could have on sickle cell patients. Mr. Carter asked that consideration be given to adding an amendment at the beginning of the documentation that states the dosing limits on the use of long-acting opioids should not be applied to patients with sickle cell disease.

The floor closed at 8:46 a.m.■

CALL TO ORDER: Dr. O'Connor called the Executive Committee meeting to order at 8:46 a.m.

ROLL CALL: Ms. Opher called the roll; a quorum was established.

MEMBERS PRESENT:
Kevin O'Connor, MD, President & Chair
Syed Salman Ali, MD
Lori Conklin, MD, Secretary-Treasurer
Alvin Edwards, MDiv, PhD
Jane Hickey, JD
Nathaniel Tuck, Jr., DC, Vice-President

MEMBERS ABSENT:
Randy Clements, DPM
Maxine Lee, MD

STAFF PRESENT:
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heaberlin, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
Sherry Gibson, Administrative Assistant
David Brown, DC, DHP Director
Elaine Yeatts, Sr. Policy Analyst

Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT:

George H. Carter, Statewide Sickle Cell Chapters of Virginia
Floyd Herdrich, Acupuncture, LAc
W. Scott Johnson, Medical Society of Virginia
James Pickral, VSPS
Chris Nolen, International Aesthetic & Laser Association
Julie Galloway, Medical Society of Virginia

EMERGENCY EGRESS INSTRUCTIONS

Dr. Tuck provided the emergency egress instructions.

APPROVAL OF MINUTES OF AUGUST 4, 2017

Dr. Edwards moved to approve the meeting minutes of August 4, 2017 as presented. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Edwards moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

There was no public comment.

DHP DIRECTOR'S REPORT

Dr. Brown began by thanking Dr. Hazel for his 8 years of service with the Commonwealth. Dr. Brown noted that the workgroup convened to develop core competencies on prescribing and pain management has submitted their report to Secretary Hazel's office and will be provided to the Governor. Secretary Hazel asked that the document be used by non-prescribers and from its use, see how to derive a tool that can be useful in the schools.

Dr. Brown noted that a probable cause video designed to assist board members in their appointment duties is in the works. Additionally, a video library is being built that will cover topics such as FOIA, confidentiality, etc.; the Board's input is welcomed.

PRESIDENT'S REPORT

No report.

EXECUTIVE DIRECTOR'S REPORT

No report.

NEW BUSINESS

Chart of Regulatory Actions

Ms. Yeatts reviewed the status of regulations for the Board as of November 20, 2017 and noted that there were no additional updates.

This report was for informational purposes only.

Proposed Regulations for Performance of and for Supervision and Direction of Laser Hair Removal AND Repeal of Guidance Document on Laser Hair Removal

Ms. Yeatts went over the legislation, the proposed regulations that the Regulatory Advisory Panel (RAP) on Laser Hair developed, and the public comment received on the subject. She said that the consensus was that the supervising licensee should be on-site to oversee the procedures performed by non-licensed personnel. She also advised that an identical set of regulations will be presented to the Joint Boards of Nursing and Medicine before coming back to the Full Board of Medicine in February 2018.

Dr. O'Connor asked if the RAP discussed the number of cases a supervisor should oversee before considering the non-licensed individual "properly trained".

Ms. Yeatts advised that there was discussion but no recommendation.

Dr. Ali noted that in other regulated disciplines there are stringent continuing education requirements in the regulations (e.g., AMA accredited), and asked if the RAP had considered specifying formalized training that can be pointed to or to capture the user's participation.

Ms. Deschenes stated there does not appear to be a nationally recognized accrediting body for the practice of laser hair removal, as is seen with other accrediting organizations that offer training for certain specialties. Ms. Deschenes also noted that this law requires specific licensees to oversee this practice and ensure competence of themselves and those they supervise, and the licensees will be held accountable to ensure public protection. Ms. Deschenes commented that this practice has been going on for years and the Board has received very few complaints in this area.

Ms. Barrett reminded the members that the Board still has the discretion to ascertain whether training is appropriate.

Dr. Ali asked if the supervisor is required to be licensed in Virginia as the law does not indicate so.

Ms. Deschenes confirmed that the MD, PA or NP would be required to hold an active license in Virginia in order to supervise this practice in Virginia.

MOTION: Dr. Conklin moved to adopt the proposed regulations to implement HB2119 in 18VAC85-20 (Regulations for Doctors of Medicine, Osteopathic Medicine, Podiatry and

Chiropractic) and 18VAC85-50 (Regulations for Physicians as recommended by the Regulatory Advisory Panel. The motion was seconded and carried unanimously.

MOTION: After adoption of the above proposed regulations, Dr. Tuck moved to repeal Guidance Document 85-7. The motion was seconded and carried unanimously.

Guidance Document on the completion of FORM B

Mr. Heaberlin stated that the Guidance Document was developed to address reoccurring issues some applicants face with completion of FORM B as required for licensure.

MOTION: Dr. Conklin moved to adopt Guidance Document 85-3 as presented. The motion was seconded and carried unanimously.

Dr. Edwards asked the Committee to revisit the matter regarding the unintended consequences of the opioid laws and how they may affect sickle cell patients.

Dr. Ali said that the comments presented by Mr. Carter were well presented and received. However, the opioid guidelines do not apply to inpatient hospital admissions, i.e., dosages are not restricted in the treatment of acute or chronic pain during an inpatient hospital admission. Additionally, a practitioner may exceed 120 mg as long as they document the reason for doing so (for example, sickle cell crisis). A physician being fearful to prescribe is understood, but the Board has no ability to change that mindset.

Ms. Deschenes stated that the Board is aware of the levels of medication that are prescribed to sickle cell patients and she could not recall the Board ever receiving a complaint about a physician prescribing high doses of opioids to sickle cell patients. She also explained that in compliance with the law, the Board and Enforcement have recently begun receiving reports from the Prescription Monitoring Program on prescribers that exceed specified parameters, and noted a sickle cell provider appeared in that audit and the Board recognized the pain issues inherent in sickle cell patients and closed the matter. However, Ms. Deschenes stated the Board could consider carving out this condition.

Dr. O'Connor agreed but noted that if the Board begins carving out specific conditions, it could be endless. The physician has the latitude to prescribe as long as it is well documented.

Dr. Conklin agreed that the list of carve outs for conditions such as sickle cell, pancreatitis, Crohn's, etc. could require endless modification to the Regulations, when the Regulations permit prescribing the necessary dosage for these conditions with "reasonable justification" for such doses documented in the record.

Dr. Tuck noted that some places in the regulations say "should be documented' and in other places is says "should be considered". Is there a hole?

Dr. O'Connor noted it is very difficult for a practitioner to prove something occurred or was considered, if such has not been documented in the record.

ANNOUNCEMENTS

The next meeting of the Committee will be April 13, 2018 at 8:30 a.m.

ADJOURNMENT

With no additional business, the meeting adjourned at 9:20 a.m.

Kevin O'Connor, MD
President, Chair

Jennifer Deschenes, JD
Deputy Executive Director, Discipline

Colanthia M. Opher
Recording Secretary

--- DRAFT UNAPPROVED --

VIRGINIA BOARD OF MEDICINE
LEGISLATIVE COMMITTEE MINUTES

Friday, January 19, 2018 | Department of Health Professions | Henrico, VA

CALL TO ORDER: The meeting convened at 8:37 a.m.

ROLL CALL: Ms. Opher called the roll; a quorum was established.

MEMBERS PRESENT:
Ray Tuck, DC, Vice-President, Chair
Barbara Allison-Bryan, MD
David Giammittorio, MD
Jane Hickey, JD
David Taminger, MD
Svinder Toor, MD

MEMBERS ABSENT: Isaac Koziol, MD

STAFF PRESENT:
William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Alan Heaberlin, Deputy Director, Licensure
Barbara Matusiak, MD, Medical Review Coordinator
Colanthia Morton Opher, Operations Manager
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General
Sherry Gibson, Administrative Assistant

OTHERS PRESENT:
Ryan LaMura, VHHA
Ajay Manhapra, MD, Hampton VA Medical Center
Tiffany Dews, Sickle Cell Chapter of Richmond
Julie Galloway, MSV
George Harris, Statewide Sickle Cell Chapters of VA
Dionne Bobo, Statewide Sickle Cell Chapters of VA

EMERGENCY EGRESS INSTRUCTIONS

Dr. Allison-Bryan provided the emergency egress instructions.

APPROVAL OF MINUTES OF MAY 19, 2017

Ms. Hickey moved to approve the meeting minutes of May 19, 2017. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

Dr. Allison-Bryan moved to accept the agenda as presented. The motion was seconded and carried unanimously.

PUBLIC COMMENT

Dionne BoBo addressed the Committee saying that she has two children who have sickle cell disease. She asked the Committee to consider adding an exemption in the proposed opioid regulations to ensure that prescribers that treat patients with sickle cell disease know that they can provide adequate doses of opioids to control the pain.

Tiffany Dews, with Statewide Sickle Cell Chapters of Virginia and mother of two children with sickle cell, asked the Committee to exempt this population from the opioid regulations.

George Carter, with Statewide Sickle Cell Chapters of Virginia, requested an amendment to 18VAC85-21-10(B) that would include a fourth exception to the guidelines for "patients diagnosed with Sickle Cell Disease".

Ajay Manhapra, MD provided his perspective regarding the difficulty of opioid tapering in high-dose patients. He stated that restricting the writing of opioid prescriptions is not the solution and that the other side of this action is an alarming rate of suicide. Dr. Manhapra said that the policy seems based on feelings and not science. Regarding buprenorphine, it is not a detox medication or substitute therapy. The principle is that buprenorphine saves lives, and the lack of buprenorphine does not. He quoted a recent study that showed the use of buprenorphine mono-product nationwide was 8.8%. He asked the Committee to consider convening an ad hoc committee to look at the regulations again before going forward.

Julie Galloway expressed MSV's support for the existing emergency regulations.

The floor closed at 8:56 a.m.

DHP DIRECTOR'S REPORT

No report.

EXECUTIVE DIRECTOR'S REPORT

No report.

NEW BUSINESS

1. Report from the General Assembly

Elaine Yeatts distributed the most current report from the 2018 Session of the General Assembly and reviewed the bills that were of interest to the Committee. This report was for informational purposes only. No action was required.

2. Chart of Board of Medicine Regulatory Actions

Elaine Yeatts provided a brief overview of the Board's ongoing regulatory activity. She noted that the comment period on the proposed regulations for the prescribing of opioids and buprenorphine ends on January 26, 2018.

3. Review of Comments/Discussion of proposed regulations for opioid prescribing

Ms. Yeatts presented the proposed regulations. She noted that the major change from the initial emergency regulations was to incorporate the language below into the amended emergency regulations signed by Gov. McAuliffe August 24, 2017. The language below was presented to the Committee in the proposed regulations for consideration.

For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

Dr. Allison-Bryan noted that there was no language in the regulations about tapering or inpatient treatment. She noted that the amended emergency regulations do not limit the prescriber in terms of appropriate doses, and perhaps the regulations are being misunderstood. Now may be the Board's opportunity to reach out to prescribers and provide factual reassurance to those that have become reluctant to treat patients with adequate doses.

Dr. Harp stated that, based on the e-mail inquiries and phone calls he has received, a significant number of physicians have not read the regulations.

Dr. Toor agreed that sickle cell disease is like cancer; it is a chronic and deep wound pain that is not visible from the outside. In pediatric sickle cell patients, opioids are used very liberally, but that is only one part of the treatment. He feels that it would be reasonable to add sickle cell disease as an exemption, so the patients can receive proper care.

Ms. Deschenes said that public comment regarding the inclusion of an exemption for sickle cell disease was brought to the attention of the Executive Committee and discussed; however, the debate came down to, although sickle cell disease is an example of pain that requires large doses of opioids, so do many other diseases. How would the Board keep from expanding the list of such diseases/conditions? The fact remains that the practitioner needs to read and understand the regulations.

In response to Dr. Allison-Bryan's inquiry about how 3% became the threshold for total mono-product prescriptions, Ms. Yeatts advised that the Board considered 5%, which was intended to include patients with financial issues. However, the Board agreed to leave the financial piece out of the regulations, so the 3% is strictly for those that have documented naloxone intolerance.

Dr. Harp pointed out that half of the experts on the Regulatory Advisory Panel that practice medication-assisted treatment with buprenorphine did not believe in naloxone intolerance; the other half did. He said he found little information in the literature about naloxone intolerance to report to the May 2017 Legislative Committee, so it decided on 3%.

Ms. Yeatts then noted that a large number of people on treatment for chronic pain are financially strapped by the requirement for urine drug screens. The current regulations require drugs screens 2-4 times per year. She suggested looking to the Centers for Disease Control (CDC) guidelines for a different standard.

Dr. Allison-Bryan referred to page 73 of the CDC guidelines. CDC recommends that, in the context of chronic pain, clinicians should order urine drug testing before starting opioid therapy and consider urine drug testing at least annually. Such testing is to check for compliance with the prescribed regimen, other prescribed medications, and illicit drugs. Dr. Allison-Bryan said that screens are extremely helpful in disciplinary hearings. She noted that there are inexpensive screens that provide qualitative results. She believes there is still much prescriber education to be done.

Dr. Toor noted that CDC has no data to show drug testing is helpful. He thinks it should be done when the prescriber thinks it is needed. There should be some degree of freedom for those that are doing a good job. Not everyone should suffer for the mismanagement of the few.

Dr. Harp added that, anecdotally, buprenorphine + naloxone is abused as is the mono-product. A Richmond area organization that educates teenagers about drug abuse says that buprenorphine + naloxone is the most abused opioid by the youth they serve.

After discussion, the Committee agreed on the following recommendations to the Board:

- 18VAC85-21-10(B)(1) – shall read: The treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell disease, (iii) a patient in hospice care, or (iv) a patient in palliative care.

- Although it is difficult to pinpoint a percentage of patients that demonstrate naloxone intolerance, the rate allowed by the regulations should be increased to 7%. Dr. Harp stated that the increase is justified based on clinical comments to the Board.

- Drug screens should be conducted initially and then randomly at the prescriber's discretion, at least once a year.

- Insert (atypical opioid) after tramadol, where applicable, in acute pain, chronic pain and buprenorphine. This should decrease the confusion that tramadol is not considered an opioid.

4. **Proposed Consent Order**

Ms. Deschenes and Caroline McNichol presented a Consent Order for reinstatement of a physician's license. Dr. Allison-Bryan moved to accept the Consent Order as presented. The motion was seconded and carried unanimously.

5. **Reminder:** Dr. Tuck reminded the Committee members to submit their travel expense reimbursement vouchers by February 19, 2018.

ANNOUNCEMENTS

There were no additional announcements.

Next meeting – May 18, 2018

Adjournment - With no other business to conduct, the meeting adjourned at 10:45 a.m.

Ray Tuck, Jr., DC
Vice-President, Chair

William L. Harp, MD
Executive Director

Colanthia Morton Opher, Operations Manager
Recording Secretary

----DRAFT UNAPPROVED----

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Laser Hair Removal Minutes

Monday, November 20, 2017 Department of Health Professions Henrico, VA

CALL TO ORDER:	The meeting convened at 10:08 a.m.
EMERGENCY EGRESS:	Dr. Piness read the Emergency Egress Procedures
MEMBERS PRESENT:	Jane Piness, MD, Chair James Robinson, MD Sara Villalona, PA Pat Selig, PhD, FNP-BC
MEMBERS ABSENT:	None
STAFF PRESENT:	Jennifer D eschenes, JD, Deputy Executive Director, Discipline Alan Heaberlin, Deputy Director, Licensure Colanthia Morton Opher, Operations Manager Elaine Yeatts, DHP Senior Policy Analyst Deirdre Brown, Administrative Assistant
OTHERS PRESENT:	Scott Johnson, JD, Medical Society of VA James Pickral, VSPS Julie Galloway, MSV Chris Nolen, McGuire Woods/ International Aesthetics and Laser Association

MEETING SUMMARY

The meeting began with introductions from the Panel members and board staff, after which the floor opened for public comment.

James Pickral speaking on behalf of the Virginia Society of Plastic Surgeons highlighted the Society's definition of direct supervision and offered to be a resource to the Board.

Chris Nolen with International Aesthetics and Laser Association asked the Panel for a reasonable approach when defining direction and supervision so that it allows for some flexibility. He also commented that training on laser hair removal topics such as those recommended in Guidance Document 85-7 would be useful to the practitioner.

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Laser Hair Removal Minutes

Monday, November 20, 2017 Department of Health Professions Henrico, VA

Ms. Yeatts informed the members that the use of a Regulatory Advisory Panel was a relatively new creation comprised of a group of experts that can represent the issue and professions involved. She stated that this Panel's primary purpose was to develop draft regulations that will direct the practitioners about their responsibility of overseeing the practice of laser hair removal. These proposed regulations will then be provided to the respective boards. Ms. Yeatts then read the statute below:

§ 54.1-2973.1. Practice of laser hair removal.

The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A 6 of § 54.1-2901.

Ms. Yeatts went on to explain that historically there has been some confusion as to whether the Department of Professional and Occupational Regulation (DPOR) or DHP was responsible for the practice of laser hair removal. While esthetics falls under DPOR, and includes hair removal by devices other than laser, hair removal with a laser falls under DHP. Ms. Yeatts noted that the Panel is tasked with not only ensuring that the physician, physician assistant, and nurse practitioner is properly trained, but that they are trained enough to oversee those non-licensed individuals that are providing laser hair services.

Ms. Yeatts referred to the written comments received and noted that several suggested that the patient be evaluated by a physician prior to receiving treatment.

The Panel then discussed the definition of "direction and supervision".

Dr. Robinson advised that his office was one of the first facilities to offer laser hair removal services in the area many years ago. He said that once the equipment was set up in the office, the company sent an instructor to provide staff training on how to properly operate the equipment. He also noted that he does see every patient before they receive treatment, but is not sure what occurs in a non-physician setting.

Dr. Piness stated that she also had a 3-day course on the equipment, and commented it is like programming a computer with 5 settings. The operator must take into consideration factors like

skin type, hair color, etc., so there is some judgement that needs to be exercised before treatment occurs.

Dr. Robinson added that supervision should be looked at from a practical standpoint, and then from the public consumer's perspective. As laser hair removal is a popular procedure, the process should not be onerous.

Ms. Villalona said that she has been working in laser hair for over 15 years. She stated that the machine is not difficult to use, with proper training and knowledge of skin types suitable for laser hair removal the patient should experience no discomfort or issues.

Dr. Selig asked Dr. Robinson for clarification on his laser hair process. Dr. Robinson advised that he personally meets with all new patients and provides the starting setting. Dr. Selig then stated that if the decision is for the physician to see every patient before treatment, it may be seen as a new burden and she is not sure that it's essential to the practice.

Dr. Piness said that technically the person supervising should know how to operate the equipment. She then pointed to North Carolina's Q&A about who may operate the laser during a laser hair removal procedure. The response is "A physician may operate lasers that are used for hair and tattoo removal, if the physician is trained and qualified to use that particular laser. And, any individual designated by a physician as having adequate training and experience may operate a medical laser while working under a physician's supervision. A supervising physician should assure herself/himself that a non-physician is adequately trained, competent and experienced to use a medical laser safely before the physician delegates this task to the non-physician."

Ms. Yeatts added the there is a comfort level of the process among the licensed professions, but the concern is for those not overseen by a physician.

Ms. Villalona agrees with public protection and said that individuals that have been burned from laser hair removal were not treated at a physician, PA or NP practice, but at a spa and she suggested that a physician perform the initial consultation.

After a 15-minute break, the meeting reconvened and the following draft regulations were developed:

----DRAFT UNAPPROVED----

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Laser Hair Removal Minutes

Monday, November 20, 2017 Department of Health Professions Henrico, VA

BOARD OF MEDICINE

Supervision and direction for laser hair removal

18VAC85-20-91. Practice and supervision of laser hair removal.

A. A doctor of medicine or osteopathic medicine may perform or supervise the performance of laser hair removal upon completion of training in the following:

1. Skin physiology and histology;

2. Skin type and appropriate patient selection;

3. Laser safety;

4. Operation of laser device or devices to be used;

5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and

6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

B. Doctors of medicine or osteopathic medicine who have been performing laser hair removal prior to (the effective date of this regulation) are not required to complete training specified in subsection A.

C. A doctor who delegates the practice of laser hair removal and provides supervision to a person other than a licensed physician assistant or licensed nurse practitioner, shall assure that such person has completed the training required in subsection A.

D. A doctor who performs laser hair removal or who supervise others in the practice shall receive ongoing training as necessary to maintain competency in new techniques and laser devices. The doctor shall assure that persons he supervises also receive ongoing training to maintain competency.

E. A doctor may delegate laser hair removal to a properly trained person under his direction and supervision. Direction and supervision shall mean that the doctor is readily available at the time laser hair removal is being performed. The supervising doctor is not required to be physically present, but is required to see and evaluate a patient for whom the treatment has resulted in complications prior to the continuance of laser hair removal treatment.

F. Prescribing of medication shall be in accordance with provision of § 54.1-3303 of the Code of Virginia for the establishment of a practitioner/patient relationship.

18VAC85-50-191. Practice and supervision of laser hair removal.

A. A physician assistant, as authorized pursuant to § 54.1-2952, may perform or supervise the performance of laser hair removal upon completion of training in the following:

1. Skin physiology and histology;

2. Skin type and appropriate patient selection;

3. Laser safety;

4. Operation of laser device or devices to be used;

5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and

6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

B. Physician assistants who have been performing laser hair removal prior to (the effective date of this regulation) are not required to complete training specified in subsection A.

C. A physician assistant who delegates the practice of laser hair removal and provides supervision for such practice shall assure the supervised person has completed the training required in subsection A.

D. A physician assistant who performs laser hair removal or who supervise others in the practice shall receive ongoing training as necessary to maintain competency in new techniques and laser devices. The physician assistant shall assure that persons he supervises also receive ongoing training to maintain competency.

E. A physician assistant may delegate laser hair removal to a properly trained person under his direction and supervision. Direction and supervision shall mean that the physician assistant is readily available at the time laser hair removal is being performed. The supervising physician assistant is not required to be physically present, but is required to see and evaluate a patient for whom the treatment has resulted in complications prior to the continuance of laser hair removal treatment.

F. Prescribing of medication shall be in accordance with provision of § 54.1-3303 of the Code of Virginia for the establishment of a practitioner/patient relationship.

VIRGINIA BOARD OF MEDICINE
Regulatory Advisory Panel on Laser Hair Removal Minutes

Monday, November 20, 2017 Department of Health Professions Henrico, VA

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Ms. Yeatts advised that board staff will send a copy to each of the panel members for their review, comments or additional suggestions. After which, it will be presented on the agenda of the Executive Committee in December.

With no other business to conduct, the meeting adjourned at 11:45 a.m.

Jane Piness, MD
Chairperson

Jennifer Deschenes, JD, MS
Deputy Executive Director

Colanthia M. Opher
Operations Manager

---DRAFT UNAPPROVED---

ADVISORY BOARD ON BEHAVIOR ANALYSIS
Minutes
January 29, 2018

The Advisory Board on Behavior Analysis met on Monday, January 29, 2018 at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Kate Lewis, MS, BCBA, LBA Amanda Kusterer, BCaBA
MEMBERS ABSENT:	Asha Patton Smith, MD Gary Fletcher
STAFF PRESENT:	William L. Harp, M.D., Executive Director Alan Heaberlin, Deputy Director, Licensure Elaine Yeatts, DHP Senior Policy Analyst Denise Mason, Licensing Specialist Colanthia Morton Opher, Operations Manager
GUESTS PRESENT:	Christy Evanko, BACA, VABA Hannah Robicheau, Compass Counseling Services of VA Jennifer LaMothi, Compass Counseling Services of VA Lindsay Krebs, Compass Counseling Services of VA Dylan Melton, Compass Counseling Services of VA Shelby Craig, LBA, Compass Counseling Services of VA Anne Fults, Compass Counseling Services of VA Taylor Polidori, Compass Counseling Services of VA

CALL TO ORDER

Ms. Lewis called the meeting to order at 10:16 am.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Procedures.

ROLL CALL

Roll was called. A quorum was not declared.

ADOPTION OF AGENDA

The agenda was not adopted due to a quorum not being present.

APPROVAL OF MINUTES OF June 5, 2017

The minutes were not approved due to a quorum not being present.

PUBLIC COMMENT

Ms. Evanko brought several bills that VABA has been tracking in the 2018 Session to the attention of the Advisory Board.

NEW BUSINESS

1. Legislative Update

Ms. Yeatts reviewed the legislative process with the Advisory Board and the students in the gallery. She further reviewed legislation introduced in the 2018 General Assembly that might be of interest to the Advisory Board. No action was required.

The Advisory Board asked Board staff to initiate a Notice of Periodic Review of the Regulations Governing the Practice of Behavior Analysis.

Announcements

Alan Heaberlin informed the Advisory Board that there are currently 917 Behavior Analysts and 121 Assistant Behavior Analysts holding licenses with the Virginia Board of Medicine. During FY2018, 102 individuals were licensed as Behavior Analysts, and 13 were licensed as Assistant Behavior Analysts.

Mr. Heaberlin also informed the Advisory Board that the Board agreed to reduce the requirement of five years of employment verifications to two years by adding the requirement of obtaining a National Practitioner Data Bank Report (NPDB).

Next Meeting Date

The Advisory Board's next meeting is June 4, 2018 at 10:00 am.

Adjournment

The meeting was adjourned at 11:11 a.m.

Kate Lewis, MS, BCBA, LBA, Vice-Chair

William L. Harp, M.D.,
Executive Director

Denise W. Mason, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON GENETIC COUNSELING
MINUTES

January 29, 2018

The Advisory Board on Genetic Counseling met on Monday, January 29, 2018, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	John Quillin, PhD, MPH, MS, Chair Matthew Thomas, ScM, CGC Heather Creswick, MS, CGC Marilyn Foust, MD
MEMBER ABSENT:	Lori Swain, Vice-Chair
STAFF PRESENT:	William L. Harp, MD, Executive Director, Elaine Yeatts, DHP Senior Policy Analyst Alan Heaberlin, Deputy Executive Director Colanthia Morton Opher, Operations Manager Denise Mason, Licensing Specialist
GUESTS PRESENT:	None

CALL TO ORDER

Dr. Quillin called the meeting to order at 1:07 p.m.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Instructions.

ROLL CALL

Denise Mason called roll, and a quorum was declared.

DRAFT UNAPPROVED

APPROVAL OF MINUTES OF OCTOBER 2, 2017

Ms. Creswick moved to approve the minutes of October 2, 2017. The motion was seconded and carried.

ADOPTION OF AGENDA

Dr. Foust moved to approve the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

None

NEW BUSINESS

1. Legislative Update

Ms. Yeatts reviewed legislation that had been introduced in the 2018 General Assembly that might be of interest to the Advisory Board. No action was required.

2. Proposal to Reintroduce Legislation to Amend Section 54. 1-2957.19(C) of the Code of Virginia

Ms. Yeatts suggested that the Advisory Board consider asking the full Board to reintroduce the Bill to Amend the Code of Virginia by Amending Section 54.1-2957.19. This bill would allow genetic counselors that graduated from programs accredited by predecessor organizations of the American Board of Genetic Counseling to be licensed. Ms. Creswick moved to request the bill be reintroduced. The motion was seconded and carried.

3. Discussion of Possible Regulatory Action

The Advisory Board discussed revising Section 18VAC85-170-60 of the Regulations Governing Genetic Counseling due to a concern that the language regarding the "expiration of active candidate status" could be confusing. Mr. Thomas moved to strike the language "expiration of active candidate status" and replace it with "failure of the ABGC Board Certification Examination." The regulation would read, "An applicant for a temporary license shall provide documentation of having been granted active candidate status by the ABGC. Such license shall expire 12 months from issuance or upon ~~expiration of active candidate status~~, failure of the ABGC Board Certification Examination, whichever comes first." The motion was seconded and carried.

DRAFT UNAPPROVED

ANNOUNCEMENTS

Alan Heaberlin informed the Advisory Board that there are currently 92 Genetic Counselors holding licenses with the Virginia Board of Medicine. During FY2018, 89 licenses have been issued.

Ms. Opher told the Advisory Board members that they would now be receiving a $50.00 per diem payment if not employed by the Commonwealth.

NEXT MEETING DATE

June 4, 2018 at 10:00a.m.

ADJOURNMENT

The Advisory Board meeting was adjourned at 2:05 p.m.

John Quillin, PhD, MPH, MS Chair

William L. Harp, M.D., Executive Director

Denise Mason, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON OCCUPATIONAL THERAPY
Minutes
January 30, 2018

The Advisory Board on Occupational Therapy met on Tuesday, January 30, 2018 at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT: Kathryn Skibek, OT, Chair
Breshae Bedward, OT, Vice Chair
Raziuddin Ali, M.D.
Dwayne Pitre, OT
Karen Lebo, JD

MEMBERS ABSENT: None

STAFF PRESENT: William L. Harp, M.D., Executive Director
Alan Heaberlin, Deputy Director, Licensure
Elaine Yeatts, DHP Senior Regulatory Analyst
ShaRon Clanton, Licensing Specialist
Colanthia Morton Opher, Operations Manager

GUESTS PRESENT: None

CALL TO ORDER

Kathryn Skibek called the meeting to order at 10:02 a.m.

EMERGENCY EGRESS PROCEDURES

Mr. Heaberlin announced the Emergency Egress Instructions.

ROLL CALL

Roll was called, and a quorum declared.

APPROVAL OF MINUTES OF October 3, 2017 1-3

Karen Lebo moved to adopt the minutes as written. The motion was seconded and carried.

ADOPTION OF AGENDA

Breshae Bedward moved to adopt the amended agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

None

NEW BUSINESS

1. Legislative Update-Elaine Yeatts

   Mrs. Yeatts gave a brief description of the 8 bills submitted by DHP and others that were of interest to the Advisory Board.

2. Review of Draft Guidance Document for Supervisory Responsibilities

   Mr. Heaberlin described the purpose of guidance documents. Breshae Bedward moved to submit the proposed guidance document on supervision by OT's to the Full Board for approval on February 15, 2018. The motion was seconded and carried.

ANNOUNCEMENTS:

Mr. Heaberlin informed the Advisory Board that there are currently 4,152 Occupational Therapists and 1,587 Occupational Therapy Assistants who hold licenses with the Virginia Board of Medicine. The members were advised of the new mileage rates and the $50.00 per diem for attendance at meetings, if not a state employee.

NEXT MEETING DATE

January 5, 2018, 10:00 a.m.

ADJOURNMENT

The meeting of the Advisory Board was adjourned at 11:04 a.m.

_____
Kathryn Skibek, OT, Chair

_____
William L. Harp, M.D.
Executive Director

_____
ShaRon Clanton, Licensing Specialist

DRAFT UAPPROVED

Advisory Board on Respiratory Therapy
Minutes
January 30, 2018

The Advisory Board on Respiratory Therapy met on Tuesday, January 30, 2018 at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland, Suite 201, Drive, Henrico, VA.

MEMBERS PRESENT:	Daniel Rowley, RRT, Chair Lois Rowland, RRT Bruce Rubin, MD Sherry Compton, RRT
MEMBERS ABSENT:	Hollee Freeman, PhD
STAFF PRESENT:	William L. Harp, M.D., Executive Director Alan Heaberlin, Deputy Director for Licensure Elaine Yeatts, DHP Senior Policy Analyst Colanthia Morton Opher, Operations Manager Denise Mason, Licensing Specialist
GUESTS PRESENT:	There was no public comment.

Call TO ORDER

Dan Rowley called the meeting to order at 1:05 p.m.

EMERGENCY EGRESS PROCEDURES

Mr. Heaberlin announced the Emergency Egress Procedures.

ROLL CALL

Roll was called. A quorum was declared.

APPROVAL OF MINUTES OF January 31, 2017

Dr. Rubin moved to approve the minutes of January 31, 2017. The motion was seconded and carried.

ADOPTION OF AGENDA

Dan Rowley moved to adopt the agenda. The motion was seconded and carried.

DRAFT UAPPROVED

PUBLIC COMMENT ON AGENDA ITEMS

There was no public comment.

NEW BUSINESS

1. **Legislative Update**

Ms. Yeatts provided a legislative update for the 2018 Session of the General Assembly. No action was required.

2. **Election of Officers**

Dr. Rubin nominated Sherry Compton as Chair. The motion was second and carried. Lois Rowland was nominated as Vice-Chair by Dr. Rubin. The motion was second and carried.

ANNOUNCEMENTS

Dr. Harp informed the Advisory Board that they would now be receiving a $50.00 per diem payment for attending meetings, if they are not employed by the Commonwealth.

Mr. Heaberlin stated that there are 3,803 Respiratory Therapists in Virginia holding an active license and 100 with an inactive license. In FY2018, 148 Respiratory Therapists have been licensed.

Dan Rowley asked the members to recommend colleagues they thought would be interested in serving on the Advisory Board. Dr. Harp said interested individuals would need to apply on the Governor's website.

Ms. Opher made the Advisory Board members aware that applications had to be submitted by March 15, 2018.

NEXT SCHEDULED MEETING

June 5, 2018 @ 1:00pm

ADJOURNMENT

The meeting of the Advisory Board adjourned at 1:48 p.m.

_____
Daniel Rowley, RRT, Chair

_____
William L. Harp, M.D.,
Executive Director

_____
Denise Mason, Licensing Specialist

<< DRAFT UNAPPROVED >>

ADVISORY BOARD ON ACUPUNCTURE

The Advisory Board on Acupuncture met on Wednesday, January 31, 2018, at 10:00 a.m. at the Department of Health Professions at 9960 Mayland Drive, Henrico, VA 23233.

MEMBERS PRESENT: Lynn Almloff, L. Ac., Chair
Janet L. Borges, L.Ac., Vice-Chair
Sharon Crowell, L.Ac.
Leslie Rubio, Citizen Member

MEMBERS ABSENT: Chheany Ung, M.D.

STAFF PRESENT: William L. Harp, M.D., Executive Director
Alan Heaberlin, Deputy Executive Director, Licensing
Elaine Yeatts, DHP Senior Policy Analyst
Beulah Baptist Archer, Licensing Specialist
Colanthia Opher Morton, Operations Manager

GUESTS PRESENT: Kim Nguyen, Acupuncture Society of Virginia

CALL TO ORDER

Lynn Almloff called the meeting to order.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Procedures.

ROLL CALL - The roll was called, and a quorum was declared.

APPROVAL OF THE AMENDED MINUTES FROM May 30, 2017.

Lynn Almloff moved to approve the minutes. The motion was seconded and carried.

ADOPTION OF AGENDA

Sharon Crowell moved to adopt the agenda. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

There was no public comment.

NEW BUSINESS

1. **Legislative Update**

Mrs. Yeatts provided a legislative update from the 2018 Session of the General Assembly. No action was required.

2. **Election of Officers**

Janet Borges nominated Lynn Almloff to remain Chair. The nomination was seconded and carried.

Lynn Almloff nominated Janet Borges to remain Vice-Chair. The nomination was seconded and carried.

ANNOUNCMENTS –Alan Heaberlin

Mr. Heaberlin provided licensing statistics, stating that there are 511 Active Licensed Acupuncturists and 9 Inactive Acupuncturists.

Mr. Heaberlin also informed the Advisory Board of the change in the application process regarding FORM B employment verifications and the National Practitioner Data Bank.

NEXT SCHEDULED MEETING:

June 6, 2018 at 10:00 a.m.

ADJOURNMENT

Lynn Almloff adjourned the meeting.

_____ _____

Lynn Almloff, L.Ac., Chair William L. Harp, M.D., Executive Director

_____

Beulah Baptist Archer, Licensing Specialist

---DRAFT UNAPPROVED ---

ADVISORY BOARD ON RADIOLOGIC TECHNOLOGY
Virginia Board of Medicine
January 31, 2018, 1:00 p.m.

The Advisory Board on Radiologic Technology met on Wednesday, January 31, 2018 at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

MEMBERS PRESENT:	Joyce O. Hawkins, RT, Chair Jan Gillespie Clark, RT Margaret Toxopeus, M.D.
MEMBERS ABSENT:	Patti S. Hershey, RT Citizen Member seat is vacant
STAFF PRESENT:	Alan Heaberlin, Deputy Executive Director Elaine Yeatts, DHP Senior Policy Analyst Beulah Baptist Archer, Licensing Specialist Colanthia Opher Morton, Operations Manager
GUESTS PRESENT:	None

CALL TO ORDER

Joyce Hawkins called meeting to order at 1:08 p. m.

EMERGENCY EGRESS PROCEDURES – Joyce Hawkins read the emergency egress procedures.

ROLL CALL – Ms. Archer called the roll. A quorum was established.

APPROVAL OF MINUTES OF October 5, 2016 –

Dr. Toxopeus moved to approve the minutes. The motion was seconded and carried.

ADOPTION OF AGENDA

Ms. Gillespie moved to approve the agenda. The motion was seconded and carried.

PUBLIC COMMENT

There was no public comment.

NEW BUSINESS

1. **Legislative Update**

   Ms. Yeatts provided a legislative update for the 2018 Session. No action was required.

2. **What Can Be Reported to the Board for Disciplinary Investigation?**

Ms. Hawkins requested more information on what can be reported to the Board of Medicine for potential disciplinary action. Mr. Heaberlin explained that any member of the public can make a complaint to the Board of Medicine regarding any person licensed by the Board. Mr. Heaberlin reminded the Advisory Board that the Board of Medicine does not have jurisdiction over unlicensed radiologic technologists practicing in a hospital. He stated that unlicensed professionals who commit unprofessional acts could also be reported to the professional organization that certifies them. Lastly, he reminded the Advisory Board that while the Enforcement Division will accept anonymous complaints, but anonymity cannot guaranteed.

3. Election of Officers

Dr. Toxopeus nominated Jan Gillespie as Chair. Jan Gillespie nominated Joyce Hawkins as Vice-Chair. The motions were seconded and carried unanimously.

ANNOUNCEMENTS

Alan Heaberlin provided Radiological Technology licensure statistics.

4,053 licensed Radiologic Technologists
11 licensed Radiologist Assistants
562 licensed Radiologic Technologists-Limited

For the current FY2018 beginning July 1, 2017, the Board has licensed 24 Limited Radiologic Technologists and 234 Radiologic Technologists.

Mr. Heaberlin informed the Advisory Board about a change that has been made in the application process regarding employment verifications and the National Practitioner Data Bank.

NEXT MEETING DATE

June 6, 2018, at 1:00 pm.

ADJOURNMENT

Ms. Hawkins adjourned the meeting.

Joyce Hawkins, RT Chair

William L. Harp, MD, Executive Director

Beulah Baptist Archer, Recording Secretary

DRAFT UNAPPROVED

ADVISORY BOARD ON ATHLETIC TRAINING
MINUTES

February 1, 2018

The Advisory Board on Athletic Training met on Thursday, February 1, 2018, at 10:00 a.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Sara Whiteside, AT, Chair Michael Puglia, AT Jeffrey Roberts, MD
MEMBER ABSENT:	Deborah Corbatto, AT, Vice-Chair Trilizsa Trent, Citizen Member
STAFF PRESENT:	Alan Heaberlin, Deputy Director for Licensure Colanthia Morton Opher, Operations Manager Denise Mason, Licensing Specialist
GUESTS PRESENT:	Scott Powers, VATA Janet L. Borges, L.Ac. Tanner Howell, VUU Chris Jones, VATA

CALL TO ORDER

Sara Whiteside called the meeting to order at 10:04 a.m.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Instructions.

ROLL CALL

Denise Mason called the roll, and a quorum was declared.

APPROVAL OF MINUTES OF OCTOBER 5, 2017

Sara Whiteside moved to approve the minutes of October 5, 2017. The motion was seconded and carried.

DRAFT UNAPPROVED

ADOPTION OF AGENDA

Mike Puglia moved to amend the agenda to include discussion of US Senate bill, **S. 534**.

PUBLIC COMMENT ON AGENDA ITEMS

There was no public comment.

NEW BUSINESS

1. Legislative Update

Alan Heaberlin provided a legislative update for the 2018 Session of the General Assembly. No action was required.

2. Discussion of Provisional Licensure and Temporary Authorization

Mike Puglia led a discussion regarding Provisional Licensure and Temporary Authorization. The Advisory Board discussed how each is obtained and the importance of educating employers. Employers that understand these two pathways could get athletic trainers working more quickly and also reduce the disciplinary actions for athletic trainers for unlicensed practice.

3. Dry Needling by Athletic Trainers

Sara Whiteside led the discussion regarding the states that allow athletic trainers to practice dry needling as well as what is needed for athletic trainers to practice dry needling in Virginia.

Alan Heaberlin informed the Advisory Board that in order for dry needling to be included in the athletic trainers' scope of practice, the General Assembly would need to add it through legislation. Mr. Heaberlin suggested that a professional organization that represents athletic trainers might find a patron in the General Assembly willing to introduce the legislation.

4. Discussion of US Senate Bill 534

Mike Puglia led a discussion regarding Senate Bill 534. The Advisory Board discussed how athletic trainers would implement the processes noted in the bill related to patient privacy and safety, as well as what entities this bill would directly affect.

DRAFT UNAPPROVED

ANNOUNCEMENTS

Alan Heaberlin informed the Advisory Board that there are currently 1,458 Athletic Trainers licensed with the Board of Medicine, 4 of which are inactive. During FY2018, 109 Athletic Trainers have been licensed.

Alan Heaberlin also informed the Advisory Board that changes in the application process have reduced the requirement to obtain five years of employment verifications to two years, made possible by adding the requirement to obtain the National Practitioner Data Bank Report (NPDB).

NEXT MEETING DATE

June 7, 2018 at 10 a.m.

ADJOURNMENT

The Advisory Board meeting adjourned at 11:17 p.m.

Sara Whiteside, AT, Chair

William L. Harp, M.D., Executive Director

Denise Mason, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON PHYSICIAN ASSISTANTS

Board of Medicine
February 1, 2018, 1:00 PM
9960 Mayland Drive, Suite 201
Richmond, VA
Training Room 2

The Advisory Board on Physician Assistants met Thursday, February 1, 2018, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

MEMBERS PRESENT:	Portia Tomlinson, PA-C, Chair Rachel Carlson, PA-C, Vice Chair Frazier W. Frantz, MD Thomas Parish, PA-C Tracey Dunn, Citizen
MEMBERS ABSENT:	None
STAFF PRESENT:	William L. Harp, MD, Executive Director R. Alan Heaberlin, Deputy Executive Director Elaine Yeatts, Senior Regulatory Analyst ShaRon Clanton, Licensing Specialist
GUESTS PRESENT:	David Falkenstein, VAPA A. Rose Rutherford, VAPA Robert Glasgow, PA-C, VAPA

Call to Order-Portia Tomlinson, PA-C Chair

Portia Tomlinson called the meeting to order.

Emergency Egress Procedures-Alan Heaberlin

Mr. Heaberlin provided the emergency egress instructions.

Roll Call-ShaRon Clanton

Roll was called, and a quorum was declared.

Approval of Minutes October 5, 2017 1-2

Rachel Carlson moved to adopt the minutes. The motion was seconded and carried.

Adoption of Agenda

Tom Parish moved to adopt the Agenda. The motion was seconded and carried.

Public Comment on Agenda Items (15 minutes)

None

NEW BUSINESS

1. Legislative Update

   Mrs. Yeatts provided a legislative update. No action was required.

2. Discussion of Final Regulations for Prescribing Opioids.

   Upon motion made by Rachel Carlson, the Advisory Board voted to recommend to the full Board that annotations on prescriptions to indicate "acute" "post-op" and "chronic" be included. The vote was unanimous.

3. Discussion of Draft Regulations on Laser Hair Training and Supervision

   The Advisory Board reviewed the proposed regulations, "Supervision and Direction for Laser Hair Removal," that were developed by a Board of Medicine Regulatory Advisory Panel on November 20, 2017. The Advisory Board will again review the regulations when the public comment period has closed.

4. Recommendation of Proposed Regulations on Definitions of Supervision and Weight Loss Rules.

   The Advisory Board reviewed the proposed changes to the Definition of Supervision and Weight Loss Rules, the Requirements for a Practice Agreement, the Responsibilities of the Supervisor and the Responsibilities of the Physician Assistant. Ms. Carlson moved to recommend adoption of the amendments to the Full Board. The motion was seconded and carried

Announcements

Mr. Heaberlin gave the current license stats for PA's as 3, 599 active and 25 inactive. He noted that 221 new licenses have been issued since the beginning of FY2018. He also reviewed a change in the requirements for FORM B's made possible by an accompanying National Practitioners' Data Bank report.

Next Scheduled Meeting

June 7, 2018 @ 1:00 p.m.

Adjournment

The meeting adjourned at 2:15 p.m.

_____

Portia Tomlinson, PA-C, Chair

_____

William L. Harp, M.D., Executive Director

_____

ShaRon Clanton, Licensing Specialist

ADVISORY BOARD ON MIDWIFERY
Minutes
February 2, 2018

The Advisory Board on Midwifery met on Friday, February 2, 2018, at 10:00 a.m., at the Department of Health Professions, Perimeter Center; 9960 Mayland Drive, Henrico, Virginia, 23233.

MEMBERS PRESENT:	Kim Pekin, CPM, Chair Maya Gunderson, CPM Natasha Jones, MSC Mayanne Zielinski, CPM
MEMBERS ABSENT:	Ami Keatts, M.D.
STAFF PRESENT:	William L. Harp, M.D. Executive Director Alan Heaberlin, Deputy Executive Director Elaine Yeatts, DHP Senior Policy Analyst Colanthia Morton, Operations Manager Beulah Baptist Archer, Licensing Specialist
GUESTS PRESENT:	Jennifer MacDonald, Public Health Nurse Manager, VDH Willie Andrews, Director, Laboratory Operations, DGS Janet Rainey, Director and Registrar, Office of Vital Records Glenda Turner, VMA Adrianne Ross, VMA Marinda Shindler, VMA Michelle Reid, VDH Denise Cox, VDH Misty Ward, Brookhaven Birth Center

CALL TO ORDER

Kim Pekin called the meeting to order at 10:09 a.m.

EMERGENCY EGRESS PROCEDURES – Alan Heaberlin announced the Emergency Egress Procedures.

ROLL CALL –Beulah Baptist Archer called the roll, and a quorum was declared.

APPROVAL OF MEETING MINUTES of September 29, 2017

Maya Gunderson moved to approve the September 29, 2017 minutes. The motion was seconded and carried.

ADOPTION OF THE AMENDED AGENDA

Maya Gunderson moved to amend the agenda to include a presentation by Janet M. Rainey from the Office of Vital Records on the Electronic Birth Certificate process. The motion was seconded and carried.

PUBLIC COMMENT ON AGENDA ITEMS

None

NEW BUSINESS

1. **Legislative Update**

Ms. Yeatts reviewed legislation introduced in the 2018 General Assembly that might be of interest to the Advisory Board. No action was required.

2. **Discussion regarding the timeliness and process for disseminating information to the midwifery community**.

   Jennifer MacDonald (VDH) and Willie Andrews (DCLS) addressed the Advisory Board on HB 449 and HB 1174 that clarifiy newborn screening tests and the timeliness in which the screenings are administered. They also discussed HB 1362 that will require the Department of General Services to ensure timely newborn screening services by offering the screenings seven days a week. Ms. Andrews impressed upon the Advisory Board the need to quickly discover time-critical illnesses and disorders on a state level and invited its members to become a part of this initiative.

3. **Janet M. Rainey from the Office of Vital Records on the Electronic Birth Certificates.**

Ms. Rainey and her staff provided a PowerPoint presentation for the Advisory Board that reviewed the process in detail for completing and submitting electronic birth certificates. They presented the tutorial of the Electronic Birth Certificate (EBC) process that begins training from March 2018 until May 2018; registration in June 2018, with the live rollout date of July 1, 2018. They spoke to several options for training that include computer-based independent training, group training at her office facilities, or satellite group training. The presentation included records retention strategies and several features of the EBC interview process that may be of concern to CPM's. Dr. Harp inquired of Ms. Rainey if she could draft a one-page document that the Board could disseminate to the 74 Virginia licensed midwives regarding this EBC initiative. The Advisory Board and Vital Records staff discussed deadlines for submission of the documents and training opportunities for the midwifery community to complete and submit electronic birth certificates.

ANNOUNCEMENTS

Mr. Heaberlin provided Midwifery licensure statistics in Virginia as of February 2, 2018.

Licensed Midwives	74

NEXT MEETING DATE

June 8, 2018, at 10:00 a.m.

ADJOURNMENT

Maya Gunderson moved to adjourn the meeting. Motion seconded and carried.

Kim Pekin, CPM, Chair

William L. Harp, MD
Executive Director

Beulah Baptist Archer, Licensing Specialist

---DRAFT UNAPPROVED---

ADVISORY BOARD ON POLYSOMNOGRAPHIC TECHNOLOGY
Minutes
February 2, 2018

The Advisory Board on Polysomnographic Technology met on Friday, February 2, 2018 at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT: Jonathan Clark, RPSGT, Chair
Debbie Akers, RPSGT, Vice-Chair
Anna Rodriquez, RPSGT
Robert Vorona, M.D.
Marie Quinn, Citizen Member

MEMBERS ABSENT: None

STAFF PRESENT: William L. Harp M.D., Executive Director
Alan Heaberlin, Deputy Director for Licensure
Colanthia Morton, Operations Manager
Denise Mason, Licensing Specialist

GUESTS PRESENT: None

CALL TO ORDER

Jonathan Clark called the meeting to order at 1:06 p.m.

EMERGENCY EGRESS PROCEDURES

Alan Heaberlin announced the Emergency Egress Procedures.

ROLL CALL

Denise Mason called the roll; a quorum was declared.

APPROVAL OF MINUTES FROM JUNE 9, 2017

Jonathan Clark moved to adopt the minutes. The motion was seconded and carried.

ADOPTION OF AGENDA

Debbie Akers moved to adopt the agenda. The motion was seconded and carried.

---DRAFT UNAPPROVED---

PUBLIC COMMENT ON AGENDA ITEMS

None

NEW BUSINESS

1. **Legislative Report**

Dr. Harp provided a legislative update for the 2018 Session of the General Assembly. No action was required.

ANNOUNCEMENTS

Dr. Bob Vorona thanked Alan Heaberlin for speaking at the Annual Meeting of the Virginia Academy of Sleep Medicine on November 3, 2017 in Richmond. Dr. Vorona also announced that this was his last Advisory Board meeting. He said he had enjoyed working with his colleagues on the Advisory and also with Board staff.

Alan Heaberlin announced that there are currently 461 licensed Polysomnographic Technologists in Virginia. During FY2018, the Board has licensed 21 Polysomnographic Technologists.

Colanthia Opher pointed out to the members that their terms will end on June 30, 2018, and if interested in reappointment, they must submit online applications by March 15, 2018.

Dr. Harp informed the Advisory Board that since July 1, 2017, they are entitled to a $50.00 per diem payment for attending meetings, if they are not employed by the Commonwealth.

NEXT SCHEDULED MEETING

June 8, 2018 @ 1 p.m.

ADJOURNMENT

The meeting of the Advisory Board adjourned at 2:16 p.m.

_____
Jonathan Clark, Chair

_____
William Harp, Executive Director

_____
Denise W. Mason, Licensing Specialist

Agenda Item: **Other Reports**

- Assistant Attorney General*
- Board of Health Professions
- Podiatry Report*
- Chiropractic Report*
- Committee of the Joint Boards of Nursing and Medicine

Staff Note: *Reports will be given orally at the meeting

Action: These reports are for information only. No action needed unless requested by presenter.

Agenda Item: **Legislative Report**

Staff Note: Ms. Yeatts will speak to the bills in the 2018 Session of the General Assembly of interest and relevance to the Board of Medicine.

Action: The Board may choose to discuss selected bills and their impact on the mission of the Board.

Report of the 2018 General Assembly

Board of Medicine

HB 157 Right to Treat Act; requirement of Maintenance of Certification prohibited, etc.

Chief patron: Rasoul

Summary as introduced:
Right to treat; requirement of Maintenance of Certification prohibited. Prohibits hospitals and other entities that have organized medical staff or a process for credentialing physicians as members of staff or employ or enter into contracts for employment with physicians and are required to be licensed from requiring any Maintenance of Certification or Osteopathic Continuous Certification, as defined in the bill, as a condition of granting or continuing staff membership or professional privileges to a licensed physician. The bill prohibits accident and sickness insurance plans, health services plans, and health maintenance organizations from requiring any Maintenance of Certification or Osteopathic Continuous Certification as a condition of participation or reimbursement for a physician licensed by the Board of Medicine; and prohibits the Board of Medicine from requiring any Maintenance of Certification or Osteopathic Continuous Certification as a condition of licensure to practice medicine in the Commonwealth.

12/21/17 House: Prefiled and ordered printed; offered 01/10/18 18102253D
12/21/17 House: Referred to Committee on Commerce and Labor
01/17/18 House: Assigned C & L sub: Subcommittee #2
02/06/18 House: Subcommittee recommends passing by indefinitely (5-Y 2-N)

HB 169 Lyme disease; information disclosure requirement, sunset.

Chief patron: Murphy

Summary as introduced:
Lyme disease information disclosure requirement; sunset. Extends to July 1, 2023, the sunset of the provision requiring disclosure of certain information to a patient when a Lyme disease test is ordered. Under current law, the disclosure requirement will expire on July 1, 2018.

12/22/17 House: Prefiled and ordered printed; offered 01/10/18 18103474D
12/22/17 House: Referred to Committee on Health, Welfare and Institutions
01/17/18 House: Impact statement from VDH (HB169)
01/18/18 House: Stricken from docket by Health, Welfare and Institutions (21-Y 0-N)

HB 226 Patients; medically or ethically inappropriate care not required.

Chief patron: Stolle

Summary as introduced:
Medically or ethically inappropriate care not required. Establishes a process whereby a physician may cease to provide health care that has been determined to be medically or ethically inappropriate for a patient.

01/30/18 House: Subcommittee recommends reporting with amendments (5-Y 0-N)
01/30/18 House: Subcommittee recommends referring to Committee for Courts of Justice
02/01/18 House: Reported from Health, Welfare and Institutions with amendments (18-Y 2-N)
02/01/18 House: Referred to Committee for Courts of Justice
02/06/18 House: Assigned Courts sub: Subcommittee #2

HB 298 Birth control; definition.

Chief patron: Watts

Summary as introduced:
Definition of birth control. Defines "birth control" as contraceptive methods that are approved by the U.S. Food and Drug Administration and provides that birth control shall not be considered abortion for the purposes of Title 18.2.

01/03/18 House: Prefiled and ordered printed; offered 01/10/18 18102477D
01/03/18 House: Referred to Committee for Courts of Justice
01/25/18 House: Assigned Courts sub: Subcommittee #1
01/26/18 House: Subcommittee recommends passing by indefinitely (4-Y 3-N)

HB 363 Sexual orientation change efforts; prohibited as training for certain health care providers, etc.

Chief patron: Hope

Summary as introduced:

Sexual orientation change efforts prohibited. Prohibits any health care provider or person who performs counseling as part of his training for any profession licensed by a regulatory board of the Department of Health Professions from engaging in sexual orientation change efforts with any person under 18 years of age. The bill defines "sexual orientation change efforts" as any practice or treatment that seeks to change an individual's sexual orientation or gender identity, including efforts to change behaviors or gender expressions or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same gender. "Sexual orientation change efforts" does not include counseling that provides assistance to a person undergoing gender transition or counseling that provides acceptance, support, and understanding of a person or facilitates a person's coping, social support, and identity exploration and development, including sexual-orientation-neutral interventions to prevent or address unlawful conduct or unsafe sexual practices, as long as such counseling does not seek to change an individual's sexual orientation or gender identity. The bill provides that no state funds shall be expended for the purpose of conducting sexual orientation change efforts, referring a person for sexual orientation

change efforts, extending health benefits coverage for sexual orientation change efforts, or awarding a grant or contract to any entity that conducts sexual orientation change efforts or refers individuals for sexual orientation change efforts.

01/05/18 House: Prefiled and ordered printed; offered 01/10/18 18100457D
01/05/18 House: Referred to Committee on Health, Welfare and Institutions
01/25/18 House: Assigned HWI sub: Subcommittee #3
02/02/18 House: Subcommittee recommends passing by indefinitely (4-Y 2-N)

HB 621 Cobalt poisoning; notice to patients of risk.

Chief patron: Bell, Robert B.

Summary as introduced:
Notice to patients of risk of cobalt poisoning.

01/08/18 House: Prefiled and ordered printed; offered 01/10/18 18104743D
01/08/18 House: Referred to Committee on Health, Welfare and Institutions
01/17/18 House: Assigned HWI sub: Subcommittee #1
01/18/18 House: Subcommittee recommends continuing to 2019

HB 793 Nurse practitioners; practice agreements.

Chief patron: Robinson

Summary as introduced:
Nurse practitioners; practice agreements. Eliminates the requirement for a practice agreement with a patient care team physician for nurse practitioners who are licensed by the Boards of Medicine and Nursing and have completed at least 1,040 hours of clinical experience as a licensed, certified nurse practitioner. The bill replaces the term "patient care team physician" with the term "collaborating provider" and allows a nurse practitioner who is exempt from the requirement for a practice agreement to enter into a practice agreement to provide collaboration and consultation to a nurse practitioner who is not exempt from the requirement for a practice agreement. The bill establishes title protection for advanced practice registered nurses, nurse practitioners, certified registered nurse anesthetists, certified nurse midwives, and clinical nurse specialists. The bill contains technical amendments.

01/17/18 House: Assigned HWI sub: Subcommittee #1
02/01/18 House: Subcommittee recommends reporting with substitute (9-Y 0-N)
02/06/18 House: Reported from Health, Welfare and Institutions with substitute (17-Y 5-N)
02/06/18 House: Committee substitute printed 18106474D-H1

HB 842 Controlled paraphernalia; possession or distribution, hypodermic needles and syringes, naloxone.

Chief patron: LaRock

Summary as passed House:

Possession or distribution of controlled paraphernalia; hypodermic needles and syringes; naloxone. Provides that a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy may dispense or distribute hypodermic needles and syringes in conjunction with such dispensing of naloxone and that a person to whom naloxone has been distributed by such individual may possess hypodermic needles and syringes in conjunction with such possession of naloxone. The bill also allows the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone. This bill contains an emergency clause.

EMERGENCY

01/31/18 House: Read third time and passed House BLOCK VOTE (99-Y 0-N)
01/31/18 House: VOTE: BLOCK VOTE PASSAGE (99-Y 0-N)
02/01/18 House: Impact statement from DPB (HB842E)
02/01/18 Senate: Constitutional reading dispensed
02/01/18 Senate: Referred to Committee on Education and Health

HB 854 Polysomnographic technology; students or trainees, licensure.

Chief patron: Peace

Summary as introduced:
Practice of polysomnographic technology; licensure; students or trainees. Provides that a student enrolled in an educational program in polysomnographic technology or a person engaged in a traineeship does not require a license to practice polysomnographic technology, provided that such student or trainee is under the direct supervision of a licensed polysomnographic technologist or a licensed doctor of medicine or osteopathic medicine. The bill requires any such student or trainee to be identified to patients as a student or trainee in polysomnographic technology. The bill also provides that any such student or trainee is required to have a license to practice after18 months from the start of the educational program or traineeship or six months from the conclusion of such program or traineeship, whichever is earlier.

01/23/18 House: Assigned HWI sub: Subcommittee #1
01/25/18 House: Subcommittee recommends reporting (10-Y 0-N)
02/01/18 House: Reported from Health, Welfare and Institutions (21-Y 0-N)
02/05/18 House: Read first time
02/06/18 House: Read second time and engrossed

HB 882 Prescribers; notice of administration of naloxone.

Chief patron: Stolle

Summary as introduced:
Prescribers; notice of administration of naloxone. Requires every hospital that operates an emergency department to develop and implement a protocol for (i) identifying every prescriber who has prescribed opioids to a patient to whom naloxone is administered for the purpose of reversing an opioid overdose in the emergency department or by emergency medical services personnel or a law-enforcement officer prior to admission to the emergency department in the twelve month period immediately preceding the administration of naloxone and (ii) notifying each such prescriber that the patient has been treated with naloxone for the purpose of reversing an opioid overdose. Such notification shall be made in each case in which naloxone is administered for the purpose of reversing an opioid overdose by a health care provider in a hospital emergency department, emergency medical services personnel, or a law-enforcement officer to a patient to whom opioids have been prescribed by a prescriber.

01/09/18 House: Prefiled and ordered printed; offered 01/10/18 18102094D
01/09/18 House: Referred to Committee on Health, Welfare and Institutions
01/17/18 House: Assigned HWI sub: Subcommittee #2
01/30/18 House: Subcommittee recommends striking from docket (10-Y 0-N)

HB 915 Military medical personnel program; personnel may practice under supervision of physician, etc.

Chief patron: Stolle

Summary as passed House:

Military medical personnel program; supervision. Directs the Department of Veterans Services to establish a program in which military medical personnel may practice and perform certain delegated acts that constitute the practice of medicine or nursing under the supervision of a licensed physician or podiatrist or the chief medical officer of an organization participating in such program, or his designee who is licensed by the Board of Medicine and supervising within his scope of practice. The bill allows the chief medical officer of an organization participating in such program to, in consultation with the chief nursing officer of such organization, designate a registered nurse licensed by the Board of Nursing or practicing with a multistate licensure privilege to supervise military personnel participating in such program while engaged in the practice of nursing.

01/31/18 House: Read third time and passed House BLOCK VOTE (99-Y 0-N)
01/31/18 House: VOTE: BLOCK VOTE PASSAGE (99-Y 0-N)
02/01/18 Senate: Constitutional reading dispensed
02/01/18 Senate: Referred to Committee on Education and Health

HB 1037 Abortions; performance, eliminates certain requirement.

Chief patron: Convirs-Fowler

Summary as introduced:
Performance of abortions. Eliminates the requirement that two other physicians certify that a third trimester abortion is necessary to prevent the woman's death or impairment of her mental or physical health.

01/09/18 House: Referred to Committee for Courts of Justice
01/25/18 House: Assigned Courts sub: Subcommittee #1
01/26/18 House: Subcommittee recommends passing by indefinitely (4-Y 3-N)

HB 1064 Medical marijuana; written certification issued by physician.

Chief patron: Heretick

Summary as introduced:
Medical marijuana; written certification. Allows a person to possess marijuana or tetrahydrocannabinol pursuant to a valid written certification issued by a physician for the treatment of any medical condition and allows a physician or pharmacist to distribute such substances without being subject to prosecution. Under current law, a person has an affirmative defense to prosecution for possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil and the person has been issued a written certification by a physician that such marijuana is for the purposes of treating or alleviating the person's symptoms of intractable epilepsy. The bill expands the authority for a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy and under the supervision of a licensed pharmacist, to manufacture and provide marijuana in any form to be used for the treatment of any medical condition, not just marijuana in the form of cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. Finally, the bill clarifies that the penalties for forging or altering a written certification for medical marijuana or for making or uttering a false or forged written certification are the same as the penalties for committing the same acts with regard to prescriptions.

01/10/18 House: Prefiled and ordered printed; offered 01/10/18 18102811D
01/10/18 House: Referred to Committee for Courts of Justice
01/11/18 House: Impact statement from VCSC (HB1064)

HB 1071 Health regulatory boards; electronic notice of license renewal.

Chief patron: Heretick

Summary as passed House:

Health regulatory boards; license renewal; electronic notice. Provides that the Board of Funeral Directors and Embalmers, the Board of Medicine, and the Board of Nursing may send notices for license renewal electronically.

01/31/18 House: Read third time and passed House BLOCK VOTE (99-Y 0-N)
01/31/18 House: VOTE: BLOCK VOTE PASSAGE (99-Y 0-N)
02/01/18 Senate: Referred to Committee on Education and Health

HB 1182 Perinatal hospice and palliative care; notice to woman of agencies.

Chief patron: LaRock

Summary as introduced:
Perinatal hospice and palliative care; notice. Requires every health care provider that diagnoses a fetus with a profound and irremediable congenital or chromosomal anomaly that is incompatible with sustaining life after birth to provide the pregnant women with geographically indexed materials prepared by the Department of Health that are designed to inform the woman of public and private agencies providing perinatal hospice and palliative care services available to the woman if she chooses to continue the pregnancy, and requires the Department of Health to make such information available both to health care providers and on a website maintained by the Department. The bill also requires health care providers to annually report data and information about cases in which information regarding perinatal hospice and palliative care services is provided.

01/10/18 House: Prefiled and ordered printed; offered 01/10/18 18104416D
01/10/18 House: Referred to Committee on Rules

HB 1194 Schedule I controlled substances; adds various drugs to list.

Chief patron: Garrett

Summary as introduced:
Schedule I controlled substances. Adds drugs to the list of Schedule I controlled substances.

01/30/18 House: Read second time and engrossed
01/31/18 House: Read third time and passed House BLOCK VOTE (99-Y 0-N)
01/31/18 House: VOTE: BLOCK VOTE PASSAGE (99-Y 0-N)
02/01/18 Senate: Referred to Committee on Education and Health

HB 1251 CBD oil and THC-A oil; certification for use, dispensing.

Chief patron: Cline

Summary as passed House:

CBD oil and THC-A oil; certification for use; dispensing. Provides that a practitioner may issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. The bill increases the supply of

CBD oil or THC-A oil a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply. The bill reduces the minimum amount of cannabidiol or tetrahydrocannabinol acid per milliliter for a dilution of the Cannabis plant to fall under the definition of CBD oil or THC-A oil, respectively. As introduced, this bill was a recommendation of the Joint Commission on Health Care.

02/02/18 House: Read third time and passed House (98-Y 0-N)
02/02/18 House: VOTE: PASSAGE (98-Y 0-N)
02/05/18 Senate: Constitutional reading dispensed
02/05/18 Senate: Referred to Committee on Education and Health

HB 1377 Epinephrine; possession and administration at outdoor educational programs.

Chief patron: Torian

Summary as introduced:
Possession and administration of epinephrine; outdoor educational programs. Provides that an employee of an organization that provides outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

01/30/18 House: Subcommittee recommends reporting (10-Y 0-N)
02/01/18 House: Reported from Health, Welfare and Institutions (21-Y 0-N)
02/05/18 House: Read first time
02/06/18 House: Read second time and engrossed

HB 1378 Surgical assistants; renewal of registration.

Chief patron: Robinson

Summary as introduced:
Registration of surgical assistants; renewal of registration. Requires proof of a current credential as a surgical assistant or surgical first assistant issued by the National Board of Surgical Technology and Surgical Assisting, the National Surgical Assistant Association, or the National Commission for the Certification of Surgical Assistants or their successors for renewal of registration as a surgical assistant.

01/12/18 House: Referred to Committee on Health, Welfare and Institutions
01/19/18 House: Assigned HWI sub: Subcommittee #1
02/01/18 House: Subcommittee recommends reporting with amendments (9-Y 0-N)
02/06/18 House: Reported from Health, Welfare and Institutions with amendments (22-Y 0-N)

HB 1440 Schedule I and Schedule II drugs; adds various drugs to lists.

Chief patron: Garrett

Summary as introduced:

Schedule I and Schedule II drugs. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I of the Drug Control Act and Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II of the Drug Control Act and removes naldemedine from Schedule II of the Drug Control Act.

01/17/18 House: Impact statement from VCSC (HB1440)
01/25/18 House: Reported from Health, Welfare and Institutions (22-Y 0-N)
01/25/18 House: Referred to Committee on Appropriations
01/29/18 House: Assigned App. sub: Public Safety

HB 1510 Professions & occupations; recognizing licenses/certificates issued by Commonwealth of Puerto Rico.

Chief patron: Simon

Summary as introduced:
Professions and occupations; reciprocity. Directs the Department of Professional and Occupational Regulation and the Department of Health Professions to promulgate regulations recognizing licenses or certificates issued by the Commonwealth of Puerto Rico as full fulfillment of qualifications for licensure or certification in the Commonwealth. The provisions of the bill expire on July 1, 2021.

01/30/18 House: Impact statement from DPB (HB1510)
02/01/18 House: Subcommittee recommends reporting (8-Y 0-N)
02/01/18 House: Subcommittee recommends referring to Committee on Appropriations
02/06/18 House: Reported from General Laws (22-Y 0-N)
02/06/18 House: Referred to Committee on Appropriations

HB 1524 Medicine, Board of; regulations related to retention of patient records, minimum time for retention.

Chief patron: Ingram

Summary as introduced:
Board of Medicine; regulations related to retention of patient records; time. Directs the Board of Medicine to amend regulations governing retention of patient records by health practitioners to require health care providers to maintain patient records (i) for a minimum of 10 years from the date the record was created for an adult patient and (ii) until the patient reaches the age of 18 or becomes emancipated, with a minimum time for record retention of 10 years from the date the record was created, for records of a minor child patient. Currently, patient records must be maintained (a) for a minimum of six years from the date of the last patient encounter for adult patients and (b) until the patient reaches the age of 18 or becomes

emancipated, with a minimum time for record retention of six years from the date of the last patient encounter, for minor child patients.

01/19/18 House: Referred to Committee on Health, Welfare and Institutions
01/22/18 House: Assigned HWI sub: Subcommittee #1
02/06/18 House: Reported from Health, Welfare and Institutions with substitute (22-Y 0-N)
02/06/18 House: Committee substitute printed 18106681D-H1

SB 293 Controlled substances and devices, certain; Board of Pharmacy may issue limited license to dispense.

Chief patron: McClellan

Summary as introduced:
Dispensing of certain controlled substances and devices. Authorizes a prescriber to dispense controlled substances and devices without obtaining a license from the Board of Pharmacy, provided that such controlled substances and devices have been prescribed for the purposes of reproductive health and are dispensed in good faith within the course of his professional practice. The bill provides that facilities from which prescribers dispense only such controlled substances and devices are not required to obtain a permit from the Board. The bill requires the Board to establish a list of controlled substances and devices that may be so dispensed that includes controlled substances and devices used for contraception, maternal health, hormone replacement therapy, and sexually transmitted and reproductive tract infections.

02/05/18 Senate: Engrossed by Senate - committee substitute SB293S1
02/06/18 Senate: Read third time and passed Senate (35-Y 5-N)
02/06/18 Senate: Reconsideration of passage agreed to by Senate (39-Y 0-N)
02/06/18 Senate: Passed Senate (35-Y 4-N)

SB 330 THC-A oil; dispensing, tetrahydrocannabinol levels.

Chief patron: Dunnavant

Summary as introduced:
THC-A oil; dispensing. Requires the Board of Pharmacy to promulgate regulations that (i) ensure the percentage of tetrahydrocannabinol in dispensed THC-A oil is within 10 percent of the level of tetrahydrocannabinol measured for labeling and (ii) require stability testing of any pharmaceutical processor producing THC-A oil.

01/17/18 Senate: Read third time and passed Senate (40-Y 0-N)
01/23/18 House: Placed on Calendar
01/23/18 House: Read first time
01/23/18 House: Referred to Committee on Health, Welfare and Institutions

SB 357 Death certificates; electronic filing required.

Chief patron: McClellan

Summary as introduced:
Death certificates; electronic filing required. Requires a death certificate, for each death that occurs in the Commonwealth, to be electronically filed with the State Registrar. Under current law, death certificates may be filed electronically or nonelectronically.

01/08/18 Senate: Prefiled and ordered printed; offered 01/10/18 18102472D
01/08/18 Senate: Referred to Committee on Education and Health
01/16/18 Senate: Assigned Education sub: Health
02/01/18 Senate: Continued to 2019 in Education and Health (15-Y 0-N)

SB 436 Schedule I drugs; classification for fentanyl derivatives.

Chief patron: Wexton

Summary as introduced:
Schedule I drugs; classification for fentanyl derivatives. Adds to Schedule I of the Drug Control Act a classification for fentanyl derivatives.

01/09/18 Senate: Referred to Committee on Education and Health
01/11/18 Senate: Impact statement from VCSC (SB436)
01/25/18 Senate: Reported from Education and Health (15-Y 0-N)
01/25/18 Senate: Rereferred to Finance
01/31/18 Senate: Continued to 2019 in Finance (15-Y 0-N)

SB 505 Doctorate of medical science; establishes requirements for licensure and practice.

Chief patron: Carrico

Summary as introduced:

Doctorate of medical science; licensure and practice. Establishes requirements for licensure and practice as a doctorate of medical science. The bill provides that it is unlawful to practice as a doctorate of medical science unless licensed by the Board of Medicine (Board) and requires that an applicant for licensure, among other requirements, (i) hold an active unrestricted license to practice as a physician assistant in the Commonwealth or another jurisdiction and be able to demonstrate engagement in active clinical practice as a physician assistant under physician supervision for at least three years and (ii) be a graduate of at least a two-year doctor of medical science program or an equivalent program that is accredited by a regional body under the U.S Department of Education and an accrediting body approved by the Board. The bill provides that doctorates of medical science can practice only as part of a patient care team at a hospital or group medical practice engaged in primary care and are required to maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician. The bill requires the Board to establish the scope of practice for doctorates of medical science and to promulgate regulations regarding collaboration

and consultation among a patient care team and requirements for the practice agreement. The bill outlines the prescriptive authority of doctorates of medical science. The bill also authorizes various powers and requires various duties of a doctorate of medical science where such powers and duties are, under current law, given to and required of physician assistants and nurse practitioners.

01/09/18 Senate: Prefiled and ordered printed; offered 01/10/18 18103047D
01/09/18 Senate: Referred to Committee on Education and Health
02/02/18 Senate: Assigned Education sub: Health Professions

SB 511 Optometry; scope of practice.

Chief patron: Suetterlein

Summary as introduced:
Optometry; scope of practice. Provides that the practice of optometry includes the evaluation, examination, diagnosis, and treatment of abnormal or diseased conditions of the human eye and its adnexa by the use of medically recognized and appropriate devices, procedures, or technologies but that it does not include treatment by laser surgery; treatment by surgery except for treatment of styes, chalazia, or anterior segment lesions that does not require the use of general anesthesia or sutures; or the use of injections, including venipuncture and intravenous injections, except for certain injections by TPA-certified optometrists and for the treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

01/29/18 Senate: Engrossed by Senate - committee substitute SB511S1
01/30/18 Senate: Read third time and passed Senate (38-Y 0-N)
02/05/18 House: Placed on Calendar
02/05/18 House: Read first time
02/05/18 House: Referred to Committee on Health, Welfare and Institutions

SB 544 Prescription drugs; donation of used medicines.

Chief patron: Obenshain

Summary as introduced:
Prescription drug donation program. Requires that the existing prescription drug donation program regulated by the Board of Pharmacy accept eligible unused drugs from individuals, manufacturers, nursing homes, assisted living facilities, intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services. The bill also provides that pharmacies may re-dispense such drugs to the indigent. Under the current program, only hospitals and indigent care clinics may re-dispense such drugs to the indigent. The bill also provides liability protection for those who donate, accept, and dispense such unused drugs.

02/05/18 House: Placed on Calendar

02/05/18 House: Read first time
02/05/18 House: Referred to Committee on Health, Welfare and Institutions

SB 632 Controlled substances; limits on prescriptions containing opioids.

Chief patron: Dunnavant

Summary as introduced:
Limits on prescription of controlled substances containing opioids. Eliminates the surgical or invasive procedure treatment exception to the requirement that a prescriber request certain information from the Prescription Monitoring Program (PMP) when initiating a new course of treatment that includes prescribing opioids for a human patient to last more than seven days. Under current law, a prescriber is not required to request certain information from the PMP for opioid prescriptions of up to 14 days to a patient as part of treatment for a surgical or invasive procedure. The provisions of the bill will expire on July 1, 2022.

01/30/18 Senate: Read third time and passed Senate (39-Y 0-N)
02/05/18 House: Placed on Calendar
02/05/18 House: Read first time
02/05/18 House: Referred to Committee on Health, Welfare and Institutions

SB 726 CBD oil and THC-A oil; certification for use, dispensing.

Chief patron: Dunnavant

Summary as introduced:
CBD oil and THC-A oil; certification for use; dispensing. Provides that a practitioner may issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. This bill is a recommendation of the Joint Commission on Health Care.

02/02/18 Senate: Reading of substitute waived
02/02/18 Senate: Committee substitute agreed to 18106272D-S2
02/02/18 Senate: Engrossed by Senate - committee substitute SB726S2
02/05/18 Senate: Read third time and passed Senate (40-Y 0-N)

SB 728 Prescription Monitoring Program; prescriber and dispenser patterns.

Chief patron: Dunnavant

Summary as introduced:
Prescription Monitoring Program; prescriber and dispenser patterns. Requires the Director of the Department of Health Professions to annually review controlled substance prescribing and dispensing patterns. The bill requires the Director to conduct such review in consultation with an

advisory panel consisting of representatives from the relevant health regulatory boards, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services. The bill requires the Director to make any necessary changes to the criteria for unusual patterns of prescribing and dispensing and report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year.

01/29/18 Senate: Engrossed by Senate - committee substitute SB728S1
01/30/18 Senate: Read third time and passed Senate (39-Y 0-N)
02/05/18 House: Read first time
02/05/18 House: Referred to Committee on Health, Welfare and Institutions

SB 832 Prescription Monitoring Program; adds controlled substances included in Schedule Vaud naloxone.

Chief patron: Carrico

Summary as introduced:
Prescription Monitoring Program; covered substances. Adds controlled substances included in Schedule V for which a prescription is required and naloxone to the list of covered substances the dispensing of which must be reported to the Prescription Monitoring Program.

01/15/18 Senate: Presented and ordered printed 18101582D
01/15/18 Senate: Referred to Committee on Education and Health
02/02/18 Senate: Assigned Education sub: Health Professions

SB 882 Prescription refill; protocol.

Chief patron: DeSteph

Summary as introduced:
Prescription refill; protocol. Provides that a prescriber may authorize a registered nurse or licensed practical nurse to initiate a protocol for a prescription refill for Schedule VI controlled substances, provided that (i) the practitioner has established a bona-fide practitioner-patient relationship with the individual to receive the refill provided; (ii) there is a standing protocol written and maintained by the prescriber; (iii) there is a written order by the prescriber for the registered nurse or licensed practical nurse to initiate the protocol; (iv) the prescription refill is for a maintenance medication prescribed for chronic, long-term conditions and the medication is taken on a regular, recurring basis; (v) the prescription refill is for no more than 90 consecutive days; (vi) documentation sufficient to the Board of Pharmacy is maintained; and (vii) other requirements established by the Board of Pharmacy are met.

02/05/18 Senate: Read second time
02/05/18 Senate: Committee substitute agreed to 18106481D-S1
02/05/18 Senate: Engrossed by Senate - committee substitute SB882S1
02/06/18 Senate: Read third time and passed Senate (40-Y 0-N)

2018 SESSION

HOUSE SUBSTITUTE

18106681D

HOUSE BILL NO. 1524

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on February 6, 2018)

(Patron Prior to Substitute—Delegate Ingram)

A BILL to direct the Board of Medicine to amend regulations related to retention of patient records; time.

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That any health care provider that provides professional services in a family medical practice with locations in the Cities of Colonial Heights and Hopewell that has provided health care services since 1955 and currently maintains all records created since May 2006 in electronic format and all records of current patients created prior to May 2006 in paper format may destroy paper versions of records created prior to May 2006 other than paper records of patients who have not yet reached the age of 18 and shall not be subject to disciplinary action for such action. Paper records of patients who have not yet reached the age of 18 shall be maintained until such time as the patient reaches the age of 18.*

18106474D

HOUSE BILL NO. 793

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on February 6, 2018)

(Patron Prior to Substitute—Delegate Robinson)

A BILL to amend and reenact §§ 22.1-271.7, 32.1-263, 32.1-282, 54.1-2901, 54.1-2903, 54.1-2957, 54.1-2957.01, 54.1-3016, 54.1-3300, 54.1-3300.1, 54.1-3301, 54.1-3482, and 54.1-3482.1 of the Code of Virginia, relating to nurse practitioners; practice agreements.

Be it enacted by the General Assembly of Virginia:

1. That §§ 22.1-271.7, 32.1-263, 32.1-282, 54.1-2901, 54.1-2903, 54.1-2957, 54.1-2957.01, 54.1-3016, 54.1-3300, 54.1-3300.1, 54.1-3301, 54.1-3482, and 54.1-3482.1 of the Code of Virginia are amended and reenacted as follows:

§ 22.1-271.7. Public middle school student-athletes; pre-participation physical examination.

No public middle school student shall be a participant on or try out for any school athletic team or squad with a predetermined roster, regular practices, and scheduled competitions with other middle schools unless such student has submitted to the school principal a signed report from a licensed physician, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician attesting that such student has been examined, within the preceding 12 months, and found to be physically fit for athletic competition.

§ 32.1-263. Filing death certificates; medical certification; investigation by Office of the Chief Medical Examiner.

A. A death certificate, including, if known, the social security number or control number issued by the Department of Motor Vehicles pursuant to § 46.2-342 of the deceased, shall be filed for each death that occurs in the Commonwealth. Non-electronically filed death certificates shall be filed with the registrar of any district in the Commonwealth within three days after such death and prior to final disposition or removal of the body from the Commonwealth. Electronically filed death certificates shall be filed with the State Registrar of Vital Records within three days after such death and prior to final disposition or removal of the body from the Commonwealth. Any death certificate shall be registered by such registrar if it has been completed and filed in accordance with the following requirements:

1. If the place of death is unknown, but the dead body is found in the Commonwealth, the death shall be registered in the Commonwealth and the place where the dead body is found shall be shown as the place of death. If the date of death is unknown, it shall be determined by approximation, taking into consideration all relevant information, including information provided by the immediate family regarding the date and time that the deceased was last seen alive, if the individual died in his home; and

2. When death occurs in a moving conveyance, in the United States of America and the body is first removed from the conveyance in the Commonwealth, the death shall be registered in the Commonwealth and the place where it is first removed shall be considered the place of death. When a death occurs on a moving conveyance while in international waters or air space or in a foreign country or its air space and the body is first removed from the conveyance in the Commonwealth, the death shall be registered in the Commonwealth but the certificate shall show the actual place of death insofar as can be determined.

B. The licensed funeral director, funeral service licensee, office of the state anatomical program, or next of kin as defined in § 54.1-2800 who first assumes custody of a dead body shall file the certificate of death with the registrar. He shall obtain the personal data, including the social security number of the deceased or control number issued to the deceased by the Department of Motor Vehicles pursuant to § 46.2-342, from the next of kin or the best qualified person or source available and obtain the medical certification from the person responsible therefor.

C. The medical certification shall be completed, signed in black or dark blue ink, and returned to the funeral director within 24 hours after death by the physician in charge of the patient's care for the illness or condition which resulted in death except when inquiry or investigation by the Office of the Chief Medical Examiner is required by § 32.1-283 or 32.1-285.1, or by the physician that pronounces death pursuant to § 54.1-2972.

In the absence of such physician or with his approval, the certificate may be completed and signed by the following: (i) another physician employed or engaged by the same professional practice; (ii) a physician assistant supervised by such physician; (iii) a nurse practitioner practicing ~~as part of a patient care team as defined in § 54.1-2900~~ *in accordance with the provisions of § 54.1-2957*; (iv) the chief medical officer or medical director, or his designee, of the institution, hospice, or nursing home in which death occurred; (v) a physician specializing in the delivery of health care to hospitalized or emergency department patients who is employed by or engaged by the facility where the death occurred; (vi) the

physician who performed an autopsy upon the decedent; or (vii) an individual to whom the physician has delegated authority to complete and sign the certificate, if such individual has access to the medical history of the case and death is due to natural causes.

D. When inquiry or investigation by the Office of the Chief Medical Examiner is required by § 32.1-283 or 32.1-285.1, the Chief Medical Examiner shall cause an investigation of the cause of death to be made and the medical certification portion of the death certificate to be completed and signed within 24 hours after being notified of the death. If the Office of the Chief Medical Examiner refuses jurisdiction, the physician last furnishing medical care to the deceased shall prepare and sign the medical certification portion of the death certificate.

E. If the death is a natural death and a death certificate is being prepared pursuant to § 54.1-2972 and the physician, nurse practitioner, or physician assistant is uncertain about the cause of death, he shall use his best medical judgment to certify a reasonable cause of death or contact the health district physician director in the district where the death occurred to obtain guidance in reaching a determination as to a cause of death and document the same.

If the cause of death cannot be determined within 24 hours after death, the medical certification shall be completed as provided by regulations of the Board. The attending physician or the Chief Medical Examiner, an Assistant Chief Medical Examiner, or a medical examiner appointed pursuant to § 32.1-282 shall give the funeral director or person acting as such notice of the reason for the delay, and final disposition of the body shall not be made until authorized by the attending physician, the Chief Medical Examiner, an Assistant Chief Medical Examiner, or a medical examiner appointed pursuant to § 32.1-282.

F. A physician, nurse practitioner, or physician assistant who, in good faith, signs a certificate of death or determines the cause of death shall be immune from civil liability, only for such signature and determination of causes of death on such certificate, absent gross negligence or willful misconduct.

§ 32.1-282. Medical examiners.

A. The Chief Medical Examiner may appoint for each county and city one or more medical examiners, who shall be licensed as a doctor of medicine or osteopathic medicine, a physician assistant, or a nurse practitioner in the Commonwealth and appointed as agents of the Commonwealth, to assist the Office of the Chief Medical Examiner with medicolegal death investigations. A physician assistant appointed as a medical examiner shall have a practice agreement with and be under the continuous supervision of a physician medical examiner in accordance with § 54.1-2952. A nurse practitioner appointed as a medical examiner shall ~~have a practice agreement with and~~ practice ~~in collaboration with a physician medical examiner~~ in accordance with § 54.1-2957.

B. At the request of the Chief Medical Examiner, the Assistant Chief Medical Examiner, or their designees, medical examiners may assist the Office of the Chief Medical Examiner with cases requiring medicolegal death investigations in accordance with § 32.1-283.

C. The term of each medical examiner appointed, other than an appointment to fill a vacancy, shall begin on the first day of October of the year of appointment. The term of each medical examiner shall be three years; however, an appointment to fill a vacancy shall be for the unexpired term.

§ 54.1-2901. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;

2. Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;

3. Any licensed nurse practitioner from rendering care in ~~collaboration and consultation with a patient care team physician as part of a patient care team pursuant to~~ § *accordance with the provisions of §§* 54.1-2957 *and 54.1-2957.01* or any nurse practitioner licensed by the Boards of ~~Nursing and~~ Medicine *and Nursing* in the category of certified nurse midwife practicing pursuant to subsection H of § 54.1-2957 when such services are authorized by regulations promulgated jointly by the ~~Board~~ *Boards* of Medicine and ~~the Board of~~ Nursing;

4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine or osteopathy, a nurse practitioner, or a physician assistant;

5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;

6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by

practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;

7. The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state, or from a licensed nurse practitioner, to emergency medical personnel acting in an emergency situation;

8. The domestic administration of family remedies;

9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;

10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

11. The advertising or sale of commercial appliances or remedies;

12. The fitting by nonitinerant persons or manufacturers of artificial eyes, limbs or other apparatus or appliances or the fitting of plaster cast counterparts of deformed portions of the body by a nonitinerant bracemaker or prosthetist for the purpose of having a three-dimensional record of the deformity, when such bracemaker or prosthetist has received a prescription from a licensed physician, licensed nurse practitioner, or licensed physician assistant directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;

13. Any person from the rendering of first aid or medical assistance in an emergency in the absence of a person licensed to practice medicine or osteopathy under the provisions of this chapter;

14. The practice of the religious tenets of any church in the ministration to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;

15. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary authorization by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while participating in continuing educational programs prescribed by the Board, or (iii) by rendering at any site any health care services within the limits of his license, voluntarily and without compensation, to any patient of any clinic which is organized in whole or in part for the delivery of health care services without charge as provided in § 54.1-106;

17. The performance of the duties of any active duty health care provider in active service in the army, navy, coast guard, marine corps, air force, or public health service of the United States at any public or private health care facility while such individual is so commissioned or serving and in accordance with his official military duties;

18. Any masseur, who publicly represents himself as such, from performing services within the scope of his usual professional activities and in conformance with state law;

19. Any person from performing services in the lawful conduct of his particular profession or business under state law;

20. Any person from rendering emergency care pursuant to the provisions of § 8.01-225;

21. Qualified emergency medical services personnel, when acting within the scope of their certification, and licensed health care practitioners, when acting within their scope of practice, from following Durable Do Not Resuscitate Orders issued in accordance with § 54.1-2987.1 and Board of Health regulations, or licensed health care practitioners from following any other written order of a physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

22. Any commissioned or contract medical officer of the army, navy, coast guard or air force rendering services voluntarily and without compensation while deemed to be licensed pursuant to § 54.1-106;

23. Any provider of a chemical dependency treatment program who is certified as an "acupuncture detoxification specialist" by the National Acupuncture Detoxification Association or an equivalent certifying body, from administering auricular acupuncture treatment under the appropriate supervision of a National Acupuncture Detoxification Association certified licensed physician or licensed acupuncturist;

24. Any employee of any assisted living facility who is certified in cardiopulmonary resuscitation (CPR) acting in compliance with the patient's individualized service plan and with the written order of the attending physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

25. Any person working as a health assistant under the direction of a licensed medical or osteopathic doctor within the Department of Corrections, the Department of Juvenile Justice or local correctional facilities;

26. Any employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, when, upon the authorization of a prescriber and the written request of the parents as defined in § 22.1-1, assisting with the administration of insulin or administrating glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia;

27. Any practitioner of the healing arts or other profession regulated by the Board from rendering free health care to an underserved population of Virginia who (i) does not regularly practice his profession in Virginia, (ii) holds a current valid license or certificate to practice his profession in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of the Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any practitioner of the healing arts whose license or certificate has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a practitioner of the healing arts who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state;

28. Any registered nurse, acting as an agent of the Department of Health, from obtaining specimens of sputum or other bodily fluid from persons in whom the diagnosis of active tuberculosis disease, as defined in § 32.1-49.1, is suspected and submitting orders for testing of such specimens to the Division of Consolidated Laboratories or other public health laboratories, designated by the State Health Commissioner, for the purpose of determining the presence or absence of tubercle bacilli as defined in § 32.1-49.1;

29. Any physician of medicine or osteopathy or nurse practitioner from delegating to a registered nurse under his supervision the screening and testing of children for elevated blood-lead levels when such testing is conducted (i) in accordance with a written protocol between the physician or nurse practitioner and the registered nurse and (ii) in compliance with the Board of Health's regulations promulgated pursuant to §§ 32.1-46.1 and 32.1-46.2. Any follow-up testing or treatment shall be conducted at the direction of a physician or nurse practitioner;

30. Any practitioner of one of the professions regulated by the Board of Medicine who is in good standing with the applicable regulatory agency in another state or Canada from engaging in the practice of that profession when the practitioner is in Virginia temporarily with an out-of-state athletic team or athlete for the duration of the athletic tournament, game, or event in which the team or athlete is competing;

31. Any person from performing state or federally funded health care tasks directed by the consumer, which are typically self-performed, for an individual who lives in a private residence and who, by reason of disability, is unable to perform such tasks but who is capable of directing the appropriate performance of such tasks; or

32. Any practitioner of one of the professions regulated by the Board of Medicine who is in good standing with the applicable regulatory agency in another state from engaging in the practice of that profession in Virginia with a patient who is being transported to or from a Virginia hospital for care.

B. Notwithstanding any provision of law or regulation to the contrary, military medical personnel, as defined in § 2.2-2001.4, while participating in a pilot program established by the Department of Veterans Services pursuant to § 2.2-2001.4, may practice under the supervision of a licensed physician or podiatrist.

§ 54.1-2903. What constitutes practice.

Any person shall be regarded as practicing the healing arts who actually engages in such practice as defined in this chapter, or who opens an office for such purpose, or who advertises or announces to the public in any manner a readiness to practice or who uses in connection with his name the words or letters "Doctor," "Dr.," "M.D.," "D.O.," "D.P.M.," "D.C.," "Healer," *"N.P, "NP,"* or any other title, word, letter or designation intending to designate or imply that he is a practitioner of the healing arts or that he is able to heal, cure or relieve those suffering from any injury, deformity or disease. No person regulated under this chapter shall use the title "Doctor" or the abbreviation "Dr." in writing or in advertising in connection with his practice unless he simultaneously uses a clarifying title, initials, abbreviation or designation or language that identifies the type of practice for which he is licensed.

Signing a birth or death certificate, or signing any statement certifying that the person so signing has rendered professional service to the sick or injured, or signing or issuing a prescription for drugs or

other remedial agents, shall be prima facie evidence that the person signing or issuing such writing is practicing the healing arts within the meaning of this chapter except where persons other than physicians are required to sign birth certificates.

§ 54.1-2957. Licensure and practice of nurse practitioners.

A. As used in this section:

"Clinical experience" means the postgraduate delivery of health care directly to patients pursuant to a practice agreement with a patient care team physician.

"Collaboration" means the communication and decision-making process among *a nurse practitioner, patient care team physician, and other health care providers who are* members of a patient care team related to the treatment *that includes the degree of cooperation necessary to provide treatment* and care of a patient and includes (i) communication of data and information about the treatment and care of a patient, including exchange of clinical observations and assessments, and (ii) development of an appropriate plan of care, including decisions regarding the health care provided, accessing and assessment of appropriate additional resources or expertise, and arrangement of appropriate referrals, testing, or studies.

"Consultation" means the communicating of data and information, exchanging of clinical observations and assessments, accessing and assessing of additional resources and expertise, problem-solving, and arranging for referrals, testing, or studies.

B. The Board of Medicine and the Board of Nursing shall jointly prescribe the regulations governing the licensure of nurse practitioners. It ~~shall be~~ *is* unlawful for a person to practice as a nurse practitioner in the Commonwealth unless he holds such a joint license.

C. ~~Except as provided in subsection H, a~~ *Every* nurse practitioner ~~shall only practice as part of a patient care team. Each member of a patient care team shall have specific responsibilities related to the care of the patient or patients and shall provide health care services within the scope of his usual professional activities. Nurse practitioners practicing as part of a patient care team~~ *other than a nurse practitioner licensed by the Boards of Medicine and Nursing as a certified nurse midwife or a certified registered nurse anesthetist or a nurse practitioner who meets the requirements of subsection I* shall maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician. ~~Nurse practitioners~~ *A nurse practitioner who meets the requirements of subsection I may practice without a written or electronic practice agreement. A nurse practitioner who is licensed by the Boards of Medicine and Nursing as a certified nurse midwife shall practice pursuant to subsection H. A nurse practitioner* who ~~are~~ *is a* certified registered nurse anesthetists shall practice under the supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry. ~~Nurse practitioners~~*A nurse practitioner who is* appointed as *a* medical examiners pursuant to § 32.1-282 shall practice in collaboration with a licensed doctor of medicine or osteopathic medicine who has been appointed to serve as a medical examiner pursuant to § 32.1-282. Collaboration and consultation among nurse practitioners and patient care team physicians may be provided through telemedicine as described in § 38.2-3418.16. Practice of patient care teams in all settings shall include the periodic review of patient charts or electronic health records and may include visits to the site where health care is delivered in the manner and at the frequency determined by the patient care team.

Physicians on patient care teams may require that a nurse practitioner be covered by a professional liability insurance policy with limits equal to the current limitation on damages set forth in § 8.01-581.15.

Service on a patient care team by a patient care team member shall not, by the existence of such service alone, establish or create liability for the actions or inactions of other team members.

D. The ~~Board~~ *Boards* of Medicine and ~~the Board of~~ Nursing shall jointly promulgate regulations specifying collaboration and consultation among physicians and nurse practitioners working as part of patient care teams that shall include the development of, and periodic review and revision of, a written or electronic practice agreement; guidelines for availability and ongoing communications that define consultation among the collaborating parties and the patient; and periodic joint evaluation of the services delivered. Practice agreements shall include ~~a provision~~ *provisions* for ~~appropriate physician~~ *(i) periodic review of health records, which may include visits to the site where health care is delivered, in the manner and at the frequency determined by the nurse practitioner and the patient care team physician and (ii)* input *from appropriate health care providers* in complex clinical cases and patient emergencies and for referrals. Evidence of a practice agreement shall be maintained by a nurse practitioner and provided to the Boards upon request. For nurse practitioners providing care to patients within a hospital or health care system, the practice agreement may be included as part of documents delineating the nurse practitioner's clinical privileges or the electronic or written delineation of duties and responsibilities in collaboration and consultation with a patient care team physician.

E. The Boards *of Medicine and Nursing* may issue a license by endorsement to an applicant to practice as a nurse practitioner if the applicant has been licensed as a nurse practitioner under the laws

of another state and, ~~in the opinion~~ *pursuant to regulations* of the Boards, the applicant meets the qualifications for licensure required of nurse practitioners in the Commonwealth. *The Boards may issue a license by endorsement to an applicant to practice as a nurse practitioner pursuant to subsection I only if such application includes an attestation that the applicant has completed the equivalent requirements of subsection I.*

F. Pending the outcome of the next National Specialty Examination, the Boards may jointly grant temporary licensure to nurse practitioners.

G. In the event a physician who is serving as a patient care team physician dies, becomes disabled, retires from active practice, surrenders his license or has it suspended or revoked by the Board, or relocates his practice such that he is no longer able to serve, and a nurse practitioner is unable to enter into a new practice agreement with another patient care team physician, the nurse practitioner may continue to practice upon notification to the designee or his alternate of the Boards and receipt of such notification. Such nurse practitioner may continue to treat patients without a patient care team physician for an initial period not to exceed 60 days, provided the nurse practitioner continues to prescribe only those drugs previously authorized by the practice agreement with such physician and to have access to appropriate ~~physician~~ input *from appropriate health care providers* in complex clinical cases and patient emergencies and for referrals. The designee or his alternate of the Boards shall grant permission for the nurse practitioner to continue practice under this subsection for another 60 days, provided the nurse practitioner provides evidence of efforts made to secure another patient care team physician and of access to physician input.

H. Nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife shall practice in consultation with a licensed physician in accordance with a practice agreement between the nurse practitioner and the licensed physician. Such practice agreement shall address the availability of the physician for routine and urgent consultation on patient care. Evidence of a practice agreement shall be maintained by a nurse practitioner and provided to the Boards upon request. The Boards shall jointly promulgate regulations, consistent with the Standards for the Practice of Midwifery set by the American College of Nurse-Midwives, governing such practice.

I. A nurse practitioner, other than a nurse practitioner licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife or certified registered nurse anesthetist, who has (i) been issued a license to practice as a nurse practitioner from the Boards, (ii) graduated from a nurse practitioner educational program accredited by the Commission on Collegiate Nursing Education, and (iii) completed at least five years of full-time clinical experience as a licensed nurse practitioner in the specialty practice category in which he is certified and for which he is licensed by the Boards may practice in the specialty practice category in which he is certified and licensed without a written or electronic practice agreement with a patient care team physician upon receipt by the nurse practitioner of an attestation from the patient care team physician stating that (a) the patient care team physician routinely practices in the same specialty practice category for which the nurse practitioner is certified and licensed and in which the nurse practitioner has practiced and (b) the nurse practitioner meets the requirements of this subsection. A copy of such attestation shall be submitted to the Boards together with a fee established by the Boards. Upon receipt of such attestation and verification that a nurse practitioner satisfies the requirements of this subsection, the Boards shall issue to the nurse practitioner a new license that includes a designation indicating that the nurse practitioner is authorized to practice without a practice agreement.

A nurse practitioner authorized to practice without a practice agreement pursuant to this subsection shall (1) only practice within the scope of his clinical and professional training and limits of his knowledge and experience and consistent with the applicable standards of care, (2) consult and collaborate with other health care providers based on the clinical conditions of the patient to whom health care is provided, and (3) establish a plan for referral of complex medical cases and emergencies to physicians or other appropriate health care providers.

A nurse practitioner practicing without a practice agreement pursuant to this subsection shall obtain and maintain coverage by or shall be named insured on a professional liability insurance policy with limits equal to the current limitation on damages set forth in § 8.01-581.15.

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.), a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe Schedule II through Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.). ~~Nurse practitioners shall have such prescriptive authority upon the provision~~

B. A nurse practitioner who does not meet the requirements for practice without a written or electronic practice agreement set forth in subsection I of § 54.1-2957 shall prescribe controlled substances or devices only if such prescribing is authorized by a written or electronic practice

agreement entered into by the nurse practitioner and a patient care team physician. Such nurse practitioner shall provide to the ~~Board~~ *Boards* of Medicine and ~~the Board of~~ Nursing ~~of~~ such evidence as ~~they~~ *the Boards* may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written or electronic practice agreement with a patient care team physician that clearly states the prescriptive practices of the nurse practitioner. Such written or electronic practice agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as described in the practice agreement. Evidence of a practice agreement shall be maintained by a nurse practitioner pursuant to § 54.1-2957. Practice agreements authorizing a nurse practitioner to prescribe controlled substances or devices pursuant to this section *either* shall ~~either~~ be signed by the patient care team physician ~~who is practicing as part of a patient care team with the nurse practitioner~~ or shall clearly state the name of the patient care team physician who has entered into the practice agreement with the nurse practitioner.

~~B.~~ It shall be unlawful for a nurse practitioner to prescribe controlled substances or devices pursuant to this section unless *(i)* such prescription is authorized by the written or electronic practice agreement *or (ii) the nurse practitioner is authorized to practice without a written or electronic practice agreement pursuant to subsection I of § 54.1-2957.*

C. The ~~Board of Nursing and the Board~~ *Boards* of Medicine *and Nursing* shall promulgate such regulations governing the prescriptive authority of nurse practitioners as are deemed reasonable and necessary to ensure an appropriate standard of care for patients. ~~Regulations promulgated pursuant to this section~~ *Such regulations* shall include~~, at a minimum,~~ such requirements as may be necessary to ensure continued nurse practitioner competency, which may include continuing education, testing, or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients.

D. This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any nurse practitioners which are otherwise authorized by law or regulation.

E. The following restrictions shall apply to any nurse practitioner authorized to prescribe drugs and devices pursuant to this section:

1. The nurse practitioner shall disclose to the patient at the initial encounter that he is a licensed nurse practitioner. Any ~~member of a patient care team~~ *party to a practice agreement* shall disclose, upon request of a patient or his legal representative, the name of the patient care team physician and information regarding how to contact the patient care team physician.

2. Physicians shall not serve as a patient care team physician on a patient care team at any one time to more than six nurse practitioners.

F. This section shall not prohibit a licensed nurse practitioner from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

G. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of ~~Nursing and~~ Medicine *and Nursing* in the category of certified nurse midwife and holding a license for prescriptive authority may prescribe (i) Schedules II through V controlled substances in accordance with any prescriptive authority included in a practice agreement with a licensed physician pursuant to subsection H of § 54.1-2957 and (ii) Schedule VI controlled substances without the requirement for inclusion of such prescriptive authority in a practice agreement.

§ 54.1-3016. Use of titles and abbreviations for nurses.

~~Any~~ *A. Only a* person who holds a license or a multistate licensure privilege to practice professional nursing in ~~Virginia~~ *the Commonwealth* shall have the right to use the title "registered nurse" and the abbreviation "R.N." No other person shall assume such title or use such abbreviation or any other words, letters, signs or devices to indicate that the person using the same is a registered nurse.

B. Only a person who holds a license or a multistate licensure privilege to practice professional nursing in the Commonwealth who has completed an advanced graduate-level nursing education program and passed a national certifying examination to be certified as a nurse anesthetist, nurse midwife, nurse practitioner, or clinical nurse specialist shall have the right to use the title "advanced practice registered nurse" and the abbreviation "A.P.R.N." No other person shall assume such title or use such abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is an advanced practice registered nurse.

C. Only a person who is an advanced practice registered nurse, as defined in § 54.1-3000, who is jointly licensed by the Boards of Medicine and Nursing pursuant to § 54.1-2957 shall have the right to use the title "nurse practitioner" and the abbreviation "N.P." No other person shall assume such title or use such abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is a nurse practitioner.

D. Only a person who is an advanced practice registered nurse, as defined in § 54.1-3000, who has

completed an advanced graduate-level nursing education program and passed a national certifying examination to be certified as a nurse anesthetist and is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 shall have the right to use the title "certified registered nurse anesthetist" and the abbreviation "C.R.N.A." No other person shall assume such title or use such abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is a certified registered nurse anesthetist.

E. Only a person who is an advanced practice registered nurse, as defined in § 54.1-3000, who has completed an advanced graduate-level nursing education program and passed a national certifying examination to be certified as a nurse midwife and is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 shall have the right to use the title "certified nurse midwife" and the abbreviation "C.N.M." No other person shall assume such title or use such abbreviation or any other words, letters, signs, or devices to indicate that the person using the same is a certified nurse midwife.

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided *that* such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working ~~as part of a patient care team as defined in § 54.1-2900~~ *in accordance with the provisions of § 54.1-2957*, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided *that* such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working ~~as part of a patient care team as defined in § 54.1-2900~~ *in accordance with the provisions of § 54.1-2957*, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;

4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;

5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled

substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe ~~according to his practice setting and a written or electronic agreement with a physician~~;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

§ 54.1-3482. Practice of physical therapy; certain experience and referrals required; physical therapist assistants.

A. It shall be unlawful for a person to engage in the practice of physical therapy except as a licensed physical therapist, upon the referral and direction of a licensed doctor of medicine, osteopathy,

chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician, except as provided in this section.

B. A physical therapist who has completed a doctor of physical therapy program approved by the Commission on Accreditation of Physical Therapy Education or who has obtained a certificate of authorization pursuant to § 54.1-3482.1 may evaluate and treat a patient for no more than 30 consecutive days after an initial evaluation without a referral under the following conditions: (i) the patient is not receiving care from any licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician for the symptoms giving rise to the presentation at the time of the presentation to the physical therapist for physical therapy services or (ii) the patient is receiving care from a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician at the time of his presentation to the physical therapist for the symptoms giving rise to the presentation for physical therapy services and (a) the patient identifies a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician from whom he is currently receiving care; (b) the patient gives written consent for the physical therapist to release all personal health information and treatment records to the identified practitioner; and (c) the physical therapist notifies the practitioner identified by the patient no later than 14 days after treatment commences and provides the practitioner with a copy of the initial evaluation along with a copy of the patient history obtained by the physical therapist. Treatment for more than 30 consecutive days after evaluation of such patient shall only be upon the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician. A physical therapist may contact the practitioner identified by the patient at the end of the 30-day period to determine if the practitioner will authorize additional physical therapy services until such time as the patient can be seen by the practitioner. A physical therapist shall not perform an initial evaluation of a patient under this subsection if the physical therapist has performed an initial evaluation of the patient under this subsection for the same condition within the immediately preceding 60 days.

C. A physical therapist who has not completed a doctor of physical therapy program approved by the Commission on Accreditation of Physical Therapy Education or who has not obtained a certificate of authorization pursuant to § 54.1-3482.1 may conduct a one-time evaluation that does not include treatment of a patient without the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician; if appropriate, the physical therapist shall immediately refer such patient to the appropriate practitioner.

D. Invasive procedures within the scope of practice of physical therapy shall at all times be performed only under the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician.

E. It shall be unlawful for any licensed physical therapist to fail to immediately refer any patient to a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, or a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957* when such patient's medical condition is determined, at the time of evaluation or treatment, to be beyond the physical therapist's scope of practice. Upon determining that the patient's medical condition is beyond the scope of practice of a physical therapist, a physical therapist shall immediately refer such patient to an appropriate practitioner.

F. Any person licensed as a physical therapist assistant shall perform his duties only under the direction and control of a licensed physical therapist.

G. However, a licensed physical therapist may provide, without referral or supervision, physical therapy services to (i) a student athlete participating in a school-sponsored athletic activity while such student is at such activity in a public, private, or religious elementary, middle or high school, or public or private institution of higher education when such services are rendered by a licensed physical therapist who is certified as an athletic trainer by the National Athletic Trainers' Association Board of Certification or as a sports certified specialist by the American Board of Physical Therapy Specialties;

(ii) employees solely for the purpose of evaluation and consultation related to workplace ergonomics; (iii) special education students who, by virtue of their individualized education plans (IEPs), need physical therapy services to fulfill the provisions of their IEPs; (iv) the public for the purpose of wellness, fitness, and health screenings; (v) the public for the purpose of health promotion and education; and (vi) the public for the purpose of prevention of impairments, functional limitations, and disabilities.

§ 54.1-3482.1. Certain certification required.

A. The Board shall promulgate regulations establishing criteria for certification of physical therapists to provide certain physical therapy services pursuant to subsection B of § 54.1-3482 without referral from a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with ~~his practice agreement~~ *the provisions of § 54.1-2957*, or a licensed physician assistant acting under the supervision of a licensed physician. The regulations shall include but not be limited to provisions for (i) the promotion of patient safety; (ii) an application process for a one-time certification to perform such procedures; and (iii) minimum education, training, and experience requirements for certification to perform such procedures.

B. The minimum education, training, and experience requirements for certification shall include evidence that the applicant has successfully completed (i) a transitional program in physical therapy as recognized by the Board or (ii) at least three years of active practice with evidence of continuing education relating to carrying out direct access duties under § 54.1-3482.

2. That the Boards of Medicine and Nursing shall jointly promulgate regulations to implement the provisions of this act, which shall govern the practice of medicine for those nurse practitioners practicing without a practice agreement in accordance with the provisions of this act, to be effective within 280 days of its enactment.

3. That the Boards of Medicine and Nursing shall report on the number of nurse practitioners who have been authorized to practice without a practice agreement in accordance with the provisions of this act to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health and the Chairman of the Joint Commission on Health Care by November 1, 2021.

4. That the Boards of Medicine and Nursing shall recommend to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health any modifications to the clinical experience requirements for practice of a nurse practitioner practicing without a practice agreement in accordance with the provisions of this act and a process by which nurse practitioners who practice without a practice agreement may be included in the online Practitioner Profile maintained by the Department of Health Professions by November 1, 2021.

5. That the Department of Health Professions shall include in workforce data reports the geographic and specialty areas in which nurse practitioners are practicing without a practice agreement in accordance with the provisions of this act.

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of February 6, 2018

Board **Board of Medicine**

Chapter		Action / Stage Information
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Licensure by endorsement [Action 4716] Proposed - *Register Date: 1/8/18* *Comment ends: 3/9/18* *Public hearing: 2/15/18*
[18 VAC 85 - 20]	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic	Supervision and direction for laser hair removal [Action 4860] Proposed - *DPB Review in progress* [Stage 8174]
[18 VAC 85 - 21]	Regulations Governing Prescribing of Opioids and Buprenorphine	Initial regulations [Action 4760] Proposed - *Register Date: 11/27/17* *Comment closed: 1/26/18*
[18 VAC 85 - 50]	Regulations Governing the Practice of Physician Assistants	Definitions of supervision and weight loss rules [Action 4943] NOIRA - *Register Date: 12/25/17* *Comment closed: 1/24/18*
[18 VAC 85 - 130]	Regulations Governing the Practice of Licensed Midwives	Practical experience under supervision [Action 4944] Fast-Track - *At Secretary's Office for 53 days*

Agenda Item: **Guidance document for Occupational Therapy**

Staff Note:

Board staff often fields questions about the supervisory responsibilities in occupational therapy. The Advisory Board on Occupational Therapy requested a draft guidance document that addresses questions of interpretation of law or regulation. At its meeting on January 30, 2018, the Advisory Board reviewed the draft document and recommended it to the full Board for adoption.

Enclosed is:

A copy of a draft guidance document on the supervisor responsibilities in occupational therapy

Action: Motion to adopt Guidance Document 85-29.

Guidance document: 85-29 Adopted: February 15, 2018

Board of Medicine

Guidance on Supervisory Responsibilities of an Occupational Therapist

Question 1: As an Occupational Therapist who supervised Occupational Therapy Assistants and other unlicensed personnel, who is responsible for the patient care and outcome?

Answer 1: The Occupational Therapist is responsible for the care and treatment provided to the patient by any licensed or unlicensed health-care providers under the supervision of the Occupational Therapist.

Question 2: What can an occupational therapist delegate to an occupational therapy assistant or any unlicensed health care provider?

Answer 2: There is not a list of procedures that may or may not be delegated. An occupational therapist may not delegate any task that requires a clinical decision or the knowledge, skills and judgment of a licensed occupational therapist. Occupational therapists may only delegate those tasks that do not require professional judgment and can be properly and safely performed by an appropriately trained occupational therapy assistant.

Question 3: How many personnel may an occupational therapist supervise at any one time?

Answer 3: An occupational therapist my supervise up to six occupational therapy personnel including no more than three occupational therapy assistants at any one time.

Question 4: How often must the occupational therapist meet with the occupational therapy assistant to review and evaluate treatment and progress of the individual patients?

Answer 4: At a minimum, the occupational therapist must meet with the occupational therapy assistant at least once every 10^{th} treatment session or 30 calendar days, whichever occurs first. However, this is a minimum and the frequency of these meetings should be determined by the complexity of patient needs, number and diversity of patients, demonstrated competency and experience of the assistant. Check with your chief medical officer or other personnel to determine if there is a hospital policy on frequency, methods, and content of supervision.

Question 5: Who must sign patient treatment notes?

Answer 5: Occupational therapy assistants shall document all treatment notes in the patient record performed by the assistant and be countersigned by the supervising occupational therapist at the time of review and evaluation.

Question 6: Who can supervise unlicensed personnel?

Answer 6: An occupational therapist or an occupational therapy assistant may supervise unlicensed personnel.

Question 7: What procedures may unlicensed personnel perform?

Answer 7: Unlicensed personnel may perform non-client-related tasks such as clerical or room preparation. They may perform client-related tasks that in the judgment of the supervising occupational therapist have no potential to adversely impact the patient or the patient's treatment plan.

Agenda Item: Adoption of exempt amendment for fee reduction

Included in the agenda package:

Fee reduction regulation for limited licenses.

Staff note:

When the Board acted to reduce renewal fees for other professions, these limited fees were overlooked. This action will give them the same percentage reduction.

Action:

Adoption of amendments to section 18VAC85-20-22.

Project 5418 - none

BOARD OF MEDICINE

Fee reduction 18

18VAC85-20-22. Required fees.

A. Unless otherwise provided, fees established by the board shall not be refundable.

B. All examination fees shall be determined by and made payable as designated by the board.

C. The application fee for licensure in medicine, osteopathic medicine, and podiatry shall be $302, and the fee for licensure in chiropractic shall be $277.

D. The fee for a temporary authorization to practice medicine pursuant to clauses (i) and (ii) of § 54.1-2927 B of the Code of Virginia shall be $25.

E. The application fee for a limited professorial or fellow license issued pursuant to 18VAC85-20-210 shall be $55. The annual renewal fee shall be $35. For renewal of a limited professorial or fellow license in ~~2016~~ 2018, the fee shall be $30. An additional fee for late renewal of licensure shall be $15.

F. The application fee for a limited license to interns and residents pursuant to 18VAC85-20-220 shall be $55. The annual renewal fee shall be $35. For renewal of a limited license to interns and residents in ~~2016~~ 2018, the fee shall be $30. An additional fee for late renewal of licensure shall be $15.

G. The fee for a duplicate wall certificate shall be $15; the fee for a duplicate license shall be $5.00.

H. The fee for biennial renewal shall be $337 for licensure in medicine, osteopathic medicine, and podiatry and $312 for licensure in chiropractic, due in each even-numbered year in the

licensee's birth month. An additional fee for processing a late renewal application within one renewal cycle shall be $115 for licensure in medicine, osteopathic medicine, and podiatry and $105 for licensure in chiropractic. For renewal of licensure in 2018, the fee shall be $270 for licensure in medicine, osteopathic medicine, and podiatry and $250 for licensure in chiropractic.

I. The fee for requesting reinstatement of licensure or certification pursuant to § 54.1-2408.2 of the Code of Virginia or for requesting reinstatement after any petition to reinstate the certificate or license of any person has been denied shall be $2,000.

J. The fee for reinstatement of a license issued by the Board of Medicine pursuant to § 54.1-2904 of the Code of Virginia that has expired for a period of two years or more shall be $497 for licensure in medicine, osteopathic medicine, and podiatry ($382 for reinstatement application in addition to the late fee of $115) and $472 for licensure in chiropractic ($367 for reinstatement application in addition to the late fee of $105). The fee shall be submitted with an application for licensure reinstatement.

K. The fee for a letter of verification of licensure shall be $10, and the fee for certification of grades to another jurisdiction by the board shall be $25.

L. The fee for biennial renewal of an inactive license shall be $168, due in the licensee's birth month. An additional fee for late renewal of licensure shall be $55 for each renewal cycle.

M. The fee for an application or for the biennial renewal of a restricted volunteer license shall be $75, due in the licensee's birth month. An additional fee for late renewal of licensure shall be $25 for each renewal cycle. For renewal of a restricted volunteer license in 2016, the fee shall be $65.

N. The fee for a returned check shall be $35.

Agenda Item:

Proposed regulations for performance of and for supervision and direction of laser hair removal

Included in the agenda package:

Copy of Proposed Regulations for Nurse Practitioners

Staff note:

The proposed regulations are identical to those already adopted for doctors of medicine and osteopathic medicine and for physician assistants.

Proposed regulations are recommended by the Committee of the Joint Boards of Nursing and Medicine for adoption.

Action:

Adoption of proposed regulations for the proper training and direction and supervision of laser hair removal

Project 5221 - NOIRA

BOARD OF NURSING

Supervision and direction of laser hair removal

18VAC90-30-124. Direction and supervision of laser hair removal.

A. A nurse practitioner, as authorized pursuant to § 54.1-2957, may perform or supervise the performance of laser hair removal upon completion of training in the following:

1. Skin physiology and histology;

2. Skin type and appropriate patient selection;

3. Laser safety;

4. Operation of laser device or devices to be used;

5. Recognition of potential complications and response to any actual complication resulting from a laser hair removal treatment; and

6. A minimum number of 10 proctored patient cases with demonstrated competency in treating various skin types.

B. Nurse practitioners who have been performing laser hair removal prior to (the effective date of this regulation) are not required to complete training specified in subsection A.

C. A nurse practitioner who delegates the practice of laser hair removal and provides supervision for such practice shall ensure the supervised person has completed the training required in subsection A.

D. A nurse practitioner who performs laser hair removal or who supervises others in the practice shall receive ongoing training as necessary to maintain competency in new techniques

and laser devices. The nurse practitioner shall ensure that persons he supervises also receive ongoing training to maintain competency.

E. A nurse practitioner may delegate laser hair removal to a properly trained person under his direction and supervision. Direction and supervision shall mean that the nurse practitioner is readily available at the time laser hair removal is being performed. The supervising nurse practitioner is not required to be physically present, but is required to see and evaluate a patient for whom the treatment has resulted in complications prior to the continuance of laser hair removal treatment.

F. Prescribing of medication shall be in accordance with § 54.1-3303 of the Code of Virginia.

Agenda Item: Agenda Item: Adoption of Proposed Regulations for physician assistants

Included in the agenda package:

A copy of the NOIRA

A copy of comment on the NOIRA

A copy of the draft regulations as recommended by the Advisory Board on Physician Assistants

Action:

Adoption of proposed amendments to sections relating to supervision and pharmacotherapy for weight loss.

Form: TH-01
11/14

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-50
Regulation title(s)	Regulations Governing the Practice of Physician Assistants
Action title	Definition of supervision and pharmacology for weight loss
Date this document prepared	10/26/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The purpose of the proposed regulatory action is to simplify and clarify the definitions and usage of various terms for supervision for more consistency with the Code and with actual practice of physician assistants and supervising physicians. Further the action will add a provision in the regulation on pharmacotherapy for weight loss to clarify that a physician assistant can conduct the physical examination, review tests, and prescribe drugs, if so authorized in a practice agreement with a supervising physician.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code

of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...

Regulations on supervision of physician assistants are promulgated in accordance with:

§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.
A. A physician or a podiatrist licensed under this chapter may supervise physician assistants and delegate certain acts which constitute the practice of medicine to the extent and in the manner authorized by the Board. The physician shall provide continuous supervision as required by this section; however, the requirement for physician supervision of physician assistants shall not be construed as requiring the physical presence of the supervising physician during all times and places of service delivery by physician assistants. Each team of supervising physician and physician assistant shall identify the relevant physician assistant's scope of practice, including the delegation of medical tasks as appropriate to the physician assistant's level of competence, the physician assistant's relationship with and access to the supervising physician, and an evaluation process for the physician assistant's performance.

Physician assistants appointed as medical examiners pursuant to § 32.1-282 shall be under the continuous supervision of a licensed doctor of medicine or osteopathic medicine who has been appointed to serve as a medical examiner pursuant to § 32.1-282.

No licensee shall be allowed to supervise more than six physician assistants at any one time.

Any professional corporation or partnership of any licensee, any hospital and any commercial enterprise having medical facilities for its employees which are supervised by one or more physicians or podiatrists may employ one or more physician assistants in accordance with the provisions of this section.

Activities shall be delegated in a manner consistent with sound medical practice and the protection of the health and safety of the patient. Such activities shall be set forth in a practice supervision agreement between the physician assistant and the supervising physician or podiatrist and may include health care services which are educational, diagnostic, therapeutic,

preventive, or include treatment, but shall not include the establishment of a final diagnosis or treatment plan for the patient unless set forth in the practice supervision agreement. Prescribing or dispensing of drugs may be permitted as provided in § 54.1-2952.1. In addition, a licensee is authorized to delegate and supervise initial and ongoing evaluation and treatment of any patient in a hospital, including its emergency department, when performed under the direction, supervision and control of the supervising licensee. When practicing in a hospital, the physician assistant shall report any acute or significant finding or change in a patient's clinical status to the supervising physician as soon as circumstances require and shall record such finding in appropriate institutional records. The physician assistant shall transfer to a supervising physician the direction of care of a patient in an emergency department who has a life-threatening injury or illness. Prior to the patient's discharge, the services rendered to each patient by a physician assistant in a hospital's emergency department shall be reviewed in accordance with the practice agreement and the policies and procedures of the health care institution. A physician assistant who is employed to practice in an emergency department shall be under the supervision of a physician present within the facility.

Further, unless otherwise prohibited by federal law or by hospital bylaws, rules, or policies, nothing in this section shall prohibit any physician assistant who is not employed by the emergency physician or his professional entity from practicing in a hospital emergency department, within the scope of his practice, while under continuous physician supervision as required by this section, whether or not the supervising physician is physically present in the facility. The supervising physician who authorizes such practice by his physician assistant shall (i) retain exclusive supervisory control of and responsibility for the physician assistant and (ii) be available at all times for consultation with both the physician assistant and the emergency department physician. Prior to the patient's discharge from the emergency department, the physician assistant shall communicate the proposed disposition plan for any patient under his care to both his supervising physician and the emergency department physician. No person shall have control of or supervisory responsibility for any physician assistant who is not employed by the person or the person's business entity.

B. No physician assistant shall perform any delegated acts except at the direction of the licensee and under his supervision and control. No physician assistant practicing in a hospital shall render care to a patient unless the physician responsible for that patient has signed the practice agreement, pursuant to regulations of the Board, to act as supervising physician for that physician assistant. Every licensee, professional corporation or partnership of licensees, hospital or commercial enterprise that employs a physician assistant shall be fully responsible for the acts of the physician assistant in the care and treatment of human beings.

C. Notwithstanding the provisions of § 54.1-2956.8:1, a licensed physician assistant who (i) is working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, (ii) has been trained in the proper use of equipment for the purpose of performing radiologic technology procedures consistent with Board regulations, and (iii) has successfully completed the exam administered by the American Registry of Radiologic Technologists for physician assistants for the purpose of performing radiologic technology procedures may use fluoroscopy for guidance of diagnostic and therapeutic procedures.

Town Hall Agency Background Document **Form: TH- 01**

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of the regulatory action is clarity and consistency in rules relating to supervision of physician assistants and removal of any unnecessary rules that may impede the ability of assistants to practice to the full extent of their training and competency as permitted by law. There are no substantive changes that affect the supervisory role of a physician, and proposed regulations will continue to protect public health and safety.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

Relating to the use of supervision in regulation, the Board intends to:

1) Amend the definition of "supervision" by combining the meanings of general and continuous supervision, so the new definition would be: Supervision means the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients (current definition of "continuous supervision") and is easily available and can be physically present or accessible for consultation with the physician assistant within one hour (current definition of "general supervision");
2) Eliminate definitions of "direct supervision" and "personal supervision" The definitions of "alternative supervising physician" and "supervising physician" will be moved to the appropriate places in the listing of words and terms being defined;
3) Delete in Section 101 the examples of various levels of supervision that may be spelled out in the practice agreement between the parties; and
4) Amend Section 110 to change the word "supervising" to "observing" in order to clarify the responsibility of the physician in attesting to the competency of a physician assistant to perform invasive procedures.

Relating to regulations in Section 181 on pharmacotherapy for weight loss, the Board intends to add a subsection C, which is similar to language in subsection C of Section 90 in regulations for physicians. *The new subsection C would read: If specifically authorized in his practice agreement with a supervising physician, a physician assistant may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section.*

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The proposal is a less burdensome and intrusive alternative that meets the essential purpose of the action, so no alternatives were considered.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

The Board will utilize the Advisory Board on Physician Assistants to develop proposed amendments to regulation.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Medicine**

Chapter **Regulations Governing the Practice of Physician Assistants [18 VAC 85 - 50]**

Action	**Definitions of supervision and weight loss rules**
Stage	**NOIRA**
Comment Period	Ends 1/24/2018

Back to List of Comments

Commenter: Virginia Academy of Physician Assistants 12/29/17 10:16 am

Regulations Governing the Practice of Physician Assistants18 VAC 85 ? 50 Definitions of supervisi

The Virginia Academy of Physician Assistants (VAPA) supports the proposed regulatory changes to Regulations Governing the Practice of Physician Assistants [18 VAC 85 ? 50] in order to amend definitions of supervision and weight loss rules consistent with the current codes of Virginia.

David Falkenstein, PA-C, DFAAPA

Chair Goverenment Affairs Committee

Project 5334 - NOIRA

BOARD OF MEDICINE

Definitions of supervision and weight loss rules

Part I

General Provisions

18VAC85-50-10. Definitions.

A. The following words and terms shall have the meanings ascribed to them in § 54.1-2900 of the Code of Virginia:

"Board."

"Physician assistant."

B. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Group practice" means the practice of a group of two or more doctors of medicine, osteopathy, or podiatry licensed by the board who practice as a partnership or professional corporation.

"Institution" means a hospital, nursing home or other health care facility, community health center, public health center, industrial medicine or corporation clinic, a medical service facility, student health center, or other setting approved by the board.

"NCCPA" means the National Commission on Certification of Physician Assistants.

"Practice agreement" means a written agreement developed by the supervising physician and the physician assistant that defines the supervisory relationship between the physician assistant

and the physician, the prescriptive authority of the physician assistant, and the circumstances under which the physician will see and evaluate the patient.

"Supervision" means~~:~~

~~1. "Alternate supervising physician" means a member of the same group or professional corporation or partnership of any licensee, any hospital or any commercial enterprise with the supervising physician. Such alternating supervising physician shall be a physician licensed in the Commonwealth who has registered with the board and who has accepted responsibility for the supervision of the service that a physician assistant renders.~~

~~2. "Direct supervision" means the physician is in the room in which a procedure is being performed.~~

~~3. "General supervision" means the supervising physician is easily available and can be physically present or accessible for consultation with the physician assistant within one hour.~~

~~4. "Personal supervision" means the supervising physician is within the facility in which the physician's assistant is functioning.~~

~~5. "Supervising physician" means the doctor of medicine, osteopathy, or podiatry licensed in the Commonwealth who has accepted responsibility for the supervision of the service that a physician assistant renders.~~

~~6. "Continuous supervision" means the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients~~ the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients, is easily available, and can be physically present or accessible for consultation with the physician assistant within one hour.

Part IV

Practice Requirements

18VAC85-50-101. Requirements for a practice agreement.

A. Prior to initiation of practice, a physician assistant and his supervising physician shall enter into a written or electronic practice agreement that spells out the roles and functions of the assistant.

1. The supervising physician shall be a doctor of medicine, osteopathy, or podiatry licensed in the Commonwealth who has accepted responsibility for the supervision of the service that a physician assistant renders.

2. Any such practice agreement shall take into account such factors as the physician assistant's level of competence, the number of patients, the types of illness treated by the physician, the nature of the treatment, special procedures, and the nature of the physician availability in ensuring direct physician involvement at an early stage and regularly thereafter.

3. The practice agreement shall also provide an evaluation process for the physician assistant's performance, including a requirement specifying the time period, proportionate to the acuity of care and practice setting, within which the supervising physician shall review the record of services rendered by the physician assistant.

4. The practice agreement may include requirements for periodic site visits by supervising licensees who supervise and direct assistants who provide services at a location other than where the licensee regularly practices.

B. The board may require information regarding the level of supervision~~, (i.e., "direct," "personal," or "general")~~ with which the supervising physician plans to supervise the physician assistant for selected tasks. The board may also require the supervising physician to document the assistant's competence in performing such tasks.

C. If the role of the assistant includes prescribing for drugs and devices, the written practice agreement shall include those schedules and categories of drugs and devices that are within the scope of practice and proficiency of the supervising physician.

D. If the initial practice agreement did not include prescriptive authority, there shall be an addendum to the practice agreement for prescriptive authority.

E. If there are any changes in supervision, authorization, or scope of practice, a revised practice agreement shall be entered into at the time of the change.

18VAC85-50-110. Responsibilities of the supervisor.

The supervising physician shall:

1. Review the clinical course and treatment plan for any patient who presents for the same acute complaint twice in a single episode of care and has failed to improve as expected. The supervising physician shall be involved with any patient with a continuing illness as noted in the written or electronic practice agreement for the evaluation process.

2. Be responsible for all invasive procedures.

a. Under general supervision, a physician assistant may insert a nasogastric tube, bladder catheter, needle, or peripheral intravenous catheter, but not a flow-directed catheter, and may perform minor suturing, venipuncture, and subcutaneous intramuscular or intravenous injection.

b. All other invasive procedures not listed in subdivision 2 a of this section must be performed under direct supervision unless, after directly ~~supervising~~ observing the performance of a specific invasive procedure three times or more, the supervising physician attests on the practice agreement to the competence of the physician assistant to perform the specific procedure without direct supervision.

3. Be responsible for all prescriptions issued by the assistant and attest to the competence of the assistant to prescribe drugs and devices.

18VAC85-50-115. Responsibilities of the physician assistant.

A. The physician assistant shall not render independent health care and shall:

1. Perform only those medical care services that are within the scope of the practice and proficiency of the supervising physician as prescribed in the physician assistant's practice agreement. When a physician assistant is to be supervised by an alternate supervising physician outside the scope of specialty of the supervising physician, then the physician assistant's functions shall be limited to those areas not requiring specialized clinical judgment, unless a separate practice agreement for that alternate supervising physician is approved and on file with the board.

2. Prescribe only those drugs and devices as allowed in Part V (18VAC85-50-130 et seq.) of this chapter.

3. Wear during the course of performing his duties identification showing clearly that he is a physician assistant.

B. An alternate supervising physician shall be a member of the same group or professional corporation or partnership of any licensee, any hospital or any commercial enterprise with the supervising physician. Such alternating supervising physician shall be a physician licensed in the Commonwealth who has registered with the board and who has accepted responsibility for the supervision of the service that a physician assistant renders.

~~B.~~ C. If, due to illness, vacation, or unexpected absence, the supervising physician or alternate supervising physician is unable to supervise the activities of his assistant, such supervising physician may temporarily delegate the responsibility to another doctor of medicine, osteopathic medicine, or podiatry.

Temporary coverage may not exceed four weeks unless special permission is granted by the board.

~~C.~~D. With respect to assistants employed by institutions, the following additional regulations shall apply:

1. No assistant may render care to a patient unless the physician responsible for that patient has signed the practice agreement to act as supervising physician for that assistant. The board shall make available appropriate forms for physicians to join the practice agreement for an assistant employed by an institution.

2. Any such practice agreement as described in subdivision 1 of this subsection shall delineate the duties which said physician authorizes the assistant to perform.

3. The assistant shall, as soon as circumstances may dictate, report an acute or significant finding or change in clinical status to the supervising physician concerning the examination of the patient. The assistant shall also record his findings in appropriate institutional records.

~~D.~~E. Practice by a physician assistant in a hospital, including an emergency department, shall be in accordance with § 54.1-2952 of the Code of Virginia.

18VAC85-50-181. Pharmacotherapy for weight loss.

A. A practitioner shall not prescribe amphetamine, Schedule II, for the purpose of weight reduction or control.

B. A practitioner shall not prescribe controlled substances, Schedules III through VI, for the purpose of weight reduction or control in the treatment of obesity, unless the following conditions are met:

1. An appropriate history and physical examination are performed and recorded at the time of initiation of pharmacotherapy for obesity by the prescribing physician, and the physician reviews the results of laboratory work, as indicated, including testing for thyroid function;

2. If the drug to be prescribed could adversely affect cardiac function, the physician shall review the results of an electrocardiogram performed and interpreted within 90 days of initial prescribing for treatment of obesity;

3. A diet and exercise program for weight loss is prescribed and recorded;

4. The patient is seen within the first 30 days following initiation of pharmacotherapy for weight loss, by the prescribing physician or a licensed practitioner with prescriptive authority working under the supervision of the prescribing physician, at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy; and

5. The treating physician shall direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy. Continuation of prescribing for treatment of obesity shall occur only if the patient has continued progress toward achieving or maintaining a target weight and has no significant adverse effects from the prescribed program.

C. If specifically authorized in his practice agreement with a supervising physician, a physician assistant may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section.

Agenda Item: Regulatory Action –Genetic Counselors

Included in agenda package:

Copy of proposed change in regulations for genetic counselors

Staff note:

The amendment is requested by the Advisory Board on Genetic Counselors

Board Action:

Adoption of amendments to regulations by a fast-track action.

18VAC85-170-60. Licensure requirements.

A. An applicant for a license to practice as a genetic counselor shall provide documentation of (i) a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) a current, valid certificate issued by the ABGC or ABMG to practice genetic counseling.

B. Pursuant to § 54.1-2957.19 D of the Code of Virginia, applicants for licensure who do not meet the requirements of subsection A of this section may be issued a license provided they (i) apply for licensure before December 31, 2018; (ii) comply with the board's regulations relating to the NSGC Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the NSGC or the ABGC. For the purpose of this subsection, the board deems the provisions of Part IV (18VAC85-170-110 et seq.) of this chapter to be consistent with the NSGC Code of Ethics.

C. An applicant for a temporary license shall provide documentation of having been granted the active candidate status by the ABGC. Such license shall expire 12 months from issuance or upon ~~expiration of active candidate status~~ failure of the ABGC certification Examination, whichever comes first.

Agenda Item: Regulations Governing Prescribing of Opioids and Buprenorphine

Included in the agenda package:

Copies of public comment received during the 60-day comment period on the proposed regulations

Copy of proposed regulations

Copy of recommendations from the Legislative Committee

Staff note:

Emergency regulations for MDs, DOs, DPMs and PAs became effective on March 15, 2017

The proposed regulations replace emergency regulations currently in effect.

Action:

Adoption of final amendments to opioid regulations to replace emergency regulations.

MSV℠ MEDICAL SOCIETY OF VIRGINIA

2924 Emerywood Parkway
Suite 300
Richmond, VA 23294

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William L. Harp, M.D.
Executive Director
Board of Medicine
9960 Mayland Drive, Suite 300
Richmond, VA 23233

January 18, 2018

RE: Regulations Governing Prescribing of Opioids and Buprenorphine

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to comment on the Regulations Governing Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV commends the Board's work in developing strong regulations that reflect prescribing best practices while ensuring the flexibility of professional judgment in extenuating medical circumstances.

MSV supported the Board's development of the initial emergency opioid and buprenorphine prescribing regulations enacted in March 2017. The emergency regulations provided a comprehensive framework of best practices that included consideration of non-opioid treatments, querying the Prescription Monitoring Program, appropriate strength, length, and quantity supply parameters, family history, treatment plans, and recognition of special considerations and populations. This multi-faceted approach to opioid and buprenorphine prescribing gave prescribers appropriate guidance for the multiple factors that can contribute to opioid addiction, while preserving an option to treat extenuating medical circumstances.

These efforts by the Board and other partners to recognize, treat, and prevent opioid addiction have had a positive impact on the Commonwealth. In the past year, the number of individuals receiving high doses of opioids decreased by 18.6%, opioid doses declined by 40.15%, and multiple provider episodes per 100,000 Virginia residents decreased by 45%.[1]

To continue Virginia's progress in aligning with prescribing best practices, MSV supports enacting 18 VAC 85-21. MSV is dedicated to reducing opioid addiction in Virginia by partnering with the Board and other state government agencies and stakeholder groups and by providing prescribing resources to physicians. MSV's opioid resource webpage gives physicians access to prescribing tools, best practice guidelines, and continuing education resources: http://www.msv.org/opioids.

MSV extends its support of the Board in its attention to the opioid crisis and is dedicated to working together.

Sincerely,

Melina Davis-Martin
Executive Vice President

[1] 2017 Annual Report of Virginia's Prescription Monitoring Program.
https://www.dhp.virginia.gov/dhp_programs/pmp/docs/2017AnnualReport.pdf

STATEWIDE SICKLE CELL CHAPTERS OF VIRGINIA, INC.

POST OFFICE BOX 25205
RICHMOND, VIRGINIA 23260
sicklecell.virginia@yahoo.com
804-321-3350

Date: October 18, 2017

To: Members of the Boards of Medicine and the Medical Community
Elected and Government Officials
Federal and State Agencies
Sickle Cell Disease Association of America
Various Sickle Cell Organizations Nationwide

From: George Harris Carter, Administrator

Subject: Adverse Effects of the New Opioid Guidelines on Sickle Cell Patients

Sickle Cell Disease is an inherited blood disorder where normal soft round shaped red blood cells change to a hard sticky sickle or quarter-moon shape. This disease is produced when the sickle cell gene is transmitted by both parents to a child. Sickled shaped cells cannot squeeze through small blood vessels so they often jam up, blocking the flow of blood and oxygen to body parts and causing extreme pain. A pain crisis can last for days or even weeks and may occur several times a year. Lack of oxygen flow can also damage muscles, bones and internal organs and lead to strokes and other serious medical problems. There is no universal cure.

THE PAINFUL EPISODE OR SICKLE CELL CRISIS is the most common symptom suffered by those born with a Sickle Cell Disease. The patient experiences severe pain in chest, abdomen, back, arms, legs or hips. **Three times in my life I prayed to GOD to let me die because I could not stand the pain any longer.** Some patients live in pain on a daily basis. Pain undermines a person's physical, mental, and emotional well-being.

Statewide Sickle Cell Chapters of Virginia, Inc. (SSCCV), also known as Sickle Cell Chapters of Virginia or Statewide, a non-profit 501(c)(3) tax-exempt community-based organization, has a network of nine (9) community-based sickle cell disease organizations (chapters) that provide a variety of services across the Commonwealth. The chapters are located in Danville, Fredericksburg, Hampton, Lynchburg, Norfolk, Richmond, Rocky Mount, South Boston and Northern Virginia. Most of the chapters in this network have operated since 1972.

I am George Harris Carter and I'm 71 years old with Sickle Cell Disease. I serve as the Administrator (unpaid Executive Director) of Statewide Sickle Cell Chapters of Virginia. I want to voice concern about the potential negative effects the new CDC Opioid Guidelines are and will have on me and some or many of the **approximately 4,000 sickle cell patients around the State of Virginia and almost 96,000 in other parts of the United States.**

While illegal and excessive opioid use has increased overall, and something does need to be done about it, there is no evidence that this is true with patients who suffer with Sickle Cell Disease. Also, there is no evidence that doctors treating these patients are over prescribing opioids.

The new CDC Guidelines on Dose Limitation states the following:
"When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. " (recommendation category: A, evidence type: 3)

The guidelines were meant to **SUGGEST** levels of MME above which prescribing **MAY** be unsafe. But some doctors may have taken the suggested MME levels as **ABSOLUTES**. Prescribing above 50 to 90 or more MME/day is now more likely to be viewed as deviating from or out of the standard-of-care. In some cases it may even be viewed as **CRIMINAL**.

At the end of the first paragraph on page 4 of the CDC Opioid Guidelines is the following statement:
"In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (46)."

The referenced document has **41** pages. Chapter 3 - Managing Acute Complications of Sickle Cell Disease (pages 14 through 17) and Chapter 4 - Managing Chronic Complications of Sickle Cell Disease (pages 27 and 28) discuss pain and opioids. These sections are not entitled "Pain Management" or so listed in the table of contents, so many doctors will not look further into the document, if they refer to it at all. The problem is the CDC guidelines discuss specific **numeric** doses while the NIH Report does not. The NIH Report is more of a discussion and outline of care with NO mention of minimal, average or high dosages. Numbers have a very specific meaning whereas words are open to discussion and interpretation.

With the introduction of the CDC dosage guidelines, a knowledgeable sickle cell doctor may be afraid to give opioids to sickle cell patients or may fear exceeding 50 MME/day because they are afraid of losing their medical license. But to the ones with little knowledge of sickle cell and/or those who view us as drug seekers, the new guidelines will give them more reason or justification to **undertreat** us or not give us any opioids. We may be facing a **backlash** because of the opioid crisis.

It took a long time to get many physicians to a point that they were willing to give higher doses and/or long-acting opioids to sickle cell patients. Unfortunately, the new opioid guidelines are undoing much of the work we previously accomplished. The guidelines have had an impact on some physicians' attitudes about prescribing opioids for pain and as a result, **unintended negative consequences** are being faced by those who suffer from Sickle Cell Disease.

Please allow me to use some personal information to give you an idea about the problem.

Some years ago, I had a very bad pain crisis and went to the emergency room at a Richmond hospital. I have written hospital treatment instructions signed by my doctor stating that I should receive up to 10 mgs of Morphine two to three hours apart for a Sickle Cell Pain Crisis. I had my Sickle Cell Data Sheet with the instructions on it in my wallet and presented it. I asked for 10 mgs of Morphine. Let us just say the ER doctor did not feel the need to follow the treatment plan listed and signed by my doctor. He would only give me 4 mgs. I suffered. I managed to call my doctor who called the hospital. Later on I was given more Morphine but still not what I needed.

Ten mgs of Morphine every two to three hours is the equivalent of 80 to 120 MME/day. Based on the CDC Dosing Guidelines, this would mean that after 10 to 15 hours I may not receive any more opioids or I would only receive 10 mgs every 5 hours or 8 mgs every 3 hours or some other version of use. Many patients require a higher dose of opioids. One patient I know required 15 mgs every 2 hours during his hospitalization. This is the equivalent of 180 MME/day. **If we need this much opioids in the future, will we receive it?**

During a hospital stay in January of 2017, my crisis was rough but I did not need 10 mgs of Morphine two to three hours apart. However, I did need a larger dose of opioids at the beginning then I received. After leaving the hospital, I calculated how much Morphine I was prescribed per day. The figure came to a total of 48 MME/day, 2 MME/day below the CDC guidelines. Was I given 48 MME/day as a deliberate action to stay below the CDC guidelines?

I visited my doctor in May of **2016** for my quarterly appointment and asked for a new prescription for 60 tablets of Demerol for home use. He wrote the prescription, but informed me that after July 1st he might only be able to write a prescription for 14 tablets every 3 months. He also said he was considering not writing prescriptions for opioids at all.

I visited my doctor in May of **2017** for my quarterly appointment and asked for a new prescription for 60 tablets of Demerol for home use because I was leaving within a few days on vacation. Further, the previous prescription was used in part, but the remaining pills would expire and no longer be effective by the end of the month. My primary care doctor of thirty years informed me that he would not write me a prescription and no longer writes anyone a prescription for opioids.

My doctor did refer me to a doctor that visited me in the hospital in January. She is a hematologist working with a cancer institute who also sees sickle cell patients. Her office required me to agree not to get opioids from any other doctor and I had to agree to be drug tested at any time, but did give me a prescription.

One of my other doctors has told me that he stopped writing prescriptions for opioids. My wife's doctor is limiting writing opioid prescriptions and the doctor for a friend's family member has stopped writing prescriptions for opioids. I am sure that these are only a few of many instances where doctors have stopped writing prescriptions for opioids. **Where are sickle cell patients going to go?**

The new CDC Guidelines on Long-Acting Opioids states the following:
"When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids." (recommendation category: A, evidence type: 4)

The PiSCES Study results in the Annals of Internal Medicine January 2008, suggests the pain pattern in persons with Sickle Cell Disease is normally daily. They are in chronic pain. On a pain scale of 1 to 10, their pain intensity is from 4 and 5 to 9 as a common occurrence. To deny all Sickle Cell Disease patients long-acting opioids would result in them being in the hospital more often for pain relief at a greater cost to the taxpayers because of a lack of insurance by many. At the very least they will be less functional and/or out of work more often.

Using opioids in Sickle Cell patients is generally safe. The CDC's own data shows that opioid deaths in Sickle Cell Disease are not increasing, and are rare. [Ruta NS, Ballas SK. The Opioid Drug Epidemic and Sickle Cell Disease: Guilt by Association. Pain Med. 2016 Oct;17(10):1793-1798.].

News Article
http://www.dallasweekly.com/health/article_786129b4-7918-11e7-899b-ef54de21cbf7.html

On July 19, 2017, the Dallas Weekly published an article entitled "War on Opioids Hurts Sickle Cell Disease Patients" and subtitled "Sickle Cell Disease Sufferers Trapped in Fight Against Opioid Scourge". The article states "so many of those suffering from sickle cell anemia are prescribed a variety of powerful pain killer derivatives." According to Judy Anderson, the Executive Director of Sickle Cell Association, Inc. based in Norfolk, VA, "a growing number of people who are suffering from sickle cell anemia may be severely impacted by the government's effort to curb opioid addiction."

Ms. Anderson was quoted as saying "One lady who called the office Monday, July 10th, told me she took her last pain pill the previous Friday," said Anderson. "Her doctor is reviewing her case and has not written her a new prescription." Anderson continued: "Unable to get her pain meds, I am sure she will end up in a hospital, because she went to the emergency room to have her pain treated.''

"Anderson said that in April 2016, in the wake of the growing opioid addiction and related deaths due to overdoses, hospital emergency departments in Virginia received guidelines aimed at curbing opioid misuse and addictions."

"For the first time, the regulations apply specific guidelines to Virginia providers, dictating how many opioids can be prescribed depending on the situation and stipulating that other pain treatments should be considered before opioids are prescribed."

Other Information
It should be noted that only one hospital in our state (in Richmond) provides clinical care for adult patients. Based on over 40 years of working with the patient community, Judy Anderson of our Norfolk chapter has seen "those who use the emergency department as their adult source of

care and are at the mercy of just getting medications as a hit or miss attempt to relieve pain." She also states "the doctors here were sending patients to a Physical Therapist as their alternative to saying they were referring the patients for Pain Management."

CVS Announcement
It has been announced that CVS Pharmacies will only fill opioid prescriptions for 7 days. Will other pharmacies follow CVS's lead? If a doctor writes a prescription for opioids for 14 days, does this mean that a pharmacy will fill the order for 7 days and then fill the remainder the following week? Or will the patient have to get a new prescription? If a new prescription is needed, will the patient have to make a new doctor appointment? If so, this would be an additional cost to the patient and/or insurance company.

CIGNA Announcement
Starting in 2018, the health insurer Cigna Insurance Company, will no longer cover OxyContin, the branded version of the painkiller oxycodone. Cigna will still cover oxycodone alternatives to OxyContin. Will other insurance companies follow Cigna's lead? What effect will this have on the patient population?

What is going to happen to us? How much will I and others have to suffer?

It is my understanding that an exception or some allowance has been made in some guidelines for persons with cancer. **What I feel is needed is an amendment to the CDC guidelines or ANY other guidelines to state that "the dosing limits in the guidelines and restrictions on the use of long-acting opioids should NOT be applied to patients with Sickle Cell Disease" and have the amendment distributed to medical boards, hospitals and doctors.**

Please help us. Do not let us suffer from the backlash and unintended negative consequences of the opioid crisis.

Thank you for your consideration in this matter.

Due to an unavoidable conflict, I cannot attend the December 1 public meeting. Therefore, I am submitting comments for your consideration. I am a 79 year old male who suffers from osteoarthritis in one knee for which I take tramadol in addition to daily use of a compounded ointment, and monthly acupuncture treatments. The current treatment approach has proven an effective alternative to surgery.

I have studied data and statistics from the State and the Governor's Task Force on Opioids and do not understand how those statistics can justify the regulation that has been put into effect and is being considered for finalization.

According to a presentation by the Task Force, opioid prescription overdoses peaked in 2012 and dropped each year afterward. Between 2012 and 2016 the reduction was 18%. That clearly shows that education works. The data also confirm that the increase in opioid deaths is mainly due to illegal drug use, namely cocaine, heroin, and fentanyl. According to the Virginia Department of Health's fourth-quarter report for 2016, of the 1,420 drug-related deaths, 618 were fentanyl-related.

Robert DuPont (the first director of the National Institute of Drug Abuse) and William Bennett (the nation's first drug czar) have written, "70 percent of our nation's opioid deaths do not come via prescription abuse. ... The main problem today, and the growth for tomorrow, is illegal opioids such as heroin, illegal fentanyl, and a hundred other synthetics, not legal drugs used illegally or in ways not as prescribed." In 2015, there were 33,000 opioid overdose deaths with heroin deaths constituting almost 13,000 and synthetic opioids (mostly illegal fentanyl) another 9,600 deaths.

I recognize that for some the opioid problem starts with prescription narcotics that lead to addiction and then a search for cheaper opioids on the black market. However, that does not justify treating all prescribed opioids the same, given the documented progress made since 2012 and the potential of the prescription management system data base.

The risk of addiction from a class 4 opioid like tramadol is small but the impact of forcing patients to make quarterly doctor visits along with periodic urine tests is

not. Arthritis is mainly a disease of the elderly and the burden imposed on them is costly and unreasonable. According to the Kaiser Foundation, 50% of Medicare recipients had annual incomes of $24,150 in 2014. That means that the regulatory requirement for periodic doctor visits along with the urine tests is a regressive tax on those who can least afford it. I have been told that some patients have already decided to seek alternatives to tramadol and compliance. That is not encouraging from either a medical or potential abuse perspective.

I urge you not to treat all classes of opioids the same and to place greater reliance on the existing prescription management system to track potential over-prescribing. Most doctors want to do the right thing and will use the increased awareness to tailor prescriptions and monitoring to patient specifics. It should be self-evident that since all opioids do not carry the same risk of abuse and addiction that the stringency of requirements should be risk-related.

William O'Keefe
5450 Brickshire Drive
Providence Forge Va. 23140
804-966-7370
billo38@icloud.com

Yeatts, Elaine J. (DHP)

From: David Falkenstein <falky1@cox.net>
Sent: Saturday, November 18, 2017 2:30 PM
To: Yeatts, Elaine J. (DHP)
Subject: Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 - 21]

VIRGINIA ACADEMY OF PHYSICIAN ASSISTANTS

250 West Main Street, Suite 100
Charlottesville, VA 22902
434/977-3716 • Fax 434/979-2439
www.vapa.org • vapa@vapa.org

Elaine,
The Virginia Academy of Physician Assistants(AAPA) is supportive of the proposed regulatory changes Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 - 21]. We appreciate the given ability for comment.

David Falkenstein PA-C
Chair Government Affairs Committee

Opioid Presentation to the Board of Medicine by George Harris Carter

I request that in Chapter 21, Part 1, Section B, where it states "This chapter shall not apply to:" that the following be added/listed as the fourth exception to the guidelines, (quote) "patients diagnosed with Sickle Cell Disease." (unquote)

We were getting to the point where many doctors were more willing to give sickle cell patients the doses and types of opioids they needed to overcome a pain crisis. The issuance of your temporary regulations has decreased some physician willingness to give us the necessary opioids needed and probably set sickle cell care back ten years or more.

At least the CDC guidelines mentioned sickle cell by stating (quote) "given the challenges of managing the painful complications of sickle cell disease," (unquote). Your guidelines make no reference to sickle cell.

If we have more crisis, more pain for a longer period, it will result in more organ damage and other complications.

We are a small numbered (4,000), mostly minority disease. Some doctors see us as drug seekers, not just because of opioids we need for our pain, but because of the color of our skin.

Only VCU/MCV in Richmond has an adult sickle cell clinic to treat patients in the entire state. Outside of the Richmond area, every patient over 18 has to find a private doctor who will treat them not to mention one who really understand the treatment needed. The tidewater area has the largest population of sickle cell patients in the state but no adult clinic to serve them. Some doctors will not treat our patients because of the opioid crisis or patients do not have insurance because of their income or pre-existing conditions.

A physician's first job is to do no harm. If these regulations are passed without an exception for sickle cell, harm will be done.

Maybe consideration should be given to the concept that these regulations could cause more illegal drug use in the future because people with chronic pain cannot get the proper amount of opioid prescription relief from their doctors? It's a possibility that things could be made worse across the board.

I urge all members of the medical board to go back and review the 60 Minutes broadcast of October and the one for December about the opioid crisis before you finalize the regulations. The 60 Minute reports demonstrate that much of the problem is federal failure to stop and correct improper activity (both legal and illegal) and improper distribution supply chain activity. Patients are not the problem. Please do not let patients with sickle cell suffer even more.

Again, I request that in Chapter 21, Part 1, Section B, where it states "This chapter shall not apply to:" that the following be added/listed as the fourth exception to the guidelines, (quote) "patients diagnosed with Sickle Cell Disease." (unquote)

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

MATTHEW JAMES
POST OFFICE BOX 7487
PORTSMOUTH, VIRGINIA 23707

EIGHTIETH DISTRICT

COMMITTEE ASSIGNMENTS:
APPROPRIATIONS
HEALTH, WELFARE AND INSTITUTIONS
AGRICULTURE, CHESAPEAKE AND
NATURAL RESOURCES

January 25, 2018

Members of the Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 201
Richmond, VA 23233

Subject: Comment on the New Opioid Guidelines and Sickle Cell

Dear Members:

I have listened to stories of pain and suffering from family members about their children and the need for relief when they are in a pain crisis. It is estimated that around 1,400 persons live with sickle cell disease in the tidewater area. This is the largest population of persons suffering with sickle cell in the state. We have a clinic to help the children get proper opioid needs but do not have one to serve adults. This means many of our adults are at risk of not receiving enough opioid help from physicians.

Sickle cell disease is an inherited blood disorder. Sickled shaped red blood cells cannot squeeze through small blood vessels and block the flow of blood and oxygen to body parts and causes extreme pain. Individuals with sickle cell need large doses of opioids to overcome the pain they have in a crisis at home. They need even more when they have to go to the hospital. Some of them are in the hospital a lot. Some others are in pain every day and need long acting opioids to help control their pain. Pain undermines a person's well-being.

The opioid crisis is real and regulations are needed to curb improper use. However, I have a serious concern that too many physicians may interpret your regulations in a manner that keeps persons with this disease from receiving the necessary opioid pain relief. Because of this, I feel that the Board of Medicine should grant a written exception in the regulations for persons who suffer from sickle cell disease.

Thank you for your consideration.

Sincerely,

Delegate Matthew James

DISTRICT: (757) 967-7583 • RICHMOND: (804) 698-1080 • FAX: (804) 698-6780
E-MAIL: DELMJAMES@HOUSE.VIRGINIA.GOV

SENATE OF VIRGINIA

JENNIFER L. McCLELLAN
9TH SENATORIAL DISTRICT
ALL OF CHARLES CITY COUNTY;
PART OF HANOVER AND HENRICO COUNTIES;
AND PART OF THE CITY OF RICHMOND

POST OFFICE BOX 396
RICHMOND, VIRGINIA 23218

COMMITTEE ASSIGNMENTS:
AGRICULTURE, CONSERVATION AND NATURAL RESOURCES
LOCAL GOVERNMENT
TRANSPORTATION

January 22, 2018

Dr. William L. Harp
Executive Director
Virginia Board of Medicine
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Dear Dr. Harp & Members of the Board of Medicine:

I write on behalf of two mothers I know; each with children who have sickle cell disease. I have listened to their stories describing their children's pain, both of which have received a reduction of opioids by their physician. As a mother myself, I understand the need to protect your children and keep them from suffering.

Sickle cell disease is an inherited blood disorder. Sickle-shaped red blood cells cannot squeeze through small blood vessels and block the flow of blood and oxygen to body parts and causes extreme pain. Individuals with sickle cell need large doses of opioids to overcome the pain they have in a crisis at home, or at the hospital, which is an ongoing occurrence for these families.

With the opioid crisis continuing to rise in Virginia, regulations are needed to curb improper use. However, I have concerns that too many physicians may interpret your regulations in a manner that keeps persons with Sickle cell disease from receiving the necessary opioid pain relief. I ask that the Board of Medicine grant a written exception in the regulations for persons who suffer from sickle cell disease.

Thank you for your consideration, and please do not hesitate to contact my office if I can answer any questions related to my concerns.

Sincerely,

Jennifer L. McClellan
Virginia Senate, 9th District
(804) 698-7509 (o)
District09@senate.virginia.gov

JAN 3 0 2018
DHP

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

DELORES L. McQUINN
POST OFFICE BOX 406
RICHMOND, VIRGINIA 23218

SEVENTIETH DISTRICT

COMMITTEE ASSIGNMENTS:
GENERAL LAWS
TRANSPORTATION
APPROPRIATIONS

Date: January 24, 2018

To: Members of the Board of Medicine
Perimeter Center
9960 Mayland Drive, Suite 201
Richmond, VA 23233

From: Delegate Delores L. McQuinn

Subject: Comment on the New Opioid Guidelines and Sickle Cell

To Whom It May Concern,

I am writing this letter to ask the Board of Medicine to consider granting a written exception in the new opioid guidelines for individuals who suffer from Sickle Cell Disease. The opioid crisis is real, and regulations are definitely needed to curb improper use. However, I have a serious concern that too many physicians may interpret the new regulations in a manner that would keep persons with Sickle Cell from receiving the necessary opioid pain relief.

As you know, Sickle Cell disease is an inherited blood disorder that causes extreme pain for individuals who suffer with the disease. It is my understanding that individuals with Sickle Cell disease need large doses of opioids to overcome the pain. This pain management is imperative in order to afford the sufferers of Sickle Cell the comfort to live a better quality of life.

Over the years, I have known numerous individuals who suffered and succumbed due to Sickle Cell anemia. I have listened to parents as they share stories of their children's pain and their pleas for relief. An exception for Sickle Cell disease would ensure appropriate opioid treatment is available for the courageous persons dealing with this debilitating disease.

Thank you for your time and consideration,

Delegate Delores L. McQuinn

30JAN 18 3:54PM

SOM

From: Eduardo Fraifeld [mailto:efraifeld@me.com]
Sent: Monday, January 15, 2018 9:35 AM
To: Brown, David (DHP) <David.Brown@dhp.virginia.gov>
Subject: Re: Message for Dr Hazel

Dr Brown,
I was a pleasure to speak to you the other day.
You had requested for me to submit comments on the current guidelines for opioid management.
My apologies for the delay as it has been an unusually busy the last 2 weeks.

First let me start by saying that I think the efforts from Commonwealth have been very good overall and certainly a step in the right direction.
We all know there is a problem and we all realize addiction issues have been around as long as mood altering substances have been around. The "opioid epidemic" is but a rung in the ladder of a very complex social, economic and political issue of how to handle addiction and we all know there are insufficient resources to treat addiction that need to be addressed.

The CDC guidelines do have some methodological flaws and over time as the scientific literature evolves we all hope these will correct out. I do however have some concerns in where all this is leading
I appreciate the Board of Medicine and the Commonwealth of Virginia's efforts to preserve the option for patients who need treatment with opioid's to do so and to recognize the CDC recommendations are "Guidelines" and not prescription standards.

1) Restriction in access to care

Payors are using these guidelines to deny care.
As an example I have an older woman with chronic low back pain from a combination of degenerative disk disease and DJD managed by one of the Medicaid insurances who was on 2 Tramadol a day.
She has already been through numerous treatment, is not a medical candidate for NSAID's.
She is low risk, highly compliant and very functional with medication.
The insurance has now stated the will no longer provide any opioid analgesics including Tramadol for longer than 7 days "unless she has cancer, sickle cell' and one other condition that does not apply.

This has impacted her function and needlessly increased her suffering and is just a sample of many such patients

2) Increased Documentation Burden on providers.

I have little sympathy on physicians complaining about the burden of work required to check the PMP and document in the history a medical reason for treatment (history, physical exam) as well as effect of treatment and compliance (pill counts), etc
Thee are basics of medical treatment and long held acceptable standards of care and applaud the board for insisting on these.

Unfortunately we now have the unintended consequence of the guidelines being used by payors to delay treatment and demand additional cumbersome documentation and appeal process to be able to provide chronic opioid treatment that place an increased work and financial strain on medical practices
This is contributing to patients being discharged from practices.

3)
Increased cost due to lack of risk stratification
The requirements for urine drug screen (UDS) frequency is based on literature that is published almost entire based on industry funded research. This includes at least one "white paper" by a major medical society I reviewed. Almost every author received funding from industry. This is no better than the widely criticized papers regarding appropriate opioid use published with Pharma support.

When you have elderly patients who have medical contraindications to the use of NSAID's and acetaminophen who have significant DJD pain, very low risk for opioid abuse by history and low medication use...there is no benefit to the repeated UDS every 3-6 months.

It would be much more beneficial if pharmacies and physicians instead handed out and required patients to read & sign a simple one page notice on how to safeguard their medications.
While I am at it, there also should be a much simpler way to dispose of unused medications such as a simple required pharmacy take back for destruction program. (I do have some ideas on this if you are interested)

4)
PMP reports
I applaud the use of these but have some concerns about our current system
A) we are no longer able to get longer than 2 years of data, this was immensely helpful in populations who were poor historians
B) PMP system should be able to be tied in to all border states. I am on the border with NC and have to go to a separate state PMP to get this information
C) Gaps in PMP need to be addressed. This includes mail order pharmacies and medications obtained at the Veteran facilities as this data often does not show up
D) The Morphine equivalents on the report...only work if there is an active prescription
Thye should add another line to give a 6 months previous average

5)
Addressing the climate of fear among physicians needs to be a concern of the board of medicine. While we all fully realize opioids are over prescribed by many, there should also be education and a more realistic treatment acceptance for low risk populations with low dose use

I have been involved in multiple educational programs and concerned about insinuation of NSAID & Acetaminophen use with little regard to the their adverse effects.
One of these speakers actually suggested that this in combination with cognitive behavioral therapy would solve most of chronic pain patient issues

Unfortunately in Southern Virginia access to cognitive behavioral therapy is out of reach for the vast majority of our patients. This should not serve as an excuse for prescribing opioids but is the reality under which physicians practice

After almost 27 years of practice I have seen the pendulum swings regarding opioid use from one extreme to the other. I do not expect us to be able to solve this easily but we hope we can find a balance that will result in safe care of our patients

Please feel free to contact me if I can help in any way

I have also attached my CV
Sincerely

Eduardo (Eddy) Fraifeld, MD
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Yeatts, Elaine J. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, January 24, 2018 9:47 AM
To: Yeatts, Elaine J. (DHP)
Subject: FW: Benzodiazepine co-prescription with buprenorphine
Attachments: Press Announcements Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's continued efforts to promote the safe adoption of medication-assisted treatment for opioid addiction.pdf

Public comment from Dr. Manhapra

From: Manhapra, Ajay [mailto:ajay.manhapra@yale.edu]
Sent: Wednesday, January 24, 2018 7:18 AM
To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>; Brown, David (DHP) <David.Brown@dhp.virginia.gov>
Subject: Benzodiazepine co-prescription with buprenorphine

Drs. Brown and Harp
I would like to point out that section about benzodiazepine co-prescription in the Virginia law is outdated. Please see the latest FDA advisory on this. FDA advises that it is not appropriate to deny OUD patients buprenorphine treatment simply because they are on benzodiazepines or because they have other dependencies. The FDA press release is attached.

Regards

Ajay

Ajay Manhapra, MD
ajay.manhapra@yale.edu
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Lead Physician, Advanced PACT Pain Clinic, Hampton VA Medical Center, Hampton, Virginia
Research Scientist, VA New England Mental Illness Research, Education and Clinical Center, West Haven, CT
Lecturer, Department of Psychiatry, Yale School of Medicine, New Haven, CT
Assistant Professor, Department of Physical Medicine and Rehabilitation and Psychiatry, Eastern Virginia Medical School, Norfolk, VA

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's continued efforts to promote the safe adoption of medication-assisted treatment for opioid addiction

For Immediate Release September 20, 2017

Statement

Medication-assisted treatment (MAT) – the use of medication combined with counseling and behavioral therapies – is one of the major pillars of the federal response to the opioid epidemic in this country. This type of treatment is an important tool that has the potential to help **millions of Americans with an opioid use disorder (https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm)** regain control over their lives. In fact, patients receiving MAT cut their risk of death from all causes in half, according to the Substance Abuse and Mental Health Services Administration. Addressing the epidemic of opioid addiction is my highest public health priority. One element of that effort is promoting more widespread, safe adoption of MAT as a way to help more people overcome addiction.

However, health care providers and patients face significant challenges when determining how best to treat opioid use disorder, especially when the MAT drugs contain methadone or buprenorphine – which are also opioids. For example, many patients with opioid use disorder might abuse other substances or have a co-existing chronic condition, such as a mental health disorder. This may require separate treatment using medications that, when combined with the MAT drugs methadone or buprenorphine, may pose serious risks. Today, the FDA issued a **Drug Safety Communication (/Drugs/DrugSafety/ucm575307.htm)** alerting health care providers and patients of the increased risk of serious side effects when combining these particular MAT drugs with benzodiazepines – often prescribed to treat anxiety, insomnia, or other conditions – and how to address these risks while continuing to maintain patients on MAT. In addition, the FDA also recently strengthened labeling for the MAT drug

buprenorphine to emphasize that patients may require treatment indefinitely and should continue treatment for as long as they benefit and as long as the use of MAT contributes to their intended treatment goals.

As noted in the Drug Safety Communication, the co-administration of the MAT drugs methadone or buprenorphine with benzodiazepines or other central nervous system (CNS) depressants can pose serious risks, including difficulty breathing, coma, and death. The FDA's new alert follows the agency's warning **last year (/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm)** of the risks of using opioid analgesics (to treat pain) or prescription opioid cough products and benzodiazepines at the same time. At that time, more consideration was needed regarding the combined use of these MAT drugs and benzodiazepines or other CNS depressants due to the unique medical needs and benefit-risk considerations for this specific patient population. As a result of that consideration, the FDA's new advisory that we're issuing today asks health care providers and patients to be aware of these risks. But at the same time, the agency is also reinforcing that MAT should not necessarily be denied to patients taking these other medications. The dangers associated with failing to treat an opioid use disorder can outweigh the risks of co-prescribing MAT and benzodiazepines. Instead, careful management of the patient and coordination of care is recommended.

To underscore the importance of appropriately utilizing MAT products, the FDA is requiring changes to MAT drug labels to help decrease the risks of combining these drugs, while taking steps to address situations where the MAT drugs methadone or buprenorphine might be co-administered with benzodiazepines. The new labeling recommends that health care providers develop a treatment plan that closely monitors any concomitant use of these drugs, and carefully taper the use of benzodiazepines, while considering other treatment options to address mental health conditions that the benzodiazepines might have been initially prescribed to address.

Reducing the number of Americans who are addicted to opioids and cutting the rate of new addiction is one of the FDA's highest priorities. We must do everything possible to address the staggering human toll caused by opioid use disorders, and ensuring patients receive proper treatment for both addiction and coexisting mental health conditions is a critical step in that effort.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

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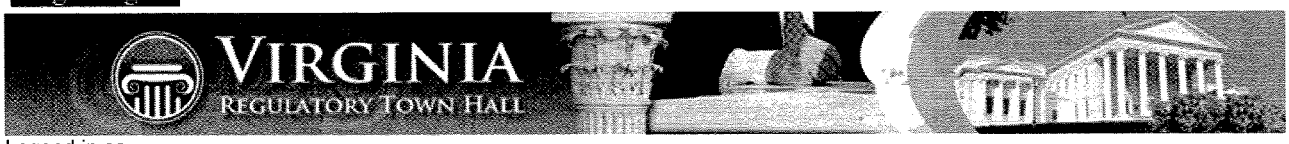
Virginia.gov Agencies | Governor



Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Medicine**

Chapter **Regulations Governing Prescribing of Opioids and Buprenorphine [18 VAC 85 - 21]**

Action	**Initial regulations**
Stage	**Proposed**
Comment Period	Ends 1/26/2018

All good comments for this forum **Show Only Flagged**

Back to List of Comments

Commenter: Melissa Messick 11/29/17 8:34 pm

Urinalysis Costs

I have a problem not with this law but with the cost to me and my insurance company, that I will explain in hopes of finding a solution. A brief Background:

I'm a 62 year old female I have documented cases of Arthritis, Sjogrens Syndrome, I also have had a pelvic sling which went very badly. These left me immobile due to swelling and pain, this was for the best part of two years. I was self-medicating with a lot Excedrin to be able to perform the smallest of daily living. My doctor that did the pelvic sling told me there was nothing else he could do for me. Two years ago my blood count bottomed out and I was hospitalized with only 4000 platelets which was life threatening.

Since that time several wonderful doctors have given me my life back. The medications and the doses were all trial and error to get to this point. I'm building myself back up and enjoying doing things with my children and grandchildren again. I am able to hold down my job now with the Virginia Employment Commission (pay band three.)

This new law that is in affect that states that I have to take a drug test every so often. I do not mind doing this. I took time off from my job and paid for an office visit that I didn't need. My doctor did the test and it was sent to Labcorp. The test came back as expected. Then I get a bill for the test at the cost of $221.00 for my part of the test and the insurance had to pay the remainder of the $425.00. I will still need to purchase the Medication. This something that I cannot afford and I certainly hate to go into debt for. I only take one Tramadol or two a day along with the other medications not on your list.

I hope you can see the issue I take with this Law. There are others I feel sure that are on a fixed income for example the elderly, terminally ill, cancer patients etc. that this will impact greatly. Again the elderly and the lower income population will not be able to received proper care.

I would be happy to speak to someone further.

Melissa Messick

lion6255@aol.com

Commenter: Debbie Peters — 11/30/17 8:46 am

Urinalysis

I am in agreement with Ms. Keswick regarding the need for lab charges for urine testing each time a needed prescription has to be refilled. Who can afford this? I am State employee with insurance and wpykd struggle to make these payments monthly in addition to the cost of the medications. I cannot imagine how a lot of people without insurance or low paying jobs could manage. I think someone needs to reconsider this issue.

Commenter: Sharon Fassold — 11/30/17 1:46 pm

Testing

While I agree with the spirit of the law, please reduce the cost of testing.

Commenter: Susan melton — 11/30/17 7:08 pm

High cost of testing

I feel that this charge is astronomical to those of already struggling to pay for overpriced meds. It is unfair to legitimate people who need these meds.

Commenter: Brenda Crouch — 12/3/17 6:16 pm

Testing Cost

For the average person this testing would be extremely high and time consuming.

Commenter: Tracy Jon — 1/13/18 1:29 pm

I think patients like see with Sickle Cell should not be limited to pain meds

As a teen, my parents have told me that I will not get the same dose or amount of pain meds I had in the past because docs are afraid to help kids like me it's not right.

Commenter: Floence Neal Cooper Smith, Retired Director of The VASCAP,VCU/MCV — 1/16/18 3:45 pm

Pain Medication or Sickle Cell Patients

It is very important that sickle cell patients continue to receive an adequate dosage of pain medications that has previously been recommended by their physician. Recently I have

spoken to several relatives of sickle cell patients and they are very concerned about the cut back of much needed pain medication relative to the pain that is experience with this health problem.

Commenter: Sitrena Woodson 1/17/18 1:55 pm

Opiod guidelines for chronic pain

Please ensure that Sickle Cell Disease be made an exception to the guidelines.

Commenter: Anthony Lofton 1/17/18 7:05 pm

Opioid prescription guidelines

Im asking that Sickle Cell Disease be made an exception to the guidelines of opioid prescriptions.

Commenter: Sickle Cell Association of Central Virginia, Inc. 1/18/18 10:51 am

Opiod crisis.

Please make Sickle Cell Disease an exception to the opiod guidelines. Thank you.

Commenter: Melina Davis-Martin, Medical Society of Virginia 1/18/18 12:02 pm

Medical Society of Virginia Comments Regarding 18 VAC 85 ? 21

William L. Harp, M.D. January 18, 2018

Executive Director

Board of Medicine

9960 Mayland Drive, Suite 300

Richmond, VA 23233

RE: Regulations Governing Prescribing of Opioids and Buprenorphine

Dear Dr. Harp:

The Medical Society of Virginia (MSV) appreciates the opportunity to comment on the Regulations Governing Prescribing of Opioids and Buprenorphine (18 VAC 85-21). MSV commends the Board's work in developing strong regulations that reflect prescribing best practices while ensuring the flexibility of professional judgment in extenuating medical circumstances.

MSV supported the Board's development of the initial emergency opioid and buprenorphine prescribing regulations enacted in March 2017. The emergency regulations provided a comprehensive framework of best practices that included consideration of non-opioid treatments, querying the Prescription Monitoring Program, appropriate strength, length, and quantity supply parameters, family history, treatment plans, and recognition of special considerations and

populations. This multi-faceted approach to opioid and buprenorphine prescribing gave prescribers appropriate guidance for the multiple factors that can contribute to opioid addiction, while preserving an option to treat extenuating medical circumstances.

These efforts by the Board and other partners to recognize, treat, and prevent opioid addiction have had a positive impact on the Commonwealth. In the past year, the number of individuals receiving high doses of opioids decreased by 18.6%, opioid doses declined by 40.15%, and multiple provider episodes per 100,000 Virginia residents decreased by 45%.

To continue Virginia's progress in aligning with prescribing best practices, MSV supports enacting 18 VAC 85-21. MSV is dedicated to reducing opioid addiction in Virginia by partnering with the Board and other state government agencies and stakeholder groups and by providing prescribing resources to physicians. MSV's opioid resource webpage gives physicians access to prescribing tools, best practice guidelines, and continuing education resources: http://www.msv.org/opioids.

MSV extends its support of the Board in its attention to the opioid crisis and is dedicated to working together.

Sincerely,

Melina Davis-Martin

Executive Vice President

CC:

David Brown, D.C., Director, Department of Health Professions

Elaine Yeatts, Policy Analyst, Department of Health Professions

Scott Johnson, General Counsel, MSV

Lauren Bates-Rowe, Assistant Vice President of Health Policy, MSV

Ralston King, Assistant Vice President of Government Affairs, MSV

Commenter: Ronald Dews Jr 1/20/18 11:10 am

Support of Sickle Cell Exception for Opiod Regulation

I have 2 boys with Sickle Cell Disease. I support regulations to control the abuse of opiods but not at the expense of Sickle Cell patients. Some, not all require available medication that goes beyond the current allowable limits to support there pain management at home or after a hospitalization. There pain management is suffering with the limits proposed and will in effect cause more ER visits which could have been avoided.

Please make Sickle Cell Disease an exception to the opiod guidelines. I thank you and my children that you.

Ronald Dews Jr.

Commenter: Mandy M. Atkinson, MD Pediatric Hematologist/Oncologist at Carilion 1/22/18 11:45 am

exception for sickle cell patients

I would also like the treatment of pain in patients with sickle cell disease to be an exception. Many of these patients live with chronic pain with acute exacerbations they can manage at home. Limitations on dosing would hinder their ability to do this and would send them to the ED, which typically would be either unnecessary or an overtreatment of something they could have handled at home. Even managing children with sickle cell disease with these limitations is challenging. I also think it is very important that patients with chronic pain know they have medicine when needed.

Commenter: Kimberly F. Johnson 1/22/18 12:56 pm

Support Patients With Sickle Cell

Due to the national opioid crisis, last year the Virginia Board of Medicine put emergency guideline/rules in place for doctors to follow when they prescribe opioids to all of their patients. Those guidelines include limits on dosage and long acting opioids needed by sickle cell patients, but they make NO rule exception for persons suffering from the pain crisis of sickle cell.

Please make Sickle Cell Disease an exception to the guidelines.

Thank you,

Kimberly F. Johnson

Commenter: Tarin Hampton, Sigma Gamma Rho Sorority, Inc. 1/22/18 7:32 pm

Opioid Prescriptions

Please make an exception for Sicle Cell Patients to be allowed access to this medication for their health condition.

Commenter: Yvette williams, Delicados Inc, 1/25/18 5:41 pm

Sickle cell patients should have access to opioids to ease their episodes of pain .

Commenter: Terrill Darling 1/25/18 6:17 pm

Sickle cell

Hello my name is Terrill Darling I'm a sickle cell patient.I'm 42 years old I have full custody of my son who also lives with sickle cell we are both prescribed opiates. I myself have been taking opiates for over 30 years I cannot live comfortably without opiates because it enables me to function. I was recently told by my provider that he wouldn't be comfortable prescribing my pain medication any longer because of the opiate crisis he offered me methadone as an alternative this will not work for me as I've had a Bad experience in the past I have been interviewing at many local and non-local providers to remedy this problem since I was pushed out of my doctors at VCI Virginia Cancer Institute I have experienced nothing but misery because of pain and fatigue I have

been hospitalized 5 times since October 31st of 2017 these days has proven to be the worst days of my life. Every doctor has refused to help me because of the opiate crisis I found a doctor who drastically reduced my quantity in potency of my pain medications to adhere to new policies rather than manage my pain. I'm not considered anymore as my Doctor instructed me to take it or leave it. My world is upside down and unbearable now the stability of my son is also in Jeopardy now because I struggle to manage his care also I'm asking for considering an exception for those of us living with this debilitating disease to continue to receive opiates as it is essential to us being able to live a manageable and more comfortable life and not allow us to be victims of our circumstances. Please hear our plea because now were merely only existing. With adequate care many of sickle cell patients are able to function as active members in society.

Commenter: TONI T BUMPASS 1/25/18 6:29 pm

Emergency Guidelines for ER opioid prescribing

I'm commenting on behalf of a patient with Sickle Cell disease. My 21 year old daughter battles daily with the pain associated with this debilitating blood disorder. Currently the only medicine prescribed for her to use is oxycodone and morphine. Although these meds are addicting, I plead with this medical board to decide on exceptions for individuals with chronic pain such as Sickle Cell. This is an illness that individuals must attempt to cope with for the rest of their lives and currently there is no medicine readily available. Please consider drawing up exceptional regulations for individuals with Sickle Cell. Thank you.

Commenter: Yahmeshau Veney 1/25/18 6:40 pm

Exception for sickle-cell

Hi my name is Yahmeshau Vene.I am the mother of a five-year-old child living with sickle cell disease. This is a disease that not only affects my son but our whole family. I have been dealing with Doctors Hospitals and Er visits since my son's birth. I have and currently witnessed the effect this disease has on my child mentally emotionally and physically.The unbearable pain is too much for a parent to witness. I experienced long days and nights in hospitals do to pain crisis because of this disease. When I heard that there wasn't a protocol in place for sickle cell patients to continue taking opiates and or an exception for those suffering with this debilitating disease I was floored. What shall I tell my child why I can't help him anymore he needs to be able to live without suffering constantly. I can't comprehend being let down in such a way as a parent and caregiver of a child living with sickle cell. We are asking that you not turn a blind eye on the population who are suffering and at mercy from this awful disease. Life isn't promised but relief can and should be.

Project 5033 - Proposed

BOARD OF MEDICINE

Initial regulations

CHAPTER 21

REGULATIONS GOVERNING PRESCRIBING OF OPIOIDS AND BUPRENORPHINE

Part I

General Provisions

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" means the Virginia Board of Medicine.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in The Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through IV.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part II

Management of Acute Pain

18VAC85-21-30. Evaluation of the acute pain patient.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance misuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these

substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III

Management of Chronic Pain

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life, and activities of daily living;

5. Psychiatric, addiction, and substance misuse history of the patient and any family history of addiction or substance misuse;

6. A urine drug screen or serum medication level;

7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical record the presence or absence of any indicators for medication misuse or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement signed by the patient in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. The practitioner shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate, and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

4. Diagnostic, therapeutic, and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage, and quantity prescribed and refills);

11. Patient instructions; and

12. Periodic reviews.

Part IV

Prescribing of Buprenorphine for Addiction Treatment

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance misuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of

childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication-assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

3. In formulations other than tablet form for indications approved by the FDA; or

4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women may be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR Part 2 shall be followed.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

D. Compliance with 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

Recommendations on Amendments in Adoption of Final Regulations:

1) Recommendations to the Board from the January 19, 2018 Legislative Committee:

   - 18VAC85-21-10(B)(1) – shall read: The treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell disease, (iii) a patient in hospice care, or (iv) a patient in palliative care.

   - Although it is difficult to pinpoint a percentage of patients that demonstrate naloxone intolerance, the rate allowed by the regulations should be increased to 7%. Dr. Harp stated that the increase is justified based on clinical comments to the Board.

   - Drug screens should be conducted initially and then randomly at the prescriber's discretion, at least once a year.

   - After the word "tramadol" in the regulations, add in ( ) "an atypical opioid."

2) The Advisory Board on Physician Assistants voted at its meeting on February 1, 2018 to recommend to the full Board that annotations on prescriptions to indicate "acute" "post-op" and "chronic" be included.

Harp, William L. (DHP)

From: Harp, William L. (DHP)
Sent: Wednesday, December 27, 2017 2:52 PM
To: WH BALLARD
Cc: Yeatts, Elaine J. (DHP)
Subject: RE: Comment for proposed regulations regarding "Opioid Crisis"

Dear Mr. and Ms. Ballard:

Thank you for your comments.

I am not sure if you have read the proposed regulations, so I am attaching the text from Regulatory Town Hall. http://townhall.virginia.gov/L/ViewXML.cfm?textid=12132

The intent of the regulations, initially effective on March 15, 2017 and revised August 24, 2017, is to ensure that physicians/prescribers are more thoughtful in their assessment and treatment of acute and chronic pain, thereby enhancing patient safety. The Board is aware that some physicians are telling their patients that they must reduce the amount of opioid they are taking. The Board is also aware that a physician may tell a patient that he/she will no longer write opioids for chronic pain and that they must seek care from a pain management specialist. The Board was aware that some physicians took these stances after they received a memo about the Centers for Disease Control Guidelines in May 2016, which preceded the Board's development of regulations for Virginia licensees.

If you carefully read the regulations, they do not instruct a prescriber to reduce the amount of medication that has been effective and safe. The prescriber is authorized to use his/her discretion with the dosages written; there must be clear documentation of the rationale for higher doses that 120 Morphine Milligram Equivalents a day. Also, the prescriber is to ensure patient safety by writing a prescription for naloxone, the rescue drug for opioid overdose.

I am not sure of the coming restriction to which you refer. The regulations have been in effect for a little over 9 months.

The Bloomberg article has a statement from Dr. Ajay Manhapra, who was at 2 or more of the meetings the Board of Medicine had on these regulations. He has communicated with me since regarding a paper he co-authored on the difficulty of tapering long-term pain patients from their opioids. Again, the regulations give the prescriber discretion on how to adjust the medicines for a chronic pain patient.

I will make sure that your comments are reviewed by the Board of Medicine as it goes through the process of developing final regulations.

I hope this is helpful to you.

With kindest regards,

William L. Harp, MD
Executive Director
Virginia Board of Medicine

From: WH BALLARD [mailto:whballard1210@comcast.net]
Sent: Tuesday, December 26, 2017 9:00 PM

To: Harp, William L. (DHP) <William.Harp@DHP.VIRGINIA.GOV>
Subject: Comment for proposed regulations regarding "Opioid Crisis"

Dear Dr. Harp,

My wife and I hereby comment regarding Virginia's possible medical regulations regarding the "Opioid Crisis." We fully understand that there has been a rise in fatalities due to medically prescribed opiates for pain. However, making it impossible for doctors to, confidently and without fear, provide their patients in chronic pain with the necessary medicines is not a solution. We know that Virginia law currently allows doctors to prescribe opiates indefinitely to patients with chronic pain. However, there appears to be a disconnect between the spirit of the law and the actual administration. Unless you desire to have a rash of suicides resulting from an inability to obtain prescriptions in place of your overdoses, this must be recognized and addressed. Please see our experience as follows:

My wife has an autoimmune disease similar to Lupus. She began having pain in her joints in her late twenties which got progressively worse to the point where she could hardly walk. She has had two shoulder joints, a lower left leg bone replacement, and one hip replacement. She tried every known method of dealing with the pain which goes on day or night whether she is moving or still. She even tried acupuncture. She was sent to several different pain management specialists who tried various pain medications. One of her doctors was threatened by government agencies and could no longer treat his patients. Finally, our family doctor put her on enough prescription man made pain killers to allow her to function in a fairly normal manner. She has been on this treatment with minor increases for about 20 years. Now our doctor has informed us that the end of December the Virginia government is going to make it impossible for him to continue with her pain medication. He is gong to try to find her a pain management specialist but, we have been down that road before with no success. If she has to come off her medication, it may kill her. If it doesn't kill her she will be in such pain she may want to die. She is now 65 and her Lupus like disease has done great harm to her kidneys, her lungs and her heart and she has little strength with which to withstand more pain. We understand that this government program is an attempt to address the over use of legal drugs. My wife has never used her legal drugs in an illegal manner. There must be some way for you to help people in this position and allow their doctors to continue providing them them the drugs necessary to cope with their pain. Please, please put a stop to this coming restriction!

We have been in corresponding with Delegate Kirk Cox on this issue. The following is our latest letter to him. It includes a link to an article which we think expresses the problem extremely well. We would appreciate very much if you would read it.

Dear Delegate Cox,

We will be seeing our family doctor on Dec. 28th to ask if he will be willing to continue prescribing Sara's chronic pain medications. We will show him your previous letter which states that he can do so. However, If he still refuses, we will be at a loss. Please check out the included link below to see what our doctor and we will be facing. Thank you.

https://www.bloomberg.com/news/articles/2017-11-21/millions-of-patients-face-pain-and-withdrawal-as-opioid-prescriptions-plummet

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This concludes our comments regarding the proposed regulations! Thank you for your consideration of them.

Sincerely,

William and Sara Ballard.

1210 Covington Rd.

Colonial Heights, VA 23834-2716

Ph: (804) 520-4211

Harp, William L. (DHP)

From: mail@changemail.org
Sent: Wednesday, December 13, 2017 8:50 AM
To: Harp, William L. (DHP)
Subject: 100 more people signed "Terry McAuliffe: Virginia Opioid Treatment"

change.org New signatures

William L Harp – This petition addressed to you on Change.org has new activity. See progress and respond to the campaign's supporters.

Terry McAuliffe: Virginia Opioid Treatment
Petition by Steve M · 100 supporters

100 more people signed

View petition activity

RECENT SUPPORTERS

Kayla Vinson
Dante, VA · Dec 04, 2017

Why would anyone want to stop treatment with these medicines is beyond me and down right sickening to not help those who need it and are actually doing good with these medicines. Things aren't looking to getting better but worse in many ways,but let's keep supporting for what is right.

nancy Harvey
Coeburn, VA · Oct 05, 2017

These medications have helped so many. I

Savannah beckner
Hardy, VA · Sep 06, 2017

Because suboxone saved me life! I've been clean for 5 years now!

Kelly Hawley
Media, PA · Sep 06, 2017

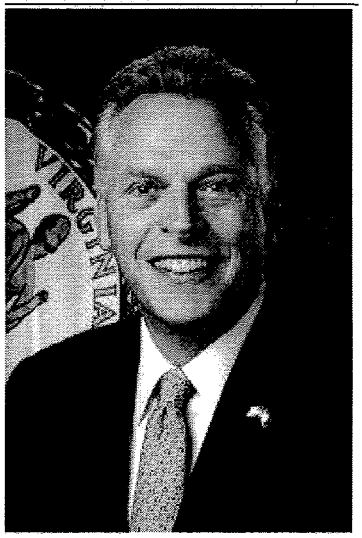
Subutex saved my life. I don't feel the government should be able to regulate what our doctors feel can save our lives. Taking away these medications is only asking for addicts to go back to the streets and overdose on heroin. Due to the crackdown on everything else. This makes it seem as if the government's way of ending the epidemic, is to let addicts kill themselves off...not help save them!

Dorene Ernst
Burke, VA · Aug 22, 2017

Only doctors should decide this not politicians

View all 100 supporters

Steve M Princeton WV, WV



0

0 have signed. Let's get to 1,000.

Steve M
Princeton WV, WV

Virginia HB 2163 wants to restrict prescriptions and federally licensed OTP clinics from using mono buprenorphine (Subutex) for opioid dependence. The bill restricts it to only patients that are pregnant or patients that are switching from methadone to buprenorphine but they cannot have mono buprenorphine for more than 7 days, or whatever the Virginia board of medicine decides. This isn't a good idea, restrictions on prescriptions are fine but also allow people that cannot have Naloxone to also be able to get a prescription.

They need to also allow the federal OTP clinics to dispense it in take homes because the patients that have them earned them. I can see and understand why limits and things need to be put into place. It is not a good idea to make this bill law, though. The problem with the bill is the patients that are already in treatment, and have a documented hypersensitivity to Naloxone will lose access to treatment. Buprenorphine is the safest alternative of 3 medications available it doesn't matter if it has Naloxone

or not. Addiction is a fight these patients will have to fight with for life. The patients that have a hypersensitivity shouldn't lose access to this medication. It isn't right that if they didn't have a hypersensitivity they could continue getting Buprenorphine but with the Naloxone. Most doctors will not prescribe Subutex unless you cannot have Suboxone anyway.

Methadone, and Buprenorphine both are proven medications used to treat addiction. Each of these medications has their uses but some patients cannot have suboxone they need a full agonist such as methadone. Some patients cannot have methadone and seek suboxone treatment. Every patient deserves the right to what medication they are being treated with. Not one of them works for everyone. Patients that have gone to federally licensed clinic need to be allowed to still have take homes, take homes they earned. Buprenorphine has a ceiling effect anything above 32 milligrams cannot be processed in a 24 hour time period so the chances of overdose are way below the average of other medications used. Some of these patients have been in maintenance replacement therapy and cannot afford to go to the clinic every day to get it. I ask the state of Virginia to look at the facts and make a decision that would save many people's lives that suffer from addiction and opioid dependency.

All of these medications are effective in treating addiction. Restrictions on prescriptions are fine, but also allow patients that have a documented allergy on file to get a prescription so these patients don't lose treatment and also allow the federally licensed clinics to continue to dispense it in take homes. While methadone is stronger than buprenorphine some people need a stronger medication. Everyone is different, and as with many medical problems, you cannot put everyone on the same medication. Experts across the nation are concerned about this bill as it will put patients back on the streets.

Buprenorphine has been offered as an atlernative at federally licensed otps across the nation for over a decade in most places. These patients deserve the right to keep their treatment with Buprenorphine just the same as the Methadone patients. Not everyone can take Methadone, and everyone cannot take buprenorphine. Both of these medications are life savers and too take this option away from otp clinics put patients in danger. The reason they seek treatment at an OTP is because most doctors will write Buprenorphine anyway. It costs clinics more to carry the combination tablet and that costs the patients more hundreds of dollars a month more to be exact. Naloxone was put into Suboxone to appease the DEA.

Naloxone was also used to help the Reckitt-Benckiser the maker of Suboxone file a patent as regular Buprenorphine has been around for over 30 years so they couldn't patent it. Generic Buprenorphine came out 4 years before generic Suboxone did. That is because they couldn't hold a patent for plain buprenorphine as long. While both drugs have their uses, some people just cannot have Naloxone. These people shouldn't be punished for an allergy nor should the patients at otps lose treatment because of a bad company. Regular Buprenorphine was available as a generic to the public 5 years before generic Suboxone was and that is because Reckitt-Benckiser couldn't hold a patient to a drug they didn't invent.

The Virginia Medical board is going to make a seriously bad decision to stop these clinics from dispensing this medication if this bill is signed into law. Many of the biggest addiction organizations also believe this to be a bad law.
If they take Buprenorphine treatment away today, what will they do tomorrow? Go after Methadone? Both are these drugs have helped many people get their lives back. SAMHSA has deemed it a safer alternative and those are their words. not mine. If the plan is to also go after Methadone there will be an even bigger crisis on our hands. These systems work, and limiting options to patients isn't a wise or

just choice.

Virginia is full of rural areas and many people travel 50 plus miles one way to be able to get to dose. Until they earn their take homes they do this everyday, and it is extremely hard for these people to have a life, work, and everything in between. Most of these patients cannot travel every day to dose so I am asking you please do not punish the patients that have done what was are required by state and federal law to obtain take homes.

We need to have access to this medication, restrictions like that are not the answer. We are fighting a war and these medications need to be more accessible. I ask for the bill to be amended and allow people that have a hypersensitivity to Naloxone and have it documented to also be allowed to get a prescription and to allow federally licensed clinics to dispense it in take homes to the patients that have earned them. If they do not many of these patients will be forced to the streets more than likely, and if they overdose Narcan isn't an option because they are allergic to it. I believe every person should have a decision in what medication they are being treated with. All three of these medications have a potential for abuse, but methadone and suboxone aren't being limited. I believe if a patient has a documented hypersensitivity to Naloxone (Narcan) they should have the same access to therapy as a person would if they could have suboxone.

The OTPs are also conservative in providing patients with any take home medication. When take home medication is provided to the patient through the OTP, the OTP must meet eight clinical standards, which have been enforced singe the regulatory authority of the FDA that continued under the regulatory oversight of SAMHSA. These criteria include absence of recent drug abuse, which is determined through toxicology reports in addition to established regularity of clinic attendance, absence of serious behavioral problems, absence of known recent criminal activity, stability in the patient's home environment, length of time comprehensive maintenance treatment, ensuring that take home medication can be safely stored within the patient's home whether the rehabilitative benefit the patient derives from decreasing the frequency of clinic attendance outweighs potential risk. Compliance with the regulations is mandatory.

Restricting this medication will affect people currently in treatment at federally licensed facilities that already have diversion prevention protocols. Each take home at this moment is 1 days dose sealed in a bottle. So if a patient has 13 take homes he gets 13 sealed bottles. These bottles cannot be tampered with, if they were to be called in and a bottle be missing even the plastic on one before it was due to be taken the take homes are revoked.

Most patients being treated for addiction/opioid dependency get the combination pill anyway. Most patients that go to a clinic go because they cannot have suboxone or its the closest option they have.

These facts below represent all forms of buprenorphine products. Mono buprenorphine isn't the problem.

Patches
Tablets (Mono and Combined)
Buccal films
Sublingual Films

NATIONAL ESTIMATES FOR THE MOST FREQUENTLY IDENTIFIED
CONTROLLED SUBSTANCES: Estimated number and percentage of total drug reports submitted

to laboratories from January 1, 2014, through December 31, 2014, and analyzed by March 31, 2015.

Buprenorphine drug reports represented only 1.01% of all drug reports Nationwide.

Inability to access to treatment is a predictor of increased use of diverted buprenorphine. The finding that the most robust risk factor for buprenorphine use was failing to access legitimate buprenorphine treatment implies that increasing, not limiting, buprenorphine treatment access may be an effective response to buprenorphine diversion among persons not in treatment.

Studies have shown that buprenorphine is safe and highly efficacious,(11)decreases hospital admissions, morbidity, and mortality;(12) reduces illicit opioid use; (13)increases treatment retention; (14)and is much more effective when used in ongoing maintenance treatment than when patients are tapered off the medication.(15)

(U.S. Drug Enforcement Administration, Office of Diversion Control. (2015). National Forensic Laboratory
Information System: Year 2014 Annual Report. Springfield, VA: U.S. Drug Enforcement Administration. Available at:
http://www.deadiversion.usdoj.gov/nflis/NFLIS2014AR.pdf

(Lofwall MR and Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug Alcohol Depend. 2012;126:379-383.+)

(11) Johan Kakko et al., 1-Year Retention & Social Function After Buprenorphine-Assisted Relapse Prevention Treatment
for Heroin Dependence in Sweden: a randomized, placebo-controlled trial, LANCET, VOL. 361 (Feb. 22, 2003).

(12)Sofie Mauger, Ronald Fraser, & Kathryn Grill, Utilizing buprenorphine to treat illicit and prescription opioid
dependence, NEUROPSYCHIATRIC DISEASE & TREATMENT 2014:10 587-598, 588 (2014).

(13) Roger D. Weiss et al., Adjunctive Counseling During Brief and Extended Buprenorphine Treatment for Prescription Opioid Dependence, ARCH. GEN. PSYCHIATRY (Dec. 2011), 9, available at
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3470422/

(14) Cindy Parks Thomas et al., Medication-Assisted Treatment with Buprenorphine: Assessing the Evidence," Psychiatric
Services in Advance, (Nov. 18, 2013), 7.

This petition will be delivered to:

- **Governor**
  Terry McAuliffe
- **Executive Director of Board of Medicine**
  William L Harp

Read the letter

Letter to
Governor Terry McAuliffe
Executive Director of Board of Medicine William L Harp

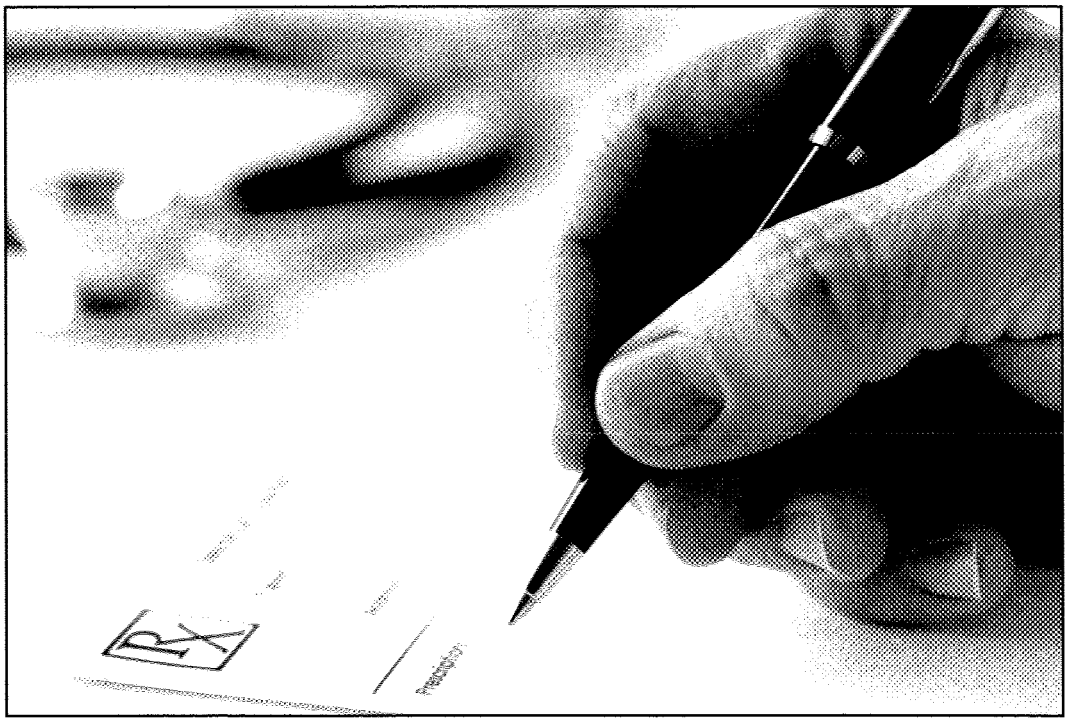
Virginia Buprenorphine Treatment doesn't need more restrictions it needs less restrictions. The amendment I purpose doesn't hurt anyone in the process. It puts the restriction in place, but also allows patients that cannot have suboxone to also be able to get a prescription. It also allows federally licensed clinics to dispense it in take homes because those patients went for a years to earn them. It isn't right, nor possible to make these patients travel 50 plus miles one way to dose than drive back. It puts undue hardships on patients in treatment already, and will have a drastic effect on these people's lives. If we could take a look at the data of diverted buprenorphine and that includes all forms of this medication with and without naloxone we would see the same results we did with Methadone. It was around 10 years ago that data was looked over and most of the diverted medication came from pain patients with little to no oversight. These clinics have multiple diversion protocols in place, and most patients suffering from opioid dependence cannot even get Buprenorphine Mono wrote to them anyway unless they cannot have Naloxone. Buprenorphine mono isn't the problem, the problem is treatment is inaccessible. Please take all of this information into consideration before making a decision that will alter thousands of Virginians life. I have linked multiple statistical facts, and the sources of those facts. Narcan isn't the deterrent in these drugs, it is buprenorphine itself. It binds to the receptors much more aggressively than other opioids and therefor makes those other drugs ineffective. Narcan has nothing to do with it, and all it effectively does is sky rocket the price of treatment because generics have to keep up with the price of brand names. I hope you make the right decision and support these people.

OK

Today: Steve is counting on you

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 1
March 18, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CONTENTS

Disclosure of Relationship

The Core Expert Group (CEG) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Pam Archer discloses authorship of the Oklahoma Emergency Department and Urgent Care Clinic Opioid Prescribing Guidelines and the Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office Based Setting; Bonnie Burman discloses authorship of the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain; Jane Ballantyne discloses that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC, and has special advisory committee responsibilities on the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies committee; Phillip Coffin discloses that in 2012 he provided expert testimony to the California State Assembly regarding a bill to expand naloxone access and reports that he is the principal investigator on a research study of methamphetamine dependence that receives donated injectable naltrexone from Alkermes, Inc.; Gary Franklin discloses authorship of the AMDG Interagency Guideline on Prescribing Opioids for Pain; Erin Krebs discloses that she represented the American College of Physicians at a 2014 Food and Drug Administration meeting on Abuse Deterrent Opioid Formulations; Lewis Nelson discloses his ad-hoc membership on the FDA Drug Safety and Risk Management Advisory Committee; Trupti Patel discloses authorship of the Arizona Opioid Prescribing Guidelines; Robert "Chuck" Rich discloses that he was an author of the 2013 American Academy of Family Physicians position paper on opioids and pain management; Joanna Starrels discloses that she received honoraria from the Betty Ford Institute; Thomas Tape discloses that he was an author of the 2013 American College of Physicians policy position paper on prescription drug abuse. CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support. No foundation or industry support was accepted.

The Opioid Guideline Workgroup (OGW) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Anne Burns discloses that she participated in a congressional briefing sponsored by Reps. Carter and DeSaulnier on the pharmacist's role of furnishing Naloxone and that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit. Chinazo Cunningham discloses that her husband is employed by Quest Diagnostics and Dr. Cunningham was recused from any discussion related to urine drug testing. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Erin Krebs discloses that she served on the CDC Opioid Prescribing Guideline CEG. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG. Greg Terman discloses that he serves as the President of the American Pain Society. Mark Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone formulation to treat acute postoperative pain and Dr. Wallace was recused form any discussion related to abuse-deterrent drugs.

The NCIPC Board of Scientific Counselors (BSC) members disclose that they have no financial conflicts of interest. Two BSC members, Traci Green and Christina Porucznik, served on the Opioid Guideline Workgroup. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Title]. MMWR Recomm Rep 2016;65(No. RR-#):[inclusive page numbers].

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Prepared by
Deborah Dowell, MD[1]
Tamara M. Haegerich, PhD[1]
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[1]*Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, Atlanta, Georgia*

Summary

This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.

Introduction

Background

Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription (*1*). In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills (*2*). Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties (*3*). Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication (*2*).

Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients, particularly members of racial and ethnic minority groups, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment (*4*). Patients can experience persistent pain that is not well controlled. There are clinical, psychological, and social consequences associated with chronic pain including limitations in complex activities, lost work productivity, reduced quality of life, and stigma, emphasizing the importance of appropriate and compassionate patient care (*4*). Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options.

Chronic pain has been variably defined but is defined within this guideline as pain that typically lasts >3 months or past the time of normal tissue healing (*5*). Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (*4*). Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated that 14.6% of adults have current widespread or localized pain lasting at least 3 months (*6*). Based on a survey conducted during 2001–2003 (*7*), the overall prevalence of common, predominantly musculoskeletal pain conditions (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the

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United States, although minimum duration of symptoms was not specified. Most recently, analysis of data from the 2012 National Health Interview Study showed that 11.2% of adults report having daily pain (*8*). Clinicians should consider the full range of therapeutic options for the treatment of chronic pain. However, it is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Evidence supports short-term efficacy of opioids for reducing pain and improving function in noncancer nociceptive and neuropathic pain in randomized clinical trials lasting primarily ≤12 weeks (*9,10*), and patients receiving opioid therapy for chronic pain report some pain relief when surveyed (*11–13*). However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later (*14*). On the basis of data available from health systems, researchers estimate that 9.6–11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005 (*15*).

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States (*16*). In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly (*17*). Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths (*18*). The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available (*19*). Although clinical criteria have varied over time, opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home (*20*). This diagnosis has also been referred to as "abuse or dependence" and "addiction" in the literature, and is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped), both of which can exist without a diagnosed disorder. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (*21*). Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder (*22–24*), highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years receiving opioids for chronic noncancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose (*25*).

This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. Although the guideline does not focus broadly on pain management, appropriate use of long-term opioid therapy must be considered within the context of all pain management strategies (including nonopioid pain medications and nonpharmacologic treatments). CDC's recommendations are made on the basis of a systematic review of the best available evidence, along with input from experts, and further review and deliberation by a federally chartered advisory committee. The guideline is intended to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Rationale

Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids (*26*). Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain (*27*). These attitudes and beliefs, combined with increasing trends in opioid-related overdose, underscore the need for better clinician guidance on opioid prescribing. Clinical practice guidelines focused on prescribing can improve clinician knowledge, change prescribing practices (*28*), and ultimately benefit patient health.

Professional organizations, states, and federal agencies (e.g., the American Pain Society/American Academy of Pain Medicine, 2009; the Washington Agency Medical Directors Group, 2015; and the U.S. Department of Veterans Affairs/Department of Defense, 2010) have developed guidelines for opioid prescribing (*29–31*). Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest (*32*). Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

This CDC guideline offers clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain) (*24,33,34*). Using guidelines to address problematic prescribing has the potential to optimize care and improve patient safety based on evidence-based practice (*28*), as well as reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic.

Scope and Audience

This guideline is intended for primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians has been above average (*3*). Primary care clinicians include physicians as well as nurse practitioners and physician assistants. Although the focus is on primary care clinicians, because clinicians work within team-based care, the recommendations refer to and promote integrated pain management and collaborative working relationships with other providers (e.g., behavioral health providers, pharmacists, and pain management specialists). Although the transition from use of opioid therapy for acute pain to use for chronic pain is hard to predict and identify, the guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.

This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms (*35*). End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. Patients within the scope of this guideline include cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, and are under cancer surveillance only. The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant women) and in populations with conditions posing special risks (e.g., a history of substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and harms of long-term opioid therapy in children and adolescents is limited, and few opioid medications provide information on the label regarding safety and effectiveness in pediatric patients. However, observational research shows significant increases in opioid prescriptions for pediatric populations from 2001 to 2010 (*36*), and a large proportion of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries (e.g., in one study, 50% of adolescents presenting with headache received a prescription for an opioid pain medication [*37,38*]). Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions (*39*), with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs (*40*). Use of prescribed opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse (*41*). Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use (*42*). Thus, risk of opioid medication use in pediatric populations is of great concern. Additional clinical trial and observational research is needed,

and encouraged, to inform development of future guidelines for this critical population.

The recommendations are not intended to provide guidance on use of opioids as part of medication-assisted treatment for opioid use disorder. Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline. Readers are referred to other sources for prescribing recommendations within acute care settings and in dental practice, such as the American College of Emergency Physicians' guideline for prescribing of opioids in the emergency department (*43*); the American Society of Anesthesiologists' guideline for acute pain management in the perioperative setting (*44*); the Washington Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Part II: Prescribing Opioids in the Acute and Subacute Phase (*30*); and the Pennsylvania Guidelines on the Use of Opioids in Dental Practice (*45*). In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (*46*).

Guideline Development Methods

Guideline Development Using the Grading of Recommendations Assessment, Development, and Evaluation Method

CDC developed this guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (http://www.gradeworkinggroup.org). This method specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. The method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP) (*47*). CDC has applied the ACIP translation of the GRADE framework in this guideline. Within the ACIP GRADE framework, the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence in the effect of a clinical action on health outcomes. The categories include type 1 evidence (randomized clinical trials or overwhelming evidence from observational studies), type 2 evidence (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 evidence (observational studies or randomized clinical trials with notable limitations), and type 4 evidence (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). Type of evidence is categorized by study design as well as limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and a constellation of plausible biases that could change observations of effects. Type 1 evidence indicates that one can be very confident that the true effect lies close to that of the estimate of the effect; type 2 evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; type 3 evidence means that confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect; and type 4 evidence indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect (*47,48*). When no studies are present, evidence is considered to be insufficient. The ACIP GRADE framework places recommendations in two categories, Category A and Category B. Four major factors determine the category of the recommendation: the quality of evidence, the balance between desirable and undesirable effects, values and preferences, and resource allocation (cost). Category A recommendations apply to all persons in a specified group and indicate that most patients should receive the recommended course of action. Category B recommendations indicate that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (*47*). According to the GRADE methodology, a particular quality of evidence does not necessarily imply a particular strength of recommendation (*48–50*). Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs. Category B recommendations are made when the advantages and disadvantages of a clinical action are more balanced. GRADE methodology is discussed extensively elsewhere (*47,51*). The U.S. Preventive Services Task Force (USPSTF) follows different methods for developing and categorizing recommendations (http://www.uspreventiveservicestaskforce.org). USPSTF recommendations focus on preventive services and are categorized as A, B, C, D, and I. Under the Affordable Care Act, all "nongrandfathered" health plans (that is, those health plans not in existence prior to March 23, 2010 or those with significant changes to their coverage) and expanded Medicaid plans are required to cover

preventive services recommended by USPSTF with a category A or B rating with no cost sharing. The coverage requirements went into effect September 23, 2010. Similar requirements are in place for vaccinations recommended by ACIP, but do not exist for other recommendations made by CDC, including recommendations within this guideline.

A previously published systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness and risks of long-term opioid treatment of chronic pain (*14*,*52*) initially served to directly inform the recommendation statements. This systematic clinical evidence review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk-prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, addiction, abuse, or misuse. For the current guideline development, CDC conducted additional literature searches to update the evidence review to include more recently available publications and to answer an additional clinical question about the effect of opioid therapy for acute pain on long-term use. More details about the literature search strategies and GRADE methods applied are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026). CDC developed GRADE evidence tables to illustrate the quality of the evidence for each clinical question.

As identified in the AHRQ-sponsored clinical evidence review, the overall evidence base for the effectiveness and risks of long-term opioid therapy is low in quality per the GRADE criteria. Thus, contextual evidence is needed to provide information about the benefits and harms of nonpharmacologic and nonopioid pharmacologic therapy and the epidemiology of opioid pain medication overdose and inform the recommendations. Further, as elucidated by the GRADE Working Group, supplemental information on clinician and patient values and preferences and resource allocation can inform judgments of benefits and harms and be helpful for translating the evidence into recommendations. CDC conducted a contextual evidence review to supplement the clinical evidence review based on systematic searches of the literature. The review focused on the following four areas: effectiveness of nonpharmacologic and nonopioid pharmacologic treatments; benefits and harms related to opioid therapy (including additional studies not included in the clinical evidence review such as studies that evaluated outcomes at any duration or used observational study designs related to specific opioid pain medications, high-dose opioid therapy, co-prescription of opioids with other controlled substances, duration of opioid use, special populations, risk stratification/mitigation approaches, and effectiveness of treatments for addressing potential harms of opioid therapy); clinician and patient values and preferences; and resource allocation. CDC constructed narrative summaries of this contextual evidence and used the information to support the clinical recommendations. More details on methods for the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

On the basis of a review of the clinical and contextual evidence (review methods are described in more detail in subsequent sections of this report), CDC drafted recommendation statements focused on determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. To help assure the draft guideline's integrity and credibility, CDC then began a multistep review process to obtain input from experts, stakeholders, and the public to help refine the recommendations.

Solicitation of Expert Opinion

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology.* CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

Prior to their participation, CDC asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Experts could not serve if they had conflicts that might have a direct and predictable effect on the recommendations. CDC excluded experts who had a financial or promotional relationship with a company

* A list of the members appears at the end of this report. The recommendations and all statements included in this guideline are those of CDC and do not necessarily represent the official position of any persons or organizations providing comments on the draft guideline.

that makes a product that might be affected by the guideline. CDC reviewed potential nonfinancial conflicts carefully (e.g., intellectual property, travel, public statements or positions such as congressional testimony) to determine if the activities would have a direct and predictable effect on the recommendations. CDC determined the risk of these types of activities to be minimal for the identified experts. All experts completed a statement certifying that there was no potential or actual conflict of interest. Activities that did not pose a conflict (e.g., participation in Food and Drug Administration [FDA] activities or other guideline efforts) are disclosed.

CDC provided to each expert written summaries of the scientific evidence (both the clinical and contextual evidence reviews conducted for this guideline) and CDC's draft recommendation statements. Experts provided individual ratings for each draft recommendation statement based on the balance of benefits and harms, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC hosted an in-person meeting of the experts that was held on June 23–24, 2015, in Atlanta, Georgia, to seek their views on the evidence and draft recommendations and to better understand their premeeting ratings. CDC sought the experts' individual opinions at the meeting. Although there was widespread agreement on some of the recommendations, there was disagreement on others. Experts did not vote on the recommendations or seek to come to a consensus. Decisions about recommendations to be included in the guideline, and their rationale, were made by CDC. After revising the guideline, CDC sent written copies of it to each of the experts for review and asked for any additional comments; CDC reviewed these written comments and considered them when making further revisions to the draft guideline. The experts have not reviewed the final version of the guideline.

Federal Partner Engagement

Given the scope of this guideline and the interest of agencies across the federal government in appropriate pain management, opioid prescribing, and related outcomes, CDC invited its National Institute of Occupational Safety and Health and CDC's federal partners to observe the expert meeting, provide written comments on the full draft guideline after the meeting, and review the guideline through an agency clearance process; CDC reviewed comments and incorporated changes. Interagency collaboration will be critical for translating these recommendations into clinical practice. Federal partners included representatives from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, FDA, the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, AHRQ, and the Office of National Drug Control Policy.

Stakeholder Comment

Given the importance of the guideline for a wide variety of stakeholders, CDC also invited review from a Stakeholder Review Group (SRG) to provide comment so that CDC could consider modifications that would improve the recommendations' specificity, applicability, and ease of implementation. The SRG included representatives from professional organizations that represent specialties that commonly prescribe opioids (e.g., pain medicine, physical medicine and rehabilitation), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organizations with interests in pain management and opioid prescribing.* Representatives from each of the SRG organizations were provided a copy of the guideline for comment. Each of these representatives provided written comments. Once input was received from the full SRG, CDC reviewed all comments and carefully considered them when revising the draft guideline.

Constituent Engagement

To obtain initial perspectives from constituents on the recommendation statements, including clinicians and prospective patients, CDC convened a constituent engagement webinar and circulated information about the webinar in advance through announcements to partners. CDC hosted the webinar on September 16 and 17, 2015, provided information about the methodology for developing the guideline, and presented the key recommendations. A fact sheet was posted on the CDC Injury Center website (http://www.cdc.gov/injury) summarizing the guideline development process and clinical practice areas addressed in the guideline; instructions were included on how to submit comments via email. CDC received comments during and for 2 days following the first webinar. Over 1,200 constituent comments were received. Comments were reviewed and carefully considered when revising the draft guideline.

Peer Review

Per the final information quality bulletin for peer review (https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf), peer review requirements applied to this guideline because it provides influential

scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations.* CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified. CDC placed the names of peer reviewers on the CDC and the National Center for Injury Prevention and Control Peer Review Agenda websites that are used to provide information about the peer review of influential documents. CDC reviewed peer review comments and revised the draft guideline accordingly.

Public Comment

To obtain comments from the public on the full guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the guideline and the supporting clinical and contextual evidence reviews for public comment. The comment period closed January 13, 2016. CDC received more than 4,350 comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when revising the draft guideline.

Federal Advisory Committee Review and Recommendation

The National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) is a federal advisory committee that advises and makes recommendations to the Secretary of the Department of Health and Human Services, the Director of CDC, and the Director of NCIPC.* The BSC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. CDC sought the BSC's advice on the draft guideline. BSC members are special government employees appointed as CDC advisory committee members; as such, all members completed an OGE Form 450 to disclose relevant interests. BSC members also reported on their disclosures during meetings. Disclosures for the BSC are reported in the guideline.

To assist in guideline review, on December 14, 2015, via Federal Register notice, CDC announced the intent to form an Opioid Guideline Workgroup (OGW) to provide observations on the draft guideline to the BSC. CDC provided the BSC with the draft guideline as well as summaries of comments provided to CDC by stakeholders, constituents, and peer reviewers, and edits made to the draft guideline in response. During an open meeting held on January 7, 2016, the BSC recommended the formation of the OGW. The OGW included a balance of perspectives from audiences directly affected by the guideline, audiences that would be directly involved with implementing the recommendations, and audiences qualified to provide representation. The OGW comprised clinicians, subject matter experts, and a patient representative, with the following perspectives represented: primary care, pain medicine, public health, behavioral health, substance abuse treatment, pharmacy, patients, and research.* Additional sought-after attributes were appropriate academic and clinical training and relevant clinical experience; high scientific standing; and knowledge of the patient, clinician, and caregiver perspectives. In accordance with CDC policy, two BSC committee members also served as OGW members, with one serving as the OGW Chair. The professional credentials and interests of OGW members were carefully reviewed to identify possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Only OGW members whose interests were determined to be minimal were selected. When an activity was perceived as having the potential to affect a specific aspect of the recommendations, the activity was disclosed, and the OGW member was recused from discussions related to that specific aspect of the recommendations (e.g., urine drug testing and abuse-deterrent formulations). Disclosures for the OGW are reported. CDC and the OGW identified ad-hoc consultants to supplement the workgroup expertise, when needed, in the areas of pediatrics, occupational medicine, obstetrics and gynecology, medical ethics, addiction psychiatry, physical medicine and rehabilitation, guideline development methodology, and the perspective of a family member who lost a loved one to opioid use disorder or overdose.

The BSC charged the OGW with reviewing the quality of the clinical and contextual evidence reviews and reviewing each of the recommendation statements and accompanying rationales. For each recommendation statement, the OGW considered the quality of the evidence, the balance of benefits and risks, the values and preferences of clinicians and patients, the cost feasibility, and the category designation

of the recommendation (A or B). The OGW also reviewed supplementary documents, including input provided by the CEG, SRG, peer reviewers, and the public. OGW members discussed the guideline accordingly during virtual meetings and drafted a summary report of members' observations, including points of agreement and disagreement, and delivered the report to the BSC.

NCIPC announced an open meeting of the NCIPC BSC in the Federal Register on January 11, 2015. The BSC met on January 28, 2016, to discuss the OGW report and deliberate on the draft guideline itself. Members of the public provided comments at this meeting. After discussing the OGW report, deliberating on specific issues about the draft guideline identified at the meeting, and hearing public comment, the BSC voted unanimously: to support the observations made by the OGW; that CDC adopt the guideline recommendations that, according to the workgroup's report, had unanimous or majority support; and that CDC further consider the guideline recommendations for which the group had mixed opinions. CDC carefully considered the OGW observations, public comments, and BSC recommendations, and revised the guideline in response.

Summary of the Clinical Evidence Review

Primary Clinical Questions

CDC conducted a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain, consistent with the GRADE approach (*47,48*). Long-term opioid therapy is defined as use of opioids on most days for >3 months. A previously published AHRQ-funded systematic review on the effectiveness and risks of long-term opioid therapy for chronic pain comprehensively addressed four clinical questions (*14,52*). CDC, with the assistance of a methodology expert, searched the literature to identify newly published studies on these four original questions. Because long-term opioid use might be affected by use of opioids for acute pain, CDC subsequently developed a fifth clinical question (last in the series below), and in collaboration with a methodologist conducted a systematic review of the scientific evidence to address it. In brief, five clinical questions were addressed:

- The effectiveness of long-term opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for long term (≥1 year) outcomes related to pain, function, and quality of life, and how effectiveness varies according to the type/cause of pain, patient demographics, and patient comorbidities (Key Question [KQ] 1).
- The risks of opioids versus placebo or no opioids on abuse, addiction, overdose, and other harms, and how harms vary according to the type/cause of pain, patient demographics, patient comorbidities, and dose (KQ2).
- The comparative effectiveness of opioid dosing strategies (different methods for initiating and titrating opioids; immediate-release versus ER/LA opioids; different ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled, continuous versus as-needed dosing; dose escalation versus dose maintenance; opioid rotation versus maintenance; different strategies for treating acute exacerbations of chronic pain; decreasing opioid doses or tapering off versus continuation; and different tapering protocols and strategies) (KQ3).
- The accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse; the effectiveness of risk mitigation strategies (use of risk prediction instruments); effectiveness of risk mitigation strategies including opioid management plans, patient education, urine drug testing, prescription drug monitoring program (PDMP) data, monitoring instruments, monitoring intervals, pill counts, and abuse-deterrent formulations for reducing risk for opioid overdose, addiction, abuse, or misuse; and the comparative effectiveness of treatment strategies for managing patients with addiction (KQ4).
- The effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain on long-term use (KQ5).

The review was focused on the effectiveness of long-term opioid therapy on long-term (>1 year) outcomes related to pain, function, and quality of life to ensure that findings are relevant to patients with chronic pain and long-term opioid prescribing. The effectiveness of short-term opioid therapy has already been established (*10*). However, opioids have unique effects such as tolerance and physical dependence that might influence assessments of benefit over time. These effects raise questions about whether findings on short-term effectiveness of opioid therapy can be extrapolated to estimate benefits of long-term therapy for chronic pain. Thus, it is important to consider studies that provide data on long-term benefit. For certain opioid-related harms (overdose, fractures, falls, motor vehicle crashes), observational studies were included with outcomes measured at shorter intervals because such outcomes can occur early during opioid therapy, and such harms are not captured well in short-term clinical trials. A detailed listing of the key questions is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Clinical Evidence Systematic Review Methods

Complete methods and data for the 2014 AHRQ report, upon which this updated systematic review is based, have been published previously (*14*,*52*). Study authors developed the protocol using a standardized process (*53*) with input from experts and the public and registered the protocol in the PROSPERO database (*54*). For the 2014 AHRQ report, a research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL for English-language articles published January 2008 through August 2014, using search terms for opioid therapy, specific opioids, chronic pain, and comparative study designs. Also included were relevant studies from an earlier review (*10*) in which searches were conducted without a date restriction, reference lists were reviewed, and ClinicalTrials.gov was searched. CDC updated the AHRQ literature search using the same search strategies as in the original review including studies published before April, 2015. Seven additional studies met inclusion criteria and were added to the review. CDC used the GRADE approach outlined in the ACIP Handbook for Developing Evidence-Based Recommendations (*47*) to rate the quality of evidence for the full body of evidence (evidence from the 2014 AHRQ review plus the update) for each clinical question. Evidence was categorized into the following types: type 1 (randomized clinical trials or overwhelming evidence from observational studies), type 2 (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 (observational studies, or randomized clinical trials with notable limitations), or type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). When no studies were present, evidence was considered to be insufficient. Per GRADE methods, type of evidence was categorized by study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects. Results were synthesized qualitatively, highlighting new evidence identified during the update process. Meta-analysis was not attempted due to the small numbers of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of the studies. More detailed information about data sources and searches, study selection, data extraction and quality assessment, data synthesis, and update search yield and new evidence for the current review is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Summary of Findings for Clinical Questions

The main findings of this updated review are consistent with the findings of the 2014 AHRQ report (*14*). In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly ≤12 weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events (*10*).

The GRADE evidence summary with type of evidence ratings for the five clinical questions for the current evidence review are outlined (Table 1). This summary is based on studies included in the AHRQ 2014 review (35 studies) plus additional studies identified in the updated search (seven studies). Additional details on findings from the original review are provided in the full 2014 AHRQ report (*14*,*52*). Full details on the clinical evidence review findings supporting this guideline are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Effectiveness

For KQ1, no study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for chronic pain evaluated long-term (≥1 year) outcomes related to pain, function, or quality of life. Most placebo-controlled randomized clinical trials were ≤6 weeks in duration. Thus, the body of evidence for KQ1 is rated as insufficient (0 studies contributing) (*14*).

Harms

For KQ2, the body of evidence is rated as type 3 (12 studies contributing; 11 from the original review plus one new study). One fair-quality cohort study found that long-term opioid therapy is associated with increased risk for an opioid abuse or dependence diagnosis (as defined by ICD-9-CM codes) versus no opioid prescription (*22*). Rates of opioid abuse or dependence diagnosis ranged from 0.7% with lower-dose (≤36 MME) chronic therapy to 6.1% with higher-dose (≥120 MME) chronic therapy, versus 0.004% with no opioids prescribed. Ten fair-quality uncontrolled studies reported estimates of opioid abuse, addiction, and related outcomes (*55*–*65*). In primary care settings, prevalence of opioid dependence

(using DSM-IV criteria) ranged from 3% to 26% (*55,56,59*). In pain clinic settings, prevalence of addiction ranged from 2% to 14% (*57,58,60,61,63–65*).

Factors associated with increased risk for misuse included history of substance use disorder, younger age, major depression, and use of psychotropic medications (*55,62*). Two studies reported on the association between opioid use and risk for overdose (*66,67*). One large fair-quality retrospective cohort study found that recent opioid use was associated with increased risk for any overdose events and serious overdose events versus nonuse (*66*). It also found higher doses associated with increased risk. Relative to 1–19 MME/day, the adjusted hazard ratio (HR) for any overdose event (consisting of mostly nonfatal overdose) was 1.44 for 20 to 49 MME/day, 3.73 for 50–99 MME/day, and 8.87 for ≥100 MME/day. A similar pattern was observed for serious overdose. A good-quality population-based, nested case-control study also found a dose-dependent association with risk for overdose death (*67*). Relative to 1–19 MME/day, the adjusted odds ratio (OR) was 1.32 for 20–49 MME/day, 1.92 for 50–99 MME/day, 2.04 for 100–199 MME/day, and 2.88 for ≥200 MME/day.

Findings of increased fracture risk for current opioid use, versus nonuse, were mixed in two studies (*68,69*). Two studies found an association between opioid use and increased risk for cardiovascular events (*70,71*). Indirect evidence was found for endocrinologic harms (increased use of medications for erectile dysfunction or testosterone from one previously included study; laboratory-defined androgen deficiency from one newly reviewed study) (*72,73*). One study found that opioid dosages ≥20 MME/day were associated with increased odds of road trauma among drivers (*74*).

Opioid Dosing Strategies

For KQ3, the body of evidence is rated as type 4 (14 studies contributing; 12 from the original review plus two new studies). For initiation and titration of opioids, the 2014 AHRQ report found insufficient evidence from three fair-quality, open-label trials to determine comparative effectiveness of ER/LA versus immediate-release opioids for titrating patients to stable pain control (*75,76*). One new fair-quality cohort study of Veterans Affairs patients found initiation of therapy with an ER/LA opioid associated with greater risk for nonfatal overdose than initiation with an immediate-release opioid, with risk greatest in the first 2 weeks after initiation of treatment (*77*).

For comparative effectiveness and harms of ER/LA opioids, the 2014 AHRQ report included three randomized, head-to-head trials of various ER/LA opioids that found no clear differences in 1-year outcomes related to pain or function (*78–80*) but had methodological shortcomings. A fair-quality retrospective cohort study based on national Veterans Health Administration system pharmacy data found that methadone was associated with lower overall risk for all-cause mortality versus morphine (*81*), and a fair-quality retrospective cohort study based on Oregon Medicaid data found no statistically significant differences between methadone and long-acting morphine in risk for death or overdose symptoms (*82*). However, a new observational study (*83*) found methadone associated with increased risk for overdose versus sustained-release morphine among Tennessee Medicaid patients. The observed inconsistency in study findings suggests that risks of methadone might vary in different settings as a function of different monitoring and management protocols, though more research is needed to understand factors associated with safer methadone prescribing.

For dose escalation, the 2014 AHRQ report included one fair-quality randomized trial that found no differences between more liberal dose escalation and maintenance of current doses after 12 months in pain, function, all-cause withdrawals, or withdrawals due to opioid misuse (*84*). However, the difference in opioid dosages prescribed at the end of the trial was relatively small (mean 52 MME/day with more liberal dosing versus 40 MME/day). Evidence on other comparisons related to opioid dosing strategies (ER/LA versus immediate-release opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled continuous dosing versus as-needed dosing; or opioid rotation versus maintenance of current therapy; long-term effects of strategies for treating acute exacerbations of chronic pain) was not available or too limited to determine effects on long-term clinical outcomes. For example, evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies (*85–87*).

Risk Assessment and Mitigation

For KQ4, the body of evidence is rated as type 3 for the accuracy of risk assessment tools and insufficient for the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms (six studies contributing; four from the original review plus two new studies). The 2014 AHRQ report included four studies (*88–91*) on the accuracy of risk assessment instruments, administered prior to opioid therapy initiation, for predicting opioid abuse or misuse. Results for the Opioid Risk Tool (ORT) (*89–91*) were extremely inconsistent; evidence for other risk assessment instruments was very sparse, and studies had serious methodological shortcomings. One additional fair-quality (*92*) and one poor-quality (*93*) study identified for this update compared the predictive accuracy of the ORT, the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview.

For the ORT, sensitivity was 0.58 and 0.75 and specificity 0.54 and 0.86; for the SOAPP-R, sensitivity was 0.53 and 0.25 and specificity 0.62 and 0.73; and for the Brief Risk Interview, sensitivity was 0.73 and 0.83 and specificity 0.43 and 0.88. For the ORT, positive likelihood ratios ranged from noninformative (positive likelihood ratio close to 1) to moderately useful (positive likelihood ratio >5). The SOAPP-R was associated with noninformative likelihood ratios (estimates close to 1) in both studies.

No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.

Effects of Opioid Therapy for Acute Pain on Long-Term Use

For KQ5, the body of evidence is rated as type 3 (two new studies contributing). Two fair-quality retrospective cohort studies found opioid therapy prescribed for acute pain associated with greater likelihood of long-term use. One study evaluated opioid-naïve patients who had undergone low-risk surgery, such as cataract surgery and varicose vein stripping (*94*). Use of opioids within 7 days of surgery was associated with increased risk for use at 1 year. The other study found that among patients with a workers' compensation claim for acute low back pain, compared to patients who did not receive opioids early after injury (defined as use within 15 days following onset of pain), patients who did receive early opioids had an increased likelihood of receiving five or more opioid prescriptions 30–730 days following onset that increased with greater early exposure. Versus no early opioid use, the adjusted OR was 2.08 (95% CI = 1.55–2.78) for 1–140 MME/day and increased to 6.14 (95% confidence interval [CI] = 4.92–7.66) for ≥450 MME/day (*95*).

Summary of the Contextual Evidence Review

Primary Areas of Focus

Contextual evidence is complementary information that assists in translating the clinical research findings into recommendations. CDC conducted contextual evidence reviews on four topics to supplement the clinical evidence review findings:

- Effectiveness of nonpharmacologic (e.g., cognitive behavioral therapy [CBT], exercise therapy, interventional treatments, and multimodal pain treatment) and nonopioid pharmacologic treatments (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, and anticonvulsants), including studies of any duration.
- Benefits and harms of opioid therapy (including additional studies not included in the clinical evidence review, such as studies that were not restricted to patients with chronic pain, evaluated outcomes at any duration, performed ecological analyses, or used observational study designs other than cohort and case-cohort control studies) related to specific opioids, high-dose therapy, co-prescription with other controlled substances, duration of use, special populations, and potential usefulness of risk stratification/mitigation approaches, in addition to effectiveness of treatments associated with addressing potential harms of opioid therapy (opioid use disorder).
- Clinician and patient values and preferences related to opioids and medication risks, benefits, and use.
- Resource allocation including costs and economic efficiency of opioid therapy and risk mitigation strategies.

CDC also reviewed clinical guidelines that were relevant to opioid prescribing and could inform or complement the CDC recommendations under development (e.g., guidelines on nonpharmacologic and nonopioid pharmacologic treatments and guidelines with recommendations related to specific clinician actions such as urine drug testing or opioid tapering protocols).

Contextual Evidence Review Methods

CDC conducted a contextual evidence review to assist in developing the recommendations by providing an assessment of the balance of benefits and harms, values and preferences, and cost, consistent with the GRADE approach. Given the public health urgency for developing opioid prescribing recommendations, a rapid review was required for the contextual evidence review for the current guideline. Rapid reviews are used when there is a need to streamline the systematic review process to obtain evidence quickly (*96*). Methods used to streamline the process include limiting searches by databases, years, and languages considered, and truncating quality assessment and data abstraction protocols. CDC conducted "rapid reviews" of the contextual evidence on nonpharmacologic and nonopioid pharmacologic treatments, benefits and harms, values and preferences, and resource allocation.

Detailed information about contextual evidence data sources and searches, inclusion criteria, study selection, and

data extraction and synthesis are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). In brief, CDC conducted systematic literature searches to identify original studies, systematic reviews, and clinical guidelines, depending on the topic being searched. CDC also solicited publication referrals from subject matter experts. Given the need for a rapid review process, grey literature (e.g., literature by academia, organizations, or government in the forms of reports, documents, or proceedings not published by commercial publishers) was not systematically searched. Database sources, including MEDLINE, PsycINFO, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews, varied by topic. Multiple reviewers scanned study abstracts identified through the database searches and extracted relevant studies for review. CDC constructed narrative summaries and tables based on relevant articles that met inclusion criteria, which are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Findings from the contextual reviews provide indirect evidence and should be interpreted accordingly. CDC did not formally rate the quality of evidence for the studies included in the contextual evidence review using the GRADE method. The studies that addressed benefits and harms, values and preferences, and resource allocation most often employed observational methods, used short follow-up periods, and evaluated selected samples. Therefore the strength of the evidence from these contextual review areas was considered to be low, comparable to type 3 or type 4 evidence. The quality of evidence for nonopioid pharmacologic and nonpharmacologic pain treatments was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines (e.g., for treatment of chronic neuropathic pain, low back pain, osteoarthritis, and fibromyalgia). Similarly, the quality of evidence on pharmacologic and psychosocial opioid use disorder treatment was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines.

Summary of Findings for Contextual Areas

Full narrative reviews and tables that summarize key findings from the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Effectiveness of Nonpharmacologic and Nonopioid Pharmacologic Treatments

Several nonpharmacologic and nonopioid pharmacologic treatments have been shown to be effective in managing chronic pain in studies ranging in duration from 2 weeks to 6 months. For example, CBT that trains patients in behavioral techniques and helps patients modify situational factors and cognitive processes that exacerbate pain has small positive effects on disability and catastrophic thinking (*97*). Exercise therapy can help reduce pain and improve function in chronic low back pain (*98*), improve function and reduce pain in osteoarthritis of the knee (*99*) and hip (*100*), and improve well-being, fibromyalgia symptoms, and physical function in fibromyalgia (*101*). Multimodal and multidisciplinary therapies (e.g., therapies that combine exercise and related therapies with psychologically based approaches) can help reduce pain and improve function more effectively than single modalities (*102,103*). Nonopioid pharmacologic approaches used for pain include analgesics such as acetaminophen, NSAIDs, and cyclooxygenase 2 (COX-2) inhibitors; selected anticonvulsants; and selected antidepressants (particularly tricyclics and serotonin and norepinephrine reuptake inhibitors [SNRIs]). Multiple guidelines recommend acetaminophen as first-line pharmacotherapy for osteoarthritis (*104–109*) or for low back pain (*110*) but note that it should be avoided in liver failure and that dosage should be reduced in patients with hepatic insufficiency or a history of alcohol abuse (*109*). Although guidelines also recommend NSAIDs as first-line treatment for osteoarthritis or low back pain (*106,110*), NSAIDs and COX-2 inhibitors do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks (*111*). FDA has recently strengthened existing label warnings that NSAIDs increase risks for heart attack and stroke, including that these risks might increase with longer use or at higher doses (*112*). Several guidelines agree that first- and second-line drugs for neuropathic pain include anticonvulsants (gabapentin or pregabalin), tricyclic antidepressants, and SNRIs (*113–116*). Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain (*117–119*). Epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (*120*).

Benefits and Harms of Opioid Therapy

Balance between benefits and harms is a critical factor influencing the strength of clinical recommendations. In particular, CDC considered what is known from the epidemiology research about benefits and harms related to specific opioids and formulations, high dose therapy, co-prescription with other controlled substances, duration of use, special populations, and risk stratification and mitigation approaches. Additional information on benefits and harms of long-term opioid therapy from studies meeting rigorous selection criteria is provided in the clinical evidence review (e.g., see KQ2). CDC also considered the number of persons experiencing chronic pain, numbers potentially benefiting

from opioids, and numbers affected by opioid-related harms. A review of these data is presented in the background section of this document, with detailed information provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). Finally, CDC considered the effectiveness of treatments that addressed potential harms of opioid therapy (opioid use disorder).

Regarding specific opioids and formulations, as noted by FDA, there are serious risks of ER/LA opioids, and the indication for this class of medications is for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain (*121*). Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study (*122*). Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (*123*).

Regarding high-dose therapy, several epidemiologic studies that were excluded from the clinical evidence review because patient samples were not restricted to patients with chronic pain also examined the association between opioid dosage and overdose risk (*23,24,124–126*). Consistent with the clinical evidence review, the contextual review found that opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. Two of these studies (*23,24*), as well as the two studies in the clinical evidence review (*66,67*), evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were between 1.3 (*67*) and 1.9 (*24*) for dosages of 20 to <50 MME/day, between 1.9 (*67*) and 4.6 (*24*) for dosages of 50 to <100 MME/day, and between 2.0 (*67*) and 8.9 (*66*) for dosages of ≥100 MME/day. Compared with dosages of 1–<20 MME/day, absolute risk difference approximation for 50–<100 MME/day was 0.15% for fatal overdose (*24*) and 1.40% for any overdose (*66*), and for ≥100 MME/day was 0.25% for fatal overdose (*24*) and 4.04% for any overdose (*66*). A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day) (*127*). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually (*128*). A listing of common opioid medications and their MME equivalents is provided (Table 2).

Regarding coprescription of opioids with benzodiazepines, epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (*67,128,129*). In one of these studies (*67*), among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time (*130*). Patients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use (*131*).

Regarding populations potentially at greater risk for harm, risk is greater for patients with sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders. Interpretation of clinical data on the effects of opioids on sleep-disordered breathing is difficult because of the types of study designs and methods employed, and there is no clear consensus regarding association with risk for developing obstructive sleep apnea syndrome (*132*). However, opioid therapy can decrease respiratory drive, a high percentage of patients on long-term opioid therapy have been reported to have an abnormal apnea-hypopnea index (*133*), opioid therapy can worsen central sleep apnea in obstructive sleep apnea patients, and it can cause further desaturation in obstructive sleep apnea patients not on continuous positive airway pressure (CPAP) (*31*). Reduced renal or hepatic function can result in greater peak effect and longer duration of action and reduce the dose at which respiratory depression and overdose occurs (*134*). Age-related changes in patients aged ≥65 years, such as reduced renal function and medication clearance, even in the absence of renal disease (*135*), result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose. Older adults might also be at increased risk for falls and fractures related to opioids (*136–138*). Opioids used

in pregnancy can be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with birth defects, including neural tube defects (*139,140*), congenital heart defects (*140*), and gastroschisis (*140*); preterm delivery (*141*), poor fetal growth (*141*), and stillbirth (*141*). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome (*142*). Patients with mental health comorbidities and patients with histories of substance use disorders might be at higher risk than other patients for opioid use disorder (*62,143,144*). Recent analyses found that depressed patients were at higher risk for drug overdose than patients without depression, particularly at higher opioid dosages, although investigators were unable to distinguish unintentional overdose from suicide attempts (*145*). In case-control and case-cohort studies, substance abuse/dependence was more prevalent among patients experiencing overdose than among patients not experiencing overdose (12% versus 6% [*66*], 40% versus 10% [*24*], and 26% versus 9% [*23*]).

Regarding risk stratification approaches, limited evidence was found regarding benefits and harms. Potential benefits of PDMPs and urine drug testing include the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder, and help determine which patients will benefit from greater caution and increased monitoring or interventions when risk factors are present. For example, one study found that most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose (*124,146*) that are available to prescribers in the PDMP (*124*). However, limited evaluation of PDMPs at the state level has revealed mixed effects on changes in prescribing and mortality outcomes (*28*). Potential harms of risk stratification include underestimation of risks of opioid therapy when screening tools are not adequately sensitive, as well as potential overestimation of risk, which could lead to inappropriate clinical decisions.

Regarding risk mitigation approaches, limited evidence was found regarding benefits and harms. Although no studies were found to examine prescribing of naloxone with opioid pain medication in primary care settings, naloxone distribution through community-based programs providing prevention services for substance users has been demonstrated to be associated with decreased risk for opioid overdose death at the community level (*147*).

Concerns have been raised that prescribing changes such as dose reduction might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (*148*) or interference with appropriate pain treatment (*149*). With the exception of a study noting an association between an abuse-deterrent formulation of OxyContin and heroin use, showing that some patients in qualitative interviews reported switching to another opioid, including heroin, for many reasons, including cost and availability as well as ease of use (*150*), CDC did not identify studies evaluating these potential outcomes.

Finally, regarding the effectiveness of opioid use disorder treatments, methadone and buprenorphine for opioid use disorder have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin (*151–153*). Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy; for example, by reducing opioid misuse and increasing retention during maintenance therapy, and improving compliance after detoxification (*154,155*).

Clinician and Patient Values and Preferences

Clinician and patient values and preferences can inform how benefits and harms of long-term opioid therapy are weighted and estimate the effort and resources required to effectively provide implementation support. Many physicians lack confidence in their ability to prescribe opioids safely (*156*), to predict (*157*) or detect (*158*) prescription drug abuse, and to discuss abuse with their patients (*158*). Although clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (*159*), most consider prescription drug abuse to be a "moderate" or "big" problem in their community, and large proportions are "very" concerned about opioid addiction (55%) and death (48%) (*160*). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs (*161,162*), urine drug testing (*163*), and opioid treatment agreements (*164*). This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems) (*165*), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results (*166*).

Many patients do not have an opinion about "opioids" or know what this term means (*167*). Most are familiar with the term "narcotics." About a third associated "narcotics" with addiction or abuse, and about half feared "addiction" from long-term "narcotic" use (*168*). Most patients taking opioids experience side effects (73% of patients taking hydrocodone for noncancer pain [*11*], 96% of patients taking opioids for chronic pain [*12*]), and side effects, rather than pain relief,

have been found to explain most of the variation in patients' preferences related to taking opioids (*12*). For example, patients taking hydrocodone for noncancer pain commonly reported side effects including dizziness, headache, fatigue, drowsiness, nausea, vomiting, and constipation (*11*). Patients with chronic pain in focus groups emphasized effectiveness of goal setting for increasing motivation and functioning (*168*). Patients taking high dosages report reliance on opioids despite ambivalence about their benefits (*169*) and regardless of pain reduction, reported problems, concerns, side effects, or perceived helpfulness (*13*).

Resource Allocation

Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. CDC searched for evidence on opioid therapy compared with other treatments; costs of misuse, abuse, and overdose from prescription opioids; and costs of specific risk mitigation strategies (e.g., urine drug testing). Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids (*170*); $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids (*171*); and $20.4 billion for direct and indirect costs related to opioid-related overdose alone (*172*). In 2012, total expenses for outpatient prescription opioids were estimated at $9.0 billion, an increase of 120% from 2002 (*173*). Although there are perceptions that opioid therapy for chronic pain is less expensive than more time-intensive nonpharmacologic management approaches, many pain treatments, including acetaminophen, NSAIDs, tricyclic antidepressants, and massage therapy, are associated with lower mean and median annual costs compared with opioid therapy (*174*). COX-2 inhibitors, SNRIs, anticonvulsants, topical analgesics, physical therapy, and CBT are also associated with lower median annual costs compared with opioid therapy (*174*). Limited information was found on costs of strategies to decrease risks associated with opioid therapy; however, urine drug testing, including screening and confirmatory tests, has been estimated to cost $211–$363 per test (*175*).

Recommendations

The recommendations are grouped into three areas for consideration:

- Determining when to initiate or continue opioids for chronic pain.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
- Assessing risk and addressing harms of opioid use.

There are 12 recommendations (Box 1). Each recommendation is followed by a rationale for the recommendation, with considerations for implementation noted. In accordance with the ACIP GRADE process, CDC based the recommendations on consideration of the clinical evidence, contextual evidence (including benefits and harms, values and preferences, resource allocation), and expert opinion. For each recommendation statement, CDC notes the recommendation category (A or B) and the type of the evidence (1, 2, 3, or 4) supporting the statement (Box 2). Expert opinion is reflected within each of the recommendation rationales. While there was not an attempt to reach consensus among experts, experts from the Core Expert Group and from the Opioid Guideline Workgroup ("experts") expressed overall, general support for all recommendations. Where differences in expert opinion emerged for detailed actions within the clinical recommendations or for implementation considerations, CDC notes the differences of opinion in the supporting rationale statements.

Category A recommendations indicate that most patients should receive the recommended course of action; category B recommendations indicate that different choices will be appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations. Consistent with the ACIP (*47*) and GRADE process (*48*), category A recommendations were made, even with type 3 and 4 evidence, when there was broad agreement that the advantages of a clinical action greatly outweighed the disadvantages based on a consideration of benefits and harms, values and preferences, and resource allocation. Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation. All recommendations are category A recommendations, with the exception of recommendation 10, which is rated as category B. Recommendations were associated with a range of evidence types, from type 2 to type 4.

In summary, the categorization of recommendations was based on the following assessment:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

*All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

BOX 2. Interpretation of recommendation categories and evidence type

Recommendation Categories

Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).

Category A recommendation: Applies to all persons; most patients should receive the recommended course of action.

Category B recommendation: Individual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

Evidence Type

Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.

Type 1 evidence: Randomized clinical trials or overwhelming evidence from observational studies.

Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.

Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.

Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3).**

Patients with pain should receive treatment that provides the greatest benefits relative to risks. The contextual evidence review found that many nonpharmacologic therapies, including physical therapy, weight loss for knee osteoarthritis, psychological therapies such as CBT, and certain interventional procedures can ameliorate chronic pain. There is high-quality evidence that exercise therapy (a prominent modality in physical therapy) for hip (*100*) or knee (*99*) osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months. Previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*). Exercise therapy also can help reduce pain and improve function in low back pain and can improve global well-being and physical function in fibromyalgia (*98,101*). Multimodal therapies and multidisciplinary biopsychosocial rehabilitation-combining approaches (e.g., psychological therapies with exercise) can reduce long-term pain and disability compared with usual care and compared with physical treatments (e.g., exercise) alone. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients. Interventional approaches such as arthrocentesis and intraarticular glucocorticoid injection for pain associated with rheumatoid arthritis (*117*) or osteoarthritis (*118*) and subacromial corticosteroid injection for rotator cuff disease (*119*) can provide short-term improvement in pain and function. Evidence is insufficient to determine the extent to which repeated glucocorticoid injection increases potential risks such as articular cartilage changes (in osteoarthritis) and sepsis (*118*). Serious adverse events are rare but have been reported with epidural injection (*120*).

Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain. Selected anticonvulsants such as pregabalin and gabapentin can improve pain in diabetic neuropathy and post-herpetic neuralgia (contextual evidence review). Pregabalin, gabapentin, and carbamazepine are FDA-approved for treatment of certain neuropathic pain conditions, and pregabalin is FDA approved for fibromyalgia management. In patients with or without depression, tricyclic antidepressants and SNRIs provide effective analgesia for neuropathic pain conditions including diabetic neuropathy and post-herpetic neuralgia, often at lower dosages and with a shorter time to onset of effect than for treatment of depression (see contextual evidence review). Tricyclics and SNRIs can also relieve fibromyalgia symptoms. The SNRI duloxetine is FDA-approved for the treatment of diabetic neuropathy and fibromyalgia. Because patients with chronic pain often suffer from concurrent depression (*144*), and depression can exacerbate physical symptoms including pain (*177*), patients with co-occurring pain and depression are especially likely to benefit from antidepressant medication (see Recommendation 8). Nonopioid pharmacologic therapies

are not generally associated with substance use disorder, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review). For example, acetaminophen, NSAIDs, and opioid pain medication were involved in 881, 228, and 16,651 pharmaceutical overdose deaths in the United States in 2010 (*178*). However, nonopioid pharmacologic therapies are associated with certain risks, particularly in older patients, pregnant patients, and patients with certain co-morbidities such as cardiovascular, renal, gastrointestinal, and liver disease (see contextual evidence review). For example, acetaminophen can be hepatotoxic at dosages of >3–4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease (*109*). NSAID use has been associated with gastritis, peptic ulcer disease, cardiovascular events (*111,112*), and fluid retention, and most NSAIDs (choline magnesium trilisate and selective COX-2 inhibitors are exceptions) interfere with platelet aggregation (*179*). Clinicians should review FDA-approved labeling including boxed warnings before initiating treatment with any pharmacologic therapy.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy (KQ1). While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury (KQ2). At a population level, more than 165,000 persons in the United States have died from opioid pain-medication-related overdoses since 1999 (see Contextual Evidence Review).

Integrated pain management requires coordination of medical, psychological, and social aspects of health care and includes primary care, mental health care, and specialist services when needed (*180*). Nonpharmacologic physical and psychological treatments such as exercise and CBT are approaches that encourage active patient participation in the care plan, address the effects of pain in the patient's life, and can result in sustained improvements in pain and function without apparent risks. Despite this, these therapies are not always or fully covered by insurance, and access and cost can be barriers for patients. For many patients, aspects of these approaches can be used even when there is limited access to specialty care. For example, previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*) and maintenance of activity for patients with low back pain (*110*). A randomized trial found no difference in reduced chronic low back pain intensity, frequency or disability between patients assigned to relatively low-cost group aerobics and individual physiotherapy or muscle reconditioning sessions (*181*). Low-cost options to integrate exercise include brisk walking in public spaces or use of public recreation facilities for group exercise. CBT addresses psychosocial contributors to pain and improves function (*97*). Primary care clinicians can integrate elements of a cognitive behavioral approach into their practice by encouraging patients to take an active role in the care plan, by supporting patients in engaging in beneficial but potentially anxiety-provoking activities, such as exercise (*179*), or by providing education in relaxation techniques and coping strategies. In many locations, there are free or low-cost patient support, self-help, and educational community-based programs that can provide stress reduction and other mental health benefits. Patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, can be referred for formal therapy with a mental health specialist (e.g., psychologist, psychiatrist, clinical social worker). Multimodal therapies should be considered for patients not responding to single-modality therapy, and combinations should be tailored depending on patient needs, cost, and convenience.

To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Detailed recommendations on diagnosis are provided in other guidelines (*110,179*), but evaluation should generally include a focused history, including history and characteristics of pain and potentially contributing factors (e.g., function, psychosocial stressors, sleep) and physical exam, with imaging or other diagnostic testing only if indicated (e.g., if severe or progressive neurologic deficits are present or if serious underlying conditions are suspected) (*110,179*). For complex pain syndromes, pain specialty consultation can be considered to assist with diagnosis as well as management. Diagnosis can help identify disease-specific interventions to reverse or ameliorate pain; for example, improving glucose control to prevent progression of diabetic neuropathy; immune-modulating agents for rheumatoid arthritis; physical or occupational therapy to address posture, muscle weakness, or repetitive occupational motions that contribute to musculoskeletal pain; or surgical intervention to relieve mechanical/compressive pain (*179*). The underlying mechanism for most pain syndromes can be categorized as neuropathic (e.g., diabetic neuropathy, postherpetic neuralgia, fibromyalgia), or nociceptive (e.g., osteoarthritis, muscular back pain). The diagnosis and pathophysiologic mechanism of pain have implications for symptomatic pain treatment with medication. For example, evidence is limited or insufficient

for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain (*182*), headache (*183*), and fibromyalgia (*184*). Although NSAIDs can be used for exacerbations of nociceptive pain, other medications (e.g., tricyclics, selected anticonvulsants, or transdermal lidocaine) generally are recommended for neuropathic pain. In addition, improvement of neuropathic pain can begin weeks or longer after symptomatic treatment is initiated (*179*). Medications should be used only after assessment and determination that expected benefits outweigh risks given patient-specific factors. For example, clinicians should consider falls risk when selecting and dosing potentially sedating medications such as tricyclics, anticonvulsants, or opioids, and should weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults as well as patients with hypertension, renal insufficiency, or heart failure, or those with risk for peptic ulcer disease or cardiovascular disease. Some guidelines recommend topical NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) over oral NSAIDs in patients aged ≥75 years to minimize systemic effects (*176*).

Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care, given small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms; although evidence on long-term benefits of nonopioid therapies is also limited, these therapies are also associated with short-term benefits, and risks are much lower. This does not mean that patients should be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., headache or fibromyalgia), expected benefits of initiating opioids are unlikely to outweigh risks regardless of previous nonpharmacologic and nonopioid pharmacologic therapies used. In other situations (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. In addition, when opioid pain medication is used, it is more likely to be effective if integrated with nonpharmacologic therapy. Nonpharmacologic approaches such as exercise and CBT should be used to reduce pain and improve function in patients with chronic pain. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be combined with nonpharmacologic therapy to reduce pain and improve function. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

2. **Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent. In addition, studies on currently available risk assessment instruments were sparse and showed inconsistent results (KQ4). The clinical evidence review for the current guideline considered studies with outcomes examined at ≥1 year that compared opioid use versus nonuse or placebo. Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves (*185*). These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients. Opioid therapy should not be initiated without consideration of an "exit strategy" to be used if the therapy is unsuccessful.

Experts agreed that before opioid therapy is initiated for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should determine how effectiveness will be evaluated and should establish treatment goals with patients. Because the line between acute pain and initial chronic pain is not always clear, it might be difficult for clinicians to determine when they are initiating opioids for chronic pain rather than treating acute pain. Pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition) is generally no longer considered acute. However, establishing treatment goals with a patient who has already received opioid therapy for 3 months would defer this discussion well past the point of

initiation of opioid therapy for chronic pain. Clinicians often write prescriptions for long-term use in 30-day increments, and opioid prescriptions written for ≥30 days are likely to represent initiation or continuation of long-term opioid therapy. Before writing an opioid prescription for ≥30 days, clinicians should establish treatment goals with patients. Clinicians seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy. Although the clinical evidence review did not find studies evaluating the effectiveness of written agreements or treatment plans (KQ4), clinicians and patients who set a plan in advance will clarify expectations regarding how opioids will be prescribed and monitored, as well as situations in which opioids will be discontinued or doses tapered (e.g., if treatment goals are not met, opioids are no longer needed, or adverse events put the patient at risk) to improve patient safety.

Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). However, there are some clinical circumstances under which reductions in pain without improvement in physical function might be a more realistic goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma). Experts noted that function can include emotional and social as well as physical dimensions. In addition, experts emphasized that mood has important interactions with pain and function. Experts agreed that clinicians may use validated instruments such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) to track patient outcomes. Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function (*187*). Monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities) can also contribute to the assessment of functional improvement. Clinicians should use these goals in assessing benefits of opioid therapy for individual patients and in weighing benefits against risks of continued opioid therapy (see Recommendation 7, including recommended intervals for follow-up). Because depression, anxiety, and other psychological co-morbidities often coexist with and can interfere with resolution of pain, clinicians should use validated instruments to assess for these conditions (see Recommendation 8) and ensure that treatment for these conditions is optimized. If patients receiving opioid therapy for chronic pain do not experience meaningful improvements in both pain and function compared with prior to initiation of opioid therapy, clinicians should consider working with patients to taper and discontinue opioids (see Recommendation 7) and should use nonpharmacologic and nonopioid pharmacologic approaches to pain management (see Recommendation 1).

3. **Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).**

The clinical evidence review did not find studies evaluating effectiveness of patient education or opioid treatment plans as risk-mitigation strategies (KQ4). However, the contextual evidence review found that many patients lack information about opioids and identified concerns that some clinicians miss opportunities to effectively communicate about safety. Given the substantial evidence gaps on opioids, uncertain benefits of long-term use, and potential for serious harms, patient education and discussion before starting opioid therapy are critical so that patient preferences and values can be understood and used to inform clinical decisions. Experts agreed that essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.

Clinicians should involve patients in decisions about whether to start or continue opioid therapy. Given potentially serious risks of long-term opioid therapy, clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives to opioids before starting or continuing opioid therapy. Clinicians are encouraged to have open and honest discussions with patients to inform mutual decisions about whether to start or continue opioid therapy. Important considerations include the following:

- Be explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely (clinical evidence review, KQ1).
- Emphasize improvement in function as a primary goal and that function can improve even when pain is still present.
- Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
- Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase

hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.
- Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
- Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
- Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.
- Discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient, and that young children are susceptible to unintentional ingestion. Discuss storage of opioids in a secure, preferably locked location and options for safe disposal of unused opioids (*188*).
- Discuss the importance of periodic reassessment to ensure that opioids are helping to meet patient goals and to allow opportunities for opioid discontinuation and consideration of additional nonpharmacologic or nonopioid pharmacologic treatment options if opioids are not effective or are harmful.
- Discuss planned use of precautions to reduce risks, including use of prescription drug monitoring program information (see Recommendation 9) and urine drug testing (see Recommendation 10). Consider including discussion of naloxone use for overdose reversal (see Recommendation 8).
- Consider whether cognitive limitations might interfere with management of opioid therapy (for older adults in particular) and, if so, determine whether a caregiver can responsibly co-manage medication therapy. Discuss the importance of reassessing safer medication use with both the patient and caregiver.

Given the possibility that benefits of opioid therapy might diminish or that risks might become more prominent over time, it is important that clinicians review expected benefits and risks of continued opioid therapy with patients periodically, at least every 3 months (see Recommendation 7).

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. The clinical evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids (*77*). The clinical evidence review did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/LA opioids reduces risks for opioid misuse or addiction (KQ3).

In 2014, the FDA modified the labeling for ER/LA opioid pain medications, noting serious risks and recommending that ER/LA opioids be reserved for "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment" when "alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain" and not used as "as needed" pain relievers (*121*). FDA has also noted that some ER/LA opioids are only appropriate for opioid-tolerant patients, defined as patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week (*189*). Time-scheduled opioid use can be associated with greater total average daily opioid dosage compared with intermittent, as-needed opioid use (contextual evidence review). In addition, experts indicated that there was not enough evidence to determine the safety of using immediate-release opioids for breakthrough pain when ER/LA opioids are used for chronic pain outside of active cancer pain, palliative care, or end-of-life care, and that this practice might be associated with dose escalation.

Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (*190*), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent

opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

In comparing different ER/LA formulations, the clinical evidence review found inconsistent results for overdose risk with methadone versus other ER/LA opioids used for chronic pain (KQ3). The contextual evidence review found that methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for chronic pain. In addition, methadone is associated with cardiac arrhythmias along with QT prolongation on the electrocardiogram, and it has complicated pharmacokinetics and pharmacodynamics, including a long and variable half-life and peak respiratory depressant effect occurring later and lasting longer than peak analgesic effect. Experts noted that the pharmacodynamics of methadone are subject to more inter-individual variability than other opioids. In regard to other ER/LA opioid formulations, experts noted that the absorption and pharmacodynamics of transdermal fentanyl are complex, with gradually increasing serum concentration during the first part of the 72-hour dosing interval, as well as variable absorption based on factors such as external heat. In addition, the dosing of transdermal fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing. Experts thought that these complexities might increase the risk for fatal overdose when methadone or transdermal fentanyl is prescribed to a patient who has not used it previously or by clinicians who are not familiar with its effects.

Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, clinicians should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance. Clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to patients with renal or hepatic dysfunction because decreased clearance of drugs among these patients can lead to accumulation of drugs to toxic levels and persistence in the body for longer durations. Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

- Methadone should not be the first choice for an ER/LA opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to educate and closely monitor their patients, including risk assessment for QT prolongation and consideration of electrocardiographic monitoring, should consider prescribing methadone for pain. A clinical practice guideline that contains further guidance regarding methadone prescribing for pain has been published previously (*191*).
- Because dosing effects of transdermal fentanyl are often misunderstood by both clinicians and patients, only clinicians who are familiar with the dosing and absorption properties of transdermal fentanyl and are prepared to educate their patients about its use should consider prescribing it.

5. **When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3).**

Benefits of high-dose opioids for chronic pain are not established. The clinical evidence review found only one study (*84*) addressing effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. (These groups were prescribed average dosages of 52 and 40 MME/day, respectively, at the end of the trial.) At the same time, risks for serious harms

related to opioid therapy increase at higher opioid dosage. The clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose (KQ2). The clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50–<100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–<20 MME/day, and that dosages ≥100 MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–<20 MME/day. In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose (*127*).

The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages. Experts agreed that lower dosages of opioids reduce the risk for overdose, but that a single dosage threshold for safe opioid use could not be identified. Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks, that dosages <50 MME/day are safer than dosages of 50–100 MME/day, and that dosages <20 MME/day are safer than dosages of 20–50 MME/day. One expert thought that a specific dosage at which the benefit/risk ratio of opioid therapy decreases could not be identified. Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function and that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosages to ≥50 MME/day. Most experts also agreed that opioid dosages should not be increased to ≥90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.

When opioids are used for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should start opioids at the lowest possible effective dosage (the lowest starting dosage on product labeling for patients not already taking opioids and according to product labeling guidance regarding tolerance for patients already taking opioids). Clinicians should use additional caution when initiating opioids for patients aged ≥65 years and for patients with renal or hepatic insufficiency because decreased clearance of drugs in these patients can result in accumulation of drugs to toxic levels. Clinicians should use caution when increasing opioid dosages and increase dosage by the smallest practical amount because overdose risk increases with increases in opioid dosage. Although there is limited evidence to recommend specific intervals for dosage titration, a previous guideline recommended waiting at least five half-lives before increasing dosage and waiting at least a week before increasing dosage of methadone to make sure that full effects of the previous dosage are evident (*31*). Clinicians should re-evaluate patients after increasing dosage for changes in pain, function, and risk for harm (see Recommendation 7). Before increasing total opioid dosage to ≥50 MME/day, clinicians should reassess whether opioid treatment is meeting the patient's treatment goals (see Recommendation 2). If a patient's opioid dosage for all sources of opioids combined reaches or exceeds 50 MME/day, clinicians should implement additional precautions, including increased frequency of follow-up (see Recommendation 7) and considering offering naloxone and overdose prevention education to both patients and the patients' household members (see Recommendation 8). Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at ≥90 MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids (see Recommendation 7), and consider consulting a pain specialist. Some states require clinicians to implement clinical protocols at specific dosage levels. For example, before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington state must obtain consultation from a pain specialist who agrees that this is indicated and appropriate (*30*). Clinicians should be aware of rules related to MME thresholds and associated clinical protocols established by their states.

Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is

now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (see Recommendation 7). Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages. Clinicians should remain alert to signs of anxiety, depression, and opioid use disorder (see Recommendations 8 and 12) that might be unmasked by an opioid taper and arrange for management of these co-morbidities. For patients agreeing to taper to lower opioid dosages as well as for those remaining on high opioid dosages, clinicians should establish goals with the patient for continued opioid therapy (see Recommendation 2), maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1), and consider consulting a pain specialist as needed to assist with pain management.

6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4).**

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (*192–194*) and other settings (*195,196*) have recommended prescribing ≤3 days of opioids in most cases, whereas others have recommended ≤7 days (*197*) or <14 days (*30*). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days' supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (*198*). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, nonsurgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (*30*). Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

7. **Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).**

Although the clinical evidence review did not find studies evaluating the effectiveness of more frequent monitoring intervals (KQ4), it did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder (KQ2); therefore, follow-up earlier than 3 months might be necessary to provide the greatest opportunity to prevent the development of opioid use disorder. In addition, risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment (KQ3). The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months. Although evidence is insufficient to determine at what point within the first 3 months of opioid therapy the risks for opioid use disorder increase, reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications. Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when methadone or transdermal fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.

Clinicians should evaluate patients to assess benefits and harms of opioids within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Clinicians should consider follow-up intervals within the lower end of this range when ER/LA opioids are started or increased or when total daily opioid dosage is ≥50 MME/day. Shorter follow-up intervals (within 3 days) should be strongly considered when starting or increasing the dosage of methadone. At follow up, clinicians should assess benefits in function, pain control, and quality of life using tools such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) and/or asking patients about progress toward functional goals that have meaning for them (see Recommendation 2). Clinicians should also ask patients about common adverse effects such as constipation and drowsiness (see Recommendation 3), as well as asking about and assessing for effects that might be early warning signs for more serious problems such as overdose (e.g., sedation or slurred speech) or opioid use disorder (e.g., craving, wanting to take opioids in greater quantities or more frequently than prescribed, or difficulty controlling use). Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.

Because of potential changes in the balance of benefits and risks of opioid therapy over time, clinicians should regularly reassess all patients receiving long-term opioid therapy, including patients who are new to the clinician but on long-term opioid therapy, at least every 3 months. At reassessment, clinicians should determine whether opioids continue to meet treatment goals, including sustained improvement in pain and function, whether the patient has experienced common or serious adverse events or early warning signs of serious adverse events, signs of opioid use disorder (e.g., difficulty controlling use, work or family problems related to opioid use), whether benefits of opioids continue to outweigh risks, and whether opioid dosage can be reduced or opioids can be discontinued. Ideally, these reassessments would take place in person and be conducted by the prescribing clinician. In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other issues make follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through video and audio could be conducted, with in-person visits occurring at least once per year. Clinicians should re-evaluate patients who are exposed to greater risk of opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking ≥50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. If clinically meaningful improvements in pain and function are not sustained, if patients are taking high-risk regimens (e.g., dosages ≥50 MME/day or opioids combined with benzodiazepines) without evidence of benefit, if patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation, or if patients experience overdose or other serious adverse events (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events, clinicians should work with patients to reduce opioid dosage or to discontinue opioids when possible. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to assist with pain management.

Considerations for Tapering Opioids

Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued (KQ3), tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines (*199*), and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose (*30*). Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years). Opioid withdrawal during pregnancy has been associated with spontaneous abortion and premature labor.

When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point; experts agreed that tapering plans may be individualized based on patient goals and concerns. Experts noted that at times, tapers might have to be paused and restarted again when the patient is ready and might have to be slowed once patients reach low dosages. Tapers may be considered successful as long as the patient is making progress. Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped when taken less frequently than once a day. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced overdose on their current dosage). Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (*200*). Clinicians should access appropriate expertise if considering tapering opioids during pregnancy because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal. Patients who are not taking opioids (including patients who are diverting all opioids they obtain) do not require tapers. Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose. Primary care clinicians should collaborate with mental health providers and with other specialists as needed to optimize nonopioid pain management (see Recommendation 1), as well as psychosocial support for anxiety related to the taper. More detailed guidance on tapering, including management of withdrawal symptoms has been published previously (*30,201*). If a patient exhibits signs of opioid use disorder, clinicians should offer or arrange for treatment of opioid use disorder (see Recommendation 12) and consider offering naloxone for overdose prevention (see Recommendation 8).

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities (KQ2). However, based on the contextual evidence review and expert opinion, certain risk factors are likely to increase susceptibility to opioid-associated harms and warrant incorporation of additional strategies into the management plan to mitigate risk. Clinicians should assess these risk factors periodically, with frequency varying by risk factor and patient characteristics. For example, factors that vary more frequently over time, such as alcohol use, require more frequent follow up. In addition, clinicians should consider offering naloxone, re-evaluating patients more frequently (see Recommendation 7), and referring to pain and/or behavioral health specialists when factors that increase risk for harm, such as history of overdose, history of substance use disorder, higher dosages of opioids (≥50 MME/day), and concurrent use of benzodiazepines with opioids, are present.

Patients with Sleep-Disordered Breathing, Including Sleep Apnea

Risk factors for sleep-disordered breathing include congestive heart failure, and obesity. Experts noted that careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. Clinicians should avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing whenever possible to minimize risks for opioid overdose (contextual evidence review).

Pregnant Women

Opioids used in pregnancy might be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with stillbirth, poor fetal growth, pre-term delivery, and birth defects (contextual evidence review). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome. Clinicians and patients together should carefully weigh risks and benefits when making decisions

about whether to initiate opioid therapy for chronic pain during pregnancy. In addition, before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any future pregnancy. For pregnant women already receiving opioids, clinicians should access appropriate expertise if considering tapering opioids because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal (see Recommendation 7). For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine or methadone has been associated with improved maternal outcomes and should be offered (*202*) (see Recommendation 12). Clinicians caring for pregnant women receiving opioids for pain or receiving buprenorphine or methadone for opioid use disorder should arrange for delivery at a facility prepared to monitor, evaluate for, and treat neonatal opioid withdrawal syndrome. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for neonatal opioid withdrawal syndrome, and transfer the newborn for additional treatment if needed. Neonatal toxicity and death have been reported in breast-feeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breast feeding and, if used, should be limited to the lowest possible dose and to a 4-day supply (*203*).

Patients with Renal or Hepatic Insufficiency

Clinicians should use additional caution and increased monitoring (see Recommendation 7) to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, given their decreased ability to process and excrete drugs, susceptibility to accumulation of opioids, and reduced therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review; see Recommendations 4, 5, and 7).

Patients Aged ≥65 Years

Inadequate pain treatment among persons aged ≥65 years has been documented (*204*). Pain management for older patients can be challenging given increased risks of both nonopioid pharmacologic therapies (see Recommendation 1) and opioid therapy in this population. Given reduced renal function and medication clearance even in the absence of renal disease, patients aged ≥65 years might have increased susceptibility to accumulation of opioids and a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review). Some older adults suffer from cognitive impairment, which can increase risk for medication errors and make opioid-related confusion more dangerous. In addition, older adults are more likely than younger adults to experience co-morbid medical conditions and more likely to receive multiple medications, some of which might interact with opioids (such as benzodiazepines). Clinicians should use additional caution and increased monitoring (see Recommendations 4, 5, and 7) to minimize risks of opioids prescribed for patients aged ≥65 years. Experts suggested that clinicians educate older adults receiving opioids to avoid risky medication-related behaviors such as obtaining controlled medications from multiple prescribers and saving unused medications. Clinicians should also implement interventions to mitigate common risks of opioid therapy among older adults, such as exercise or bowel regimens to prevent constipation, risk assessment for falls, and patient monitoring for cognitive impairment.

Patients with Mental Health Conditions

Because psychological distress frequently interferes with improvement of pain and function in patients with chronic pain, using validated instruments such as the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for anxiety, post-traumatic stress disorder, and/or depression (*205*), might help clinicians improve overall pain treatment outcomes. Experts noted that clinicians should use additional caution and increased monitoring (see Recommendation 7) to lessen the increased risk for opioid use disorder among patients with mental health conditions (including depression, anxiety disorders, and PTSD), as well as increased risk for drug overdose among patients with depression. Previous guidelines have noted that opioid therapy should not be initiated during acute psychiatric instability or uncontrolled suicide risk, and that clinicians should consider behavioral health specialist consultation for any patient with a history of suicide attempt or psychiatric disorder (*31*). In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose (see Recommendation 11). Clinicians should ensure that treatment for depression and other mental health conditions is optimized, consulting with behavioral health specialists when needed. Treatment for depression can improve pain symptoms as well as depression and might decrease overdose risk (contextual evidence review). For treatment of chronic pain in patients with depression, clinicians should strongly consider using tricyclic or SNRI antidepressants for analgesic as well as antidepressant effects if these medications are not otherwise contraindicated (see Recommendation 1).

Patients with Substance Use Disorder

Illicit drugs and alcohol are listed as contributory factors on a substantial proportion of death certificates for opioid-related overdose deaths (contextual evidence review). Previous guidelines have recommended screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids. However, the clinical evidence review found that currently available risk-stratification tools (e.g., Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain Version 1, SOAPP-R, and Brief Risk Interview) show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse (KQ4). Clinicians should always exercise caution when considering or prescribing opioids for any patient with chronic pain outside of active cancer, palliative, and end-of-life care and should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.

Clinicians should ask patients about their drug and alcohol use. Single screening questions can be used (*206*). For example, the question "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview (*207*). Validated screening tools such as the Drug Abuse Screening Test (DAST) (*208*) and the Alcohol Use Disorders Identification Test (AUDIT) (*209*) can also be used. Clinicians should use PDMP data (see Recommendation 9) and drug testing (see Recommendation 10) as appropriate to assess for concurrent substance use that might place patients at higher risk for opioid use disorder and overdose. Clinicians should also provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol (see Recommendation 3) and ensure that patients receive effective treatment for substance use disorders when needed (see Recommendation 12).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder (KQ2), although a history of substance use disorder was associated with misuse. Similarly, based on contextual evidence, patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. If clinicians consider opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care for patients with drug or alcohol use disorders, they should discuss increased risks for opioid use disorder and overdose with patients, carefully consider whether benefits of opioids outweigh increased risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed. Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse. Experts also noted that clinicians should communicate with patients' substance use disorder treatment providers if opioids are prescribed.

Patients with Prior Nonfatal Overdose

Although studies were not identified that directly addressed the risk for overdose among patients with prior nonfatal overdose who are prescribed opioids, based on clinical experience, experts thought that prior nonfatal overdose would substantially increase risk for future nonfatal or fatal opioid overdose. If patients experience nonfatal opioid overdose, clinicians should work with them to reduce opioid dosage and to discontinue opioids when possible (see Recommendation 7). If clinicians continue opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care in patients with prior opioid overdose, they should discuss increased risks for overdose with patients, carefully consider whether benefits of opioids outweigh substantial risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed.

Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

Naloxone is an opioid antagonist that can reverse severe respiratory depression; its administration by lay persons, such as friends and family of persons who experience opioid overdose, can save lives. Naloxone precipitates acute withdrawal among patients physically dependent on opioids. Serious adverse effects, such as pulmonary edema, cardiovascular instability, and seizures, have been reported but are rare at doses consistent with labeled use for opioid overdose (*210*). The contextual evidence review did not find any studies on effectiveness of prescribing naloxone for overdose prevention among patients prescribed opioids for chronic pain. However, there is evidence for effectiveness of naloxone provision in preventing opioid-related overdose death at the community level through community-based distribution (e.g., through overdose education and naloxone distribution programs in community service agencies) to persons at risk for overdose

(mostly due to illicit opiate use), and it is plausible that effectiveness would be observed when naloxone is provided in the clinical setting as well. Experts agreed that it is preferable not to initiate opioid treatment when factors that increase risk for opioid-related harms are present. Opinions diverged about the likelihood of naloxone being useful to patients and the circumstances under which it should be offered. However, most experts agreed that clinicians should consider offering naloxone when prescribing opioids to patients at increased risk for overdose, including patients with a history of overdose, patients with a history of substance use disorder, patients taking benzodiazepines with opioids (see Recommendation 11), patients at risk for returning to a high dose to which they are no longer tolerant (e.g., patients recently released from prison), and patients taking higher dosages of opioids (≥50 MME/day). Practices should provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households. Experts noted that naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists. Resources for prescribing naloxone in primary care settings can be found through Prescribe to Prevent at http://prescribetoprevent.org.

9. **Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).**

PDMPs are state-based databases that collect information on controlled prescription drugs dispensed by pharmacies in most states and, in select states, by dispensing physicians as well. In addition, some clinicians employed by the federal government, including some clinicians in the Indian Health Care Delivery System, are not licensed in the states where they practice, and do not have access to PDMP data. Certain states require clinicians to review PDMP data prior to writing each opioid prescription (see state-level PDMP-related policies on the National Alliance for Model State Drug Laws website at http://www.namsdl.org/prescription-monitoring-programs.cfm). The clinical evidence review did not find studies evaluating the effectiveness of PDMPs on outcomes related to overdose, addiction, abuse, or misuse (KQ4). However, even though evidence is limited on the effectiveness of PDMP implementation at the state level on prescribing and mortality outcomes (*28*), the contextual evidence review found that most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages; information on both of these risk factors for overdose are available to prescribers in the PDMP. PDMP data also can be helpful when patient medication history is not otherwise available (e.g., for patients from other locales) and when patients transition care to a new clinician. The contextual evidence review also found that PDMP information could be used in a way that is harmful to patients. For example, it has been used to dismiss patients from clinician practices (*211*), which might adversely affect patient safety.

The contextual review found variation in state policies that affect timeliness of PDMP data (and therefore benefits of reviewing PDMP data) as well as time and workload for clinicians in accessing PDMP data. In states that permit delegating access to other members of the health care team, workload for prescribers can be reduced. These differences might result in a different balance of benefits to clinician workload in different states. Experts agreed that PDMPs are useful tools that should be consulted when starting a patient on opioid therapy and periodically during long-term opioid therapy. However, experts disagreed on how frequently clinicians should check the PDMP during long-term opioid therapy, given PDMP access issues and the lag time in reporting in some states. Most experts agreed that PDMP data should be reviewed every 3 months or more frequently during long-term opioid therapy. A minority of experts noted that, given the current burden of accessing PDMP data in some states and the lack of evidence surrounding the most effective interval for PDMP review to improve patient outcomes, annual review of PDMP data during long-term opioid therapy would be reasonable when factors that increase risk for opioid-related harms are not present.

Clinicians should review PDMP data for opioids and other controlled medications patients might have received from additional prescribers to determine whether a patient is receiving high total opioid dosages or dangerous combinations (e.g., opioids combined with benzodiazepines) that put him or her at high risk for overdose. Ideally, PDMP data should be reviewed before every opioid prescription. This is recommended in all states with well-functioning PDMPs and where PDMP access policies make this practicable (e.g., clinician and delegate access permitted), but it is not currently possible in states without functional PDMPs or in those that do not permit certain prescribers to access them. As vendors and practices facilitate integration of PDMP information into regular clinical workflow (e.g., data made available in electronic health records), clinicians' ease of access in reviewing PDMP data is expected to improve.

In addition, improved timeliness of PDMP data will improve their value in identifying patient risks.

If patients are found to have high opioid dosages, dangerous combinations of medications, or multiple controlled substance prescriptions written by different clinicians, several actions can be taken to augment clinicians' abilities to improve patient safety:

- Clinicians should discuss information from the PDMP with their patient and confirm that the patient is aware of the additional prescriptions. Occasionally, PDMP information can be incorrect (e.g., if the wrong name or birthdate has been entered, the patient uses a nickname or maiden name, or another person has used the patient's identity to obtain prescriptions).
- Clinicians should discuss safety concerns, including increased risk for respiratory depression and overdose, with patients found to be receiving opioids from more than one prescriber or receiving medications that increase risk when combined with opioids (e.g., benzodiazepines) and consider offering naloxone (see Recommendation 8).
- Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care (see Recommendation 11).
- Clinicians should calculate the total MME/day for concurrent opioid prescriptions to help assess the patient's overdose risk (see Recommendation 5). If patients are found to be receiving high total daily dosages of opioids, clinicians should discuss their safety concerns with the patient, consider tapering to a safer dosage (see Recommendations 5 and 7), and consider offering naloxone (see Recommendation 8).
- Clinicians should discuss safety concerns with other clinicians who are prescribing controlled substances for their patient. Ideally clinicians should first discuss concerns with their patient and inform him or her that they plan to coordinate care with the patient's other prescribers to improve the patient's safety.
- Clinicians should consider the possibility of a substance use disorder and discuss concerns with their patient (see Recommendation 12).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal (see Recommendations 7 and 10). A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result (see Recommendation 10).

Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder [see Recommendation 12]).

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. Urine drug tests do not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain (KQ4). The contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care). Routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use. Although random drug testing also might destigmatize urine drug testing, experts thought that truly random testing was not feasible in clinical practice. Some clinics obtain a urine specimen at every visit, but only send it for testing on a random schedule. Experts noted that in addition to direct costs of urine drug testing, which often are not covered fully by insurance and can be a burden for patients, clinician time is needed to interpret, confirm, and communicate results.

Experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should

use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. There was some difference of opinion among experts as to whether this recommendation should apply to all patients, or whether this recommendation should entail individual decision making with different choices for different patients based on values, preferences, and clinical situations. While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up interval should be left to the discretion of the clinician. Previous guidelines have recommended more frequent urine drug testing in patients thought to be at higher risk for substance use disorder (*30*). However, experts thought that predicting risk prior to urine drug testing is challenging and that currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance use disorder.

In most situations, initial urine drug testing can be performed with a relatively inexpensive immunoassay panel for commonly prescribed opioids and illicit drugs. Patients prescribed less commonly used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard immunoassays or on the presence of unexpected urine drug test results. Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. For example, a positive "opiates" immunoassay detects morphine, which might reflect patient use of morphine, codeine, or heroin, but this immunoassay does not detect synthetic opioids (e.g., fentanyl or methadone) and might not detect semisynthetic opioids (e.g., oxycodone). However, many laboratories use an oxycodone immunoassay that detects oxycodone and oxymorphone. In some cases, positive results for specific opioids might reflect metabolites from opioids the patient is taking and might not mean the patient is taking the specific opioid for which the test was positive. For example, hydromorphone is a metabolite of hydrocodone, and oxymorphone is a metabolite of oxycodone. Detailed guidance on interpretation of urine drug test results, including which tests to order and expected results, drug detection time in urine, drug metabolism, and other considerations has been published previously (*30*). Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahyrdocannabinol (THC). In addition, restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of urine drug testing, given the substantial costs associated with confirmatory testing methods. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results. Clinicians should explain to patients that urine drug testing is intended to improve their safety and should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient). Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs. Clinicians should discuss unexpected results with the local laboratory or toxicologist and with the patient. Discussion with patients prior to specific confirmatory testing can sometimes yield a candid explanation of why a particular substance is present or absent and obviate the need for expensive confirmatory testing on that visit. For example, a patient might explain that the test is negative for prescribed opioids because she felt opioids were no longer helping and discontinued them. If unexpected results are not explained, a confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted to clarify the situation.

Clinicians should use unexpected results to improve patient safety (e.g., change in pain management strategy [see Recommendation 1], tapering or discontinuation of opioids [see Recommendation 7], more frequent re-evaluation [see Recommendation 7], offering naloxone [see Recommendation 8], or referral for treatment for substance use disorder [see Recommendation 12], all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper. Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently

whenever possible (recommendation category: A, evidence type: 3).

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. The clinical evidence review did not address risks of benzodiazepine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzodiazepine use in large proportions of opioid-related overdose deaths, and a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone (*212*). Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. In addition, given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9) and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants. Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first (see Recommendation 7). Clinicians should taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death (contextual evidence review). A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (*213,214*). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper (*213*). If benzodiazepines prescribed for anxiety are tapered or discontinued, or if patients receiving opioids require treatment for anxiety, evidence-based psychotherapies (e.g., CBT) and/or specific anti-depressants or other nonbenzodiazepine medications approved for anxiety should be offered. Experts emphasized that clinicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 2).

Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year (http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf) (*20*).

The clinical evidence review found prevalence of opioid dependence (using DSM-IV diagnosis criteria) in primary care settings among patients with chronic pain on opioid therapy to be 3%–26% (KQ2). As found in the contextual evidence review and supported by moderate quality evidence, opioid agonist or partial agonist treatment with methadone maintenance therapy or buprenorphine has been shown to be more effective in preventing relapse among patients with opioid use disorder (*151–153*). Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification (*154,155*); behavioral therapies are also recommended by clinical practice guidelines (*215*). The cited studies primarily evaluated patients with a history of illicit opioid use, rather than prescription opioid use for chronic pain. Recent studies among patients with prescription opioid dependence (based on DSM-IV criteria) have found maintenance therapy with buprenorphine and buprenorphine-naloxone effective in preventing relapse (*216,217*). Treatment need in a community is often not met by capacity to provide buprenorphine or methadone maintenance therapy (*218*), and patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited (*219*). Oral or long-acting injectable formulations of naltrexone can also be used as medication-assisted treatment for opioid use disorder in nonpregnant adults, particularly for highly motivated persons (*220,221*). Experts agreed that clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community and should work together to ensure sufficient treatment capacity for opioid use disorder at the practice level.

If clinicians suspect opioid use disorder based on patient concerns or behaviors or on findings in prescription drug monitoring program data (see Recommendation 9) or from urine drug testing (see Recommendation 10), they should discuss their concern with their patient and provide an opportunity for the patient to disclose related concerns or problems. Clinicians should assess for the presence of opioid use disorder using DSM-5 criteria (*20*). Alternatively, clinicians can arrange for a substance use disorder treatment specialist to assess for the presence of opioid use disorder. For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies. Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in nonpregnant adults. Naltrexone blocks the effects of opioids if they are used but requires adherence to daily oral therapy or monthly injections. For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine (without naloxone) or methadone has been associated with improved maternal outcomes and should be offered (see Recommendation 8). Clinicians should also consider offering naloxone for overdose prevention to patients with opioid use disorder (see Recommendation 8). For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids (see Recommendation 7). For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.

Physicians not already certified to provide buprenorphine in an office-based setting can undergo training to receive a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that allows them to prescribe buprenorphine to treat patients with opioid use disorder. Physicians prescribing opioids in communities without sufficient treatment capacity for opioid use disorder should strongly consider obtaining this waiver. Information about qualifications and the process to obtain a waiver are available from SAMHSA (*222*). Clinicians do not need a waiver to offer naltrexone for opioid use disorder as part of their practice.

Additional guidance has been published previously (*215*) on induction, use, and monitoring of buprenorphine treatment (see Part 5) and naltrexone treatment (see Part 6) for opioid use disorder and on goals, components of, and types of effective psychosocial treatment that are recommended in conjunction with pharmacological treatment of opioid use disorder (see Part 7). Clinicians unable to provide treatment themselves should arrange for patients with opioid use disorder to receive care from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider, or from an opioid treatment program certified by SAMHSA to provide supervised medication-assisted treatment for patients with opioid use disorder. Clinicians should assist patients in finding qualified treatment providers and should arrange for patients to follow up with these providers, as well as arranging for ongoing coordination of care. Clinicians should not dismiss patients from their practice because of a substance use disorder because this can adversely affect patient safety and could represent patient abandonment. Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment. In addition, although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use nonpharmacologic and nonopioid pharmacologic pain treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to provide optimal pain management.

Resources to help with arranging for treatment include SAMHSA's buprenorphine physician locator (http://buprenorphine.samhsa.gov/bwns_locator); SAMHSA's Opioid Treatment Program Directory (http://dpt2.samhsa.gov/treatment/directory.aspx); SAMHSA's Provider Clinical Support System for Opioid Therapies (http://pcss-o.org), which offers extensive experience in the treatment of substance use disorders and specifically of opioid use disorder, as well as expertise on the interface of pain and opioid misuse; and SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (http://pcssmat.org), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings. CDC will translate this guideline into user-friendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and clinicians and engage in dissemination efforts. CDC has provided a

checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025), additional resources such as fact sheets (http://www.cdc.gov/drugoverdose/prescribing/resources.html), and will provide a mobile application to guide clinicians in implementing the recommendations. CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic health records to assist clinicians' treatment decisions at the point of care; identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice. In addition, policy initiatives that address barriers to implementation of the guidelines, such as increasing accessibility of PDMP data within and across states, e-prescribing, and availability of clinicians who can offer medication-assisted treatment for opioid use disorder, are strategies to consider to enhance implementation of the recommended practices. CDC will work with federal partners and payers to evaluate strategies such as payment reform and health care delivery models that could improve patient health and safety. For example, strategies might include strengthened coverage for nonpharmacologic treatments, appropriate urine drug testing, and medication-assisted treatment; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care.

As highlighted in the forthcoming report on the National Pain Strategy, an overarching federal effort that outlines a comprehensive population-level health strategy for addressing pain as a public health problem, clinical guidelines complement other strategies aimed at preventing illnesses and injuries that lead to pain. A draft of the National Pain Strategy has been published previously (*180*). These strategies include strengthening the evidence base for pain prevention and treatment strategies, reducing disparities in pain treatment, improving service delivery and reimbursement, supporting professional education and training, and providing public education. It is important that overall improvements be made in developing the workforce to address pain management in general, in addition to opioid prescribing specifically. This guideline also complements other federal efforts focused on addressing the opioid overdose epidemic including prescriber training and education, improving access to treatment for opioid use disorder, safe storage and disposal programs, utilization management mechanisms, naloxone distribution programs, law enforcement and supply reduction efforts, prescription drug monitoring program improvements, and support for community coalitions and state prevention programs.

This guideline provides recommendations that are based on the best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. To inform future guideline development, more research is necessary to fill in critical evidence gaps. The evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy. As highlighted by an expert panel in a recent workshop sponsored by the National Institutes of Health on the role of opioid pain medications in the treatment of chronic pain, "evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain" (*223*). The National Institutes of Health panel recommended that research is needed to improve our understanding of which types of pain, specific diseases, and patients are most likely to be associated with benefit and harm from opioid pain medications; evaluate multidisciplinary pain interventions; estimate cost-benefit; develop and validate tools for identification of patient risk and outcomes; assess the effectiveness and harms of opioid pain medications with alternative study designs; and investigate risk identification and mitigation strategies and their effects on patient and public health outcomes. It is also important to obtain data to inform the cost feasibility and cost-effectiveness of recommended actions, such as use of nonpharmacologic therapy and urine drug testing. Research that contributes to safer and more effective pain treatment can be implemented across public health entities and federal agencies (*4*). Additional research can inform the development of future guidelines for special populations that could not be adequately addressed in this guideline, such as children and adolescents, where evidence and guidance is needed but currently lacking. CDC is committed to working with partners to identify the highest priority research areas to build the evidence base. Yet, given that chronic pain is recognized as a significant public health problem, the risks associated with long-term opioid therapy, the availability of effective nonpharmacological and nonopioid pharmacologic treatment options for pain, and the potential for improvement in the quality of health care with the implementation of recommended practices, a guideline for prescribing is warranted with the evidence that is currently available. The balance between the benefits and the risks of long-term opioid therapy for chronic pain based on both clinical and contextual evidence is strong enough to support the issuance of category A recommendations in most cases.

CDC will revisit this guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the guideline. Until this research is conducted, clinical practice guidelines will have to be based on the best available evidence and expert opinion. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

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TABLE 1. Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness and comparative effectiveness (KQ1)							
Effectiveness of long-term opioid therapy versus placebo or no opioid therapy for long-term (≥1 year) outcomes							
Pain, function, and quality of life	None	—[†]	—	—	Insufficient	—	No evidence
Harms and adverse events (KQ2)							
Risks of opioids versus placebo or no opioids on opioid abuse, addiction, and related outcomes; overdose; and other harms							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found long-term use of prescribed opioids associated with an increased risk of abuse or dependence diagnosis versus no opioid use (adjusted OR ranged from 14.9 to 122.5, depending on dose).
Abuse or addiction	10 uncontrolled studies (n = 3,780)	Very serious limitations	Very serious inconsistency	No imprecision	4	None identified	In primary care settings, prevalence of opioid abuse ranged from 0.6% to 8% and prevalence of dependence from 3% to 26%. In pain clinic settings, prevalence of misuse ranged from 8% to 16% and addiction from 2% to 14%. Prevalence of aberrant drug-related behaviors ranged from 6% to 37%.
Overdose	1 cohort study (n = 9,940)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Current opioid use associated with increased risk of any overdose events (adjusted HR 5.2, 95% CI = 2.1–12) and serious overdose events (adjusted HR 8.4, 95% CI = 2.5–28) versus current nonuse.
Fractures	1 cohort study (n = 2,341) and 1 case–control study (n = 21,739 case patients)	Serious limitations	No inconsistency	No imprecision	3	None identified	Opioid use associated with increased risk of fracture in 1 cohort study (adjusted HR 1.28, 95% CI = 0.99–1.64) and 1 case-control study (adjusted OR 1.27, 95% CI = 1.21–1.33).
Myocardial infarction	1 cohort study (n = 426,124) and 1 case–control study (n = 11,693 case patients)	No limitations	No inconsistency	No imprecision	3	None identified	Current opioid use associated with increased risk of myocardial infarction versus nonuse (adjusted OR 1.28, 95% CI = 1.19–1.37 and incidence rate ratio 2.66, 95% CI = 2.30–3.08).
Endocrinologic harms	1 cross-sectional study (n = 11,327)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Long-term opioid use associated with increased risk for use of medications for erectile dysfunction or testosterone replacement versus nonuse (adjusted OR 1.5, 95% CI = 1.1–1.9).
How do harms vary depending on the opioid dose used?							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found higher doses of long-term opioid therapy associated with increased risk of opioid abuse or dependence than lower doses. Compared to no opioid prescription, the adjusted odds ratios were 15 (95% CI = 10–21) for 1 to 36 MME/day, 29 (95 % CI = 20–41) for 36 to120 MME/day, and 122 (95 % CI = 73–205) for ≥120 MME/day.
Overdose	1 cohort study (n = 9,940) and 1 case–control study (n = 593 case patients in primary analysis)	Serious limitations	No inconsistency	No imprecision	3	Magnitude of effect, dose response relationship	Versus 1 to <20 MME/day, one cohort study found an adjusted HR for an overdose event of 1.44 (95% CI = 0.57–3.62) for 20 to <50 MME/day that increased to 8.87 (95% CI = 3.99–19.72) at ≥100 MME/day; one case-control study found an adjusted OR for an opioid-related death of 1.32 (95% CI = 0.94–1.84) for 20 to 49 MME/day that increased to 2.88 (95% CI = 1.79–4.63) at ≥200 MME/day.
Fractures	1 cohort study (n = 2,341)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Risk of fracture increased from an adjusted HR of 1.20 (95% CI = 0.92–1.56) at 1 to <20 MME/day to 2.00 (95% CI = 1.24–3.24) at ≥50 MME/day; the trend was of borderline statistical significance.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Myocardial infarction	1 cohort study (n = 426,124)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Relative to a cumulative dose of 0 to 1,350 MME during a 90-day period, the incidence rate ratio for myocardial infarction for 1350 to <2700 MME was 1.21 (95% CI = 1.02–1.45), for 2,700 to <8,100 MME was 1.42 (95% CI = 1.21–1.67), for 8,100 to <18,000 MME was 1.89 (95% CI = 1.54–2.33), and for ≥18,000 MME was 1.73 (95% CI = 1.32–2.26).
Motor vehicle crash injuries	1 case–control study (n = 5,300 case patients)	No limitations	Unknown (1 study)	No imprecision	3	None identified	No association between opioid dose and risk of motor vehicle crash injuries even though opioid doses >20 MME/day were associated with increased odds of road trauma among drivers.
Endocrinologic harms	1 cross-sectional study (n = 11,327) New for update: 1 additional cross-sectional study (n=1,585)	Serious limitations	Consistent	No imprecision	3	None identified	Relative to 0 to <20 MME/day, the adjusted OR for ≥120 MME/day for use of medications for erectile dysfunction or testosterone replacement was 1.6 (95% CI = 1.0–2.4). One new cross-sectional study found higher-dose long-term opioid therapy associated with increased risk of androgen deficiency among men receiving immediate-release opioids (adjusted OR per 10 MME/day 1.16, 95% CI = 1.09–1.23), but the dose response was very weak among men receiving ER/LA opioids.
Dosing strategies (KQ3)							
Comparative effectiveness of different methods for initiating opioid therapy and titrating doses							
Pain	3 randomized trials (n = 93)	Serious limitations	Serious inconsistency	Very serious imprecision	4	None identified	Trials on effects of titration with immediate-release versus ER/LA opioids reported inconsistent results and had additional differences between treatment arms in dosing protocols (titrated versus fixed dosing) and doses of opioids used.
Overdose	New for update: 1 cohort study (n = 840,606)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One new cross-sectional study found initiation of therapy with an ER/LA opioid associated with increased risk of overdose versus initiation with an immediate-release opioid (adjusted HR 2.33, 95% CI = 1.26–4.32).
Comparative effectiveness of different ER/LA opioids							
Pain and function	3 randomized trials (n = 1,850)	Serious limitations	No inconsistency	No imprecision	3	None identified	No differences
All-cause mortality	1 cohort study (n = 108,492) New for update: 1 cohort study (n = 38,756)	Serious limitations	Serious inconsistency	No imprecision	4	None identified	One cohort study found methadone to be associated with lower all-cause mortality risk than sustained-release morphine in a propensity-adjusted analysis (adjusted HR 0.56, 95% CI = 0.51–0.62) and one cohort study among Tennessee Medicaid patients found methadone to be associated with higher risk of all-cause mortality than sustained-release morphine (adjusted HR 1.46, 95% CI = 1.17–1.73).
Abuse and related outcomes	1 cohort study (n = 5,684)	Serious limitations	Unknown (1 study)	Serious imprecision	4	None identified	One cohort study found some differences between ER/LA opioids in rates of adverse outcomes related to abuse, but outcomes were nonspecific for opioid-related adverse events, precluding reliable conclusions.
ER/LA versus immediate-release opioids							
Endocrinologic harms	New for update: 1 cross-sectional study (n = 1,585)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One cross-sectional study found ER/LA opioids associated with increased risk of androgen deficiency versus immediate-release opioids (adjusted OR 3.39, 95% CI = 2.39–4.77).

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Dose escalation versus dose maintenance or use of dose thresholds							
Pain, function, or withdrawal due to opioid misuse	1 randomized trial (n = 140)	Serious limitations	Unknown (1 study)	Very serious imprecision	3	None identified	No difference between more liberal dose escalation versus maintenance of current doses in pain, function, or risk of withdrawal due to opioid misuse, but there was limited separation in opioid doses between groups (52 versus 40 MME/day at the end of the trial).
Immediate-release versus ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled and continuous versus as-needed dosing of opioids; or opioid rotation versus maintenance of current therapy							
Pain, function, quality of life, and outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of decreasing or tapering opioid doses versus continuation of opioid therapy							
Pain and function	1 randomized trial (n = 10)	Very serious limitations	Unknown (1 study)	Very serious imprecision	4	None identified	Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine.
Comparative effectiveness of different tapering protocols and strategies							
Opioid abstinence	2 nonrandomized trials (n = 150)	Very serious limitations	No inconsistency	Very serious imprecision	4	None identified	No clear differences between different methods for opioid discontinuation or tapering in likelihood of opioid abstinence after 3–6 months
Risk assessment and risk mitigation strategies (KQ4)							
Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse among patients with chronic pain being considered for long-term opioid therapy							
Opioid risk tool	3 studies of diagnostic accuracy (n = 496) New for update: 2 studies of diagnostic accuracy (n = 320)	Serious limitations	Very serious inconsistency	Serious imprecision	4	None identified	Based on a cutoff score of >4 (or unspecified), five studies (two fair-quality, three poor-quality) reported sensitivity that ranged from 0.20 to 0.99 and specificity that ranged from 0.16 to 0.88.
Screener and Opioid Assessment for Patients with Pain, Version 1	2 studies of diagnostic accuracy (n = 203)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of ≥8, sensitivity was 0.68 and specificity was 0.38 in one study, for a positive likelihood ratio of 1.11 and a negative likelihood ratio of 0.83. Based on a cutoff score of >6, sensitivity was 0.73 in one study.
Screener and Opioid Assessment for Patients with Pain-Revised	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of >3 or unspecified, sensitivity was 0.25 and 0.53 and specificity was 0.62 and 0.73 in two studies, for likelihood ratios close to 1.
Brief Risk Interview	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a "high risk" assessment, sensitivity was 0.73 and 0.83 and specificity was 0.43 and 0.88 in two studies, for positive likelihood ratios of 1.28 and 7.18 and negative likelihood ratios of 0.63 and 0.19.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of opioid therapy for acute pain on long-term use (KQ5)							
Long-term opioid use	New for update: 2 cohort studies (n = 399,852)	Serious limitations	No inconsistency	No imprecision	3	None identified	One study found use of opioids within 7 days of low-risk surgery associated with increased likelihood of opioid use at 1 year (adjusted OR 1.44, 95% CI = 1.39–1.50), and one study found use of opioids within 15 days of onset of low back pain among workers with a compensation claim associated with increased risk of late opioid use (adjusted OR 2.08, 95% CI = 1.55–2.78 for 1 to 140 MME/day and OR 6.14, 95% CI = 4.92–7.66 for ≥450 MME/day).

Abbreviations: CI = confidence interval; ER/LA = extended release/long-acting; HR = hazard ratio; MME = morphine milligram equivalents; OR = odds ratio.
* Ratings were made per GRADE quality assessment criteria; "no limitations" indicates that limitations assessed through the GRADE method were not identified.
† Not applicable as no evidence was available for rating.

TABLE 2. Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf).

* Multiply the dose for each opioid by the conversion factor to determine the dose in MMEs. For example, tablets containing hydrocodone 5 mg and acetaminophen 300 mg taken four times a day would contain a total of 20 mg of hydrocodone daily, equivalent to 20 MME daily; extended-release tablets containing oxycodone 10mg and taken twice a day would contain a total of 20mg of oxycodone daily, equivalent to 30 MME daily. The following cautions should be noted: 1) All doses are in mg/day except for fentanyl, which is mcg/hr. 2) Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics. 3) Do not use the calculated dose in MMEs to determine the doses to use when converting opioid to another; when converting opioids the new opioid is typically dosed at substantially lower than the calculated MME dose to avoid accidental overdose due to incomplete cross-tolerance and individual variability in opioid pharmacokinetics. 4) Use particular caution with methadone dose conversions because the conversion factor increases at higher doses. 5) Use particular caution with fentanyl since it is dosed in mcg/hr instead of mg/day, and its absorption is affected by heat and other factors.

† Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

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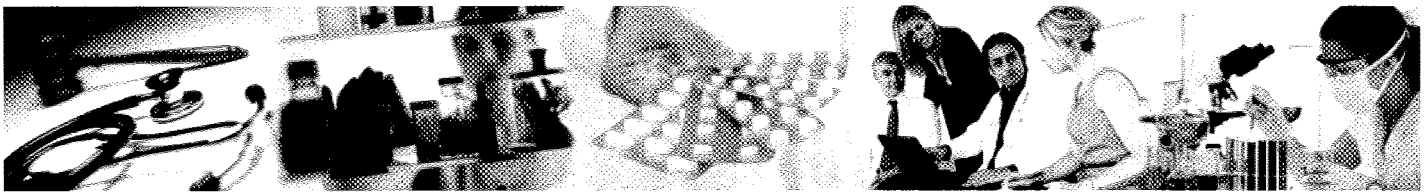

Rules - 2018

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-450]

RIN 1117-AB42

Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Comprehensive Addiction and Recovery Act (CARA) of 2016, which became law on July 22, 2016, amended the Controlled Substances Act (CSA) to expand the categories of practitioners who may, under certain conditions on a temporary basis, dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. Separately, the Department of Health and Human Services, by final rule effective August 8, 2016, increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA for that purpose. The Drug Enforcement Administration (DEA) is hereby amending its regulations to incorporate these statutory and regulatory changes.

DATES: Effective: January 22, 2018.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION: It has been determined this is a major rule within the meaning of the Congressional Review Act (CRA). 5 U.S.C. 804(2). Major rules generally cannot take effect until 60 days after the date on which the rule is published in the Federal Register. 5 U.S.C. 801(a)(3). However, the CRA provides that "any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808. As is discussed below, DEA finds there is good cause to issue these amendments as a final rule without notice and comment, because these amendments merely conform the implementing regulations with recent amendments to the CSA contained in CARA that have already taken effect. Accordingly, DEA has determined this rule will take effect January 22, 2018.

Background and Legal Authority

Pertinent Provisions of the CARA

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) into law as Public Law 114-198. Section 303 of the CARA amended certain provisions of **21 U.S.C. 823**(g)(2), which is the subsection of the Controlled Substance Act (CSA) that sets forth the conditions under which a practitioner may, without being separately registered under subsection 823(g)(1), dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. Maintenance treatment is the dispensing of a narcotic drug, in excess of twenty-one days, for the treatment of dependence upon heroin or other morphine-like drugs (**21 U.S.C. 802**(29)). A detoxification treatment is the term given when a narcotic drug is dispensed in decreasing doses, not exceeding one hundred and eighty days, "to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug," with the ultimate goal of bringing a patient to a narcotic drug-free state (21 U.S.C. 802(30)).

Specifically, section 303 of the CARA temporarily expands the types of practitioners who may dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment without being separately registered as a narcotic treatment program. Whereas prior to the CARA, only qualified physicians were permitted to dispense narcotic drugs in this manner, the CARA now temporarily permits certain nurse practitioners and physician assistants to qualify to do so. The CARA achieves this result by (1) inserting the term "qualifying practitioner" in place of "qualifying physician" in **21 U.S.C. 823**(g)(2)(B)(i) and (2) defining "qualifying practitioner" to include not only a physician, but also (until October 1, 2021) a "qualifying other practitioner," which includes a nurse practitioner or physician assistant who meets certain qualifications set forth in paragraph 823(g)(2)(G)(iv). More precisely, section 303 of the CARA defines "qualifying other practitioner" as a nurse practitioner or physician assistant who satisfies each of the following criteria:

> (I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain;
>
> (II) The nurse practitioner or physician assistant must complete not fewer than 24 hours of initial training.
>
> (III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the

supervision of a physician; and

The Secretary determines in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner can treat and manage opiate-dependent patients. The Secretary may, by regulation, revise the requirements for being qualifying other practitioner.

This section of the CARA further provides that the Secretary of Health and Human Services (HHS) may, by regulation, revise the foregoing

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requirements for being a qualifying other practitioner.

The CARA also makes some technical revisions to **21 U.S.C. 823**(g)(2) that do not materially alter the meaning of this subsection. Nonetheless, because the DEA regulations currently contain the older statutory language, DEA is hereby revising this part of the regulations to reflect the new statutory language.

*HHS Final Rule Increasing the Patient Limit for Purposes of **21 U.S.C. 823**(g)(2)*

Under the CSA, the Secretary of HHS may, by regulation, increase the maximum number of patients that a practitioner may treat pursuant to **21 U.S.C. 823**(g)(2). 21 U.S.C. 823(g)(2)(B)(iii)(III). On July 8, 2016, the Secretary issued a final rule increasing this number to 275. 81 FR 44712. As stated therein, to be eligible for the patient limit of 275, the practitioner must possess a current waiver to treat up to 100 patients under 21 U.S.C. 823(g)(2) and meet additional criteria set forth in 42 CFR 8.610-8.625.\1\ DEA is hereby amending its regulations to reflect these new limits.

\1\ The HHS final rule further provides that the approval by HHS to treat up to 275 patients is for a term of three years and that the practitioner must submit a renewal request with HHS every three years to continue to treat up to 275 patients. 42 CFR 8.625-8.655.

Good Cause for Issuing This Rule as a Final Rule Without Notice and Comment

As indicated, this final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under **21 U.S.C. 823**(g)(2), and where HHS does so, DEA is obligated to apply that number. As a result, DEA has no discretion not to amend its regulations as is being done in this final rule. Indeed, the new provisions issued under this final rule are already in effect by virtue of the CARA and the HHS final rule regarding patient limits. This final rule simply updates the DEA regulations to reflect these new provisions. Public comment on these amendments to the DEA regulations would therefore serve no purpose. Because notice and public comment are unnecessary, DEA finds there is good cause within the meaning of the Administrative Procedure Act (APA) to issue these amendments as a final rule without notice and comment, because these amendments merely conform the implementing regulations with recent amendments to the CSA contained in CARA that have already taken effect (see 5 U.S.C. 553(b)(B), relating to notice and comment procedures). "[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary". Gray Panthers Advocacy Committee v. Sullivan, 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also Komjathy v. Nat. Trans. Safety Bd., 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule "does no more than repeat, virtually verbatim, the statutory grant of authority" notice-and-comment procedures are not required). Therefore, we are issuing these amendments as a final rule, effective upon publication in the Federal Register. This rule constitutes final action on these changes under the APA (5 U.S.C. 553).

Regulatory Analysis

As explained above, DEA is obligated to issue this final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the CARA and the HHS final rule increasing the patient limit under **21 U.S.C. 823**(g)(2). In issuing this final rule, DEA has not gone beyond the statutory text enacted by Congress or the final rule issued by HHS. Thus, DEA would have to issue this final rule regardless of the outcome of the agency's regulatory analysis. Nonetheless, DEA conducted this analysis as discussed below.

Executive Orders 12866 (Regulatory Planning and Review) and 13563, (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders 12866 and 13563. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

1. The DEA expects that this final rule will have an annual effect on the economy of $100 million or more in at least one year and therefore is an economically significant regulatory action. The analysis of benefits and costs is below.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under **21 U.S.C. 823**(g)(2), and where HHS does so, DEA is obligated to apply that number.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. The Diversion Control Fee Account, which the DEA administers and which involves registration fees, is not directly affected. This regulatory action temporarily expanding the types of practitioners and increasing the maximum number of patients that a practitioner may treat as described in detail above represents a minor modification to the registration procedures within the Diversion Control Program and does not necessitate a change in registration fees.

4. This regulatory action is not likely to result in a rule that may raise novel

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legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under **21 U.S.C. 823**(g)(2), and where HHS does so, DEA is obligated to apply that number. This regulatory action therefore does not raise novel legal or policy issues.

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866, and therefore, has been submitted to the OMB for review.

I. Need for the Rule

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) became law. One section of the CARA amended the Controlled Substances Act (CSA) to expand the categories of practitioners who may, under certain conditions on a temporary basis, dispense a narcotic drug in Schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. Separately, the Department of Health and Human Services (HHS), by final rule effective August 8, 2016, increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA for that purpose. The DEA is amending its regulations to incorporate these statutory and regulatory changes.

In addition to the legal requirement to implement the statute, this rule also implements one of the objectives of the statute; expand availability of medication-assisted treatment (MAT) for opioid addiction. As supported by research, there is a gap between those who need treatment for opioid addition and treatment providers ("treatment gap"). An increase in treatment availability is expected to result in more patients treated.

Substance Abuse and Mental Health Services Administration (SAMHSA) independently researched the issue of the treatment gap in its recent rule: Medication Assisted Treatment for Opioid Use Disorders, 81 FR 44712, 44729 (July 8, 2016). SAMHSA found that ". . . there is significant unmet need for MAT treatment among individuals with opioid use disorders . . . Evidence suggests that utilization of buprenorphine is limited directly by the existence of treatment limits." A research article in American Journal of Public Health concluded that there are significant gaps between treatment need and capacity at the state and national levels, with 96% of states and District of Columbia having opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates.\2\ According to research by The Pew Charitable Trust, "[i]n the U.S. only 49 percent of people with an opioid dependence can potentially receive treatment because too few doctors prescribe the medicine, and those that do can serve only a limited number of patients because of federal restrictions." \3\ Also, patients located in rural areas are negatively impacted by the limits because there are fewer doctors certified to prescribe buprenorphine.\4\ One research article examined the availability of MAT by U.S. counties and determined that more than 30 million persons live in counties without access to buprenorphine treatment.\5\

\2\ Christopher M. Jones, PharmD, MPH, Melinda Campopiano, MD, Grant Baldwin, Ph.D., MPH, and Elinore McCance-Katz, MD, Ph.D., "National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment," Am J Public Health, August 2015. Vol 105. No. 8.

\3\ Christine Vestal, "Few Doctors Are Willing, Able to Prescribe Powerful Anti-Addiction Drugs," January 15, 2016.

\4\ The Coming Economic Bonanza In Addiction Treatment, Anson, Pat, (May 25, 2016), https://www.painnewsnetwork.org/stories/2016/5/25/the-coming-economic-bonanza-in-addiction-treatment.

\5\ Roger A. Rosenblatt, MD, MPH, MFR1, C. Holly A. Andrilla, MS, Mary Catlin, BSN, MPH, Eric H. Larson, Ph.D. "Geographic and Specialty Distribution of U.S. Physicians Trained to Treat Opioid Use Disorder," Annals of Family Medicine, Vol. 13, No. 1, January/ February 2015.

II. Alternative Approaches

This final rule amends the DEA regulations only to the extent necessary to be consistent with current federal law (as modified by the CARA) and current federal regulations issued by HHS. The qualifying practitioner amendments in the CARA alter the provisions of the CSA that DEA previously implemented in its regulations, and DEA is therefore obligated to update those regulations. With respect to the HHS regulations, the CSA gives sole authority to HHS to change the maximum number of patients per practitioner under **21 U.S.C. 823**(g)(2), and where HHS does so, DEA is obligated to apply that number. As a result, DEA has no discretion not to amend its regulations as is being done in this final rule. Indeed, the new provisions issued under this final rule are already in effect by virtue of the CARA and the HHS final rule regarding patient limits. This final rule simply updates the DEA regulations to reflect these new provisions; thus, no alternative approaches are possible.

III. Analysis of Benefits and Costs

This analysis is limited to the provisions associated with the section of the CARA that amended the CSA to expand the categories of practitioners who may, under certain conditions on a temporary basis, dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. The HHS rule that increased to 275 the maximum number of patients that a practitioner may treat for opioid use disorder without being separately registered under the CSA was promulgated under HHS' authority; therefore, that section of the CARA was excluded from this analysis. This is a summary; a detailed economic analysis of the proposed rule can be found in the rulemaking docket at http://www.regulations.gov.

Benefits, in the form of economic burden (health care costs, criminal justice costs, and lost productivity costs) reductions, are expected to be generated from the expansion of the categories of practitioners who may dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. The DEA anticipates the expansion of the categories of practitioners will lead to an increase in the number of treatment providers, which will lead to an increase in the number of patients (who did not have access to treatment prior to this rule) treated, resulting in the reduction in the economic burden due to opioid abuse.

Cost of the rule is associated with treatment cost and the cost to practitioners of obtaining authority to dispense a narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment. While these costs are not directly attributable to this rule, obtaining dispensing authority and treating patients are required to generate the benefits of the rule, and thus, included in this analysis. Although the new treatment providers in the expanded category, qualifying other practitioners, will also need to comply with treatment-specific recordkeeping requirements, the cost of compliance is included in the estimated cost of treatment. Finally, there is potential for added risk of diversion from more

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practitioners having the authority to dispense narcotic drug in schedule III, IV, or V for the purpose of maintenance treatment or detoxification treatment.

The DEA estimates the total benefit (economic burden reduction) is $208 million, $374 million, $467 million, $560 million, and $654 million in years 1, 2, 3, 4, and 5, respectively; the total cost of treatment is $133 million, $238 million, $298 million, $358 million, and $417 million in years 1, 2, 3, 4, and 5, respectively; and the total cost of obtaining DATA-waived status is $7 million and $4 million in years 1 and 2, respectively; resulting in a net benefit of $68 million, $132 million, $169 million, $202 million, and $237 million in years 1, 2, 3, 4, and 5, respectively. The table below contains the summary of benefits and costs.

	Year 1	Year 2	Year 3	Year 4	Year 5
Total economic burden reduction ($MM)	208	374	467	560	654
Cost of treatment ($MM)	133	238	298	358	417
Cost of obtaining DATA-waived status ($MM)	7	4	.....	.....	.....
Total cost ($MM)	140	242	298	358	417
Annual net benefit ($MM)	68	132	169	202	237

Figures are rounded.

At 3% discount rate, the present value of benefits is $2,044 million, the present value of costs is $1,315 million and the net present value (NPV) is $729 million. At 7% discount rate, the present value of benefits is $1,796 million, the present value of costs is $1,156 million and the NPV is $640 million.\6\ The net benefits in years 1 to 5 equate to an annualized net benefit of $159 million at 3% and $156 million at 7% over five years. The table below summarizes the present value and annualized benefit calculations.

\6\ See Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A-4, Regulatory Analysis (2003).

	3%	7%
Present value of benefits ($MM)	2,044	1,796
Present value of costs ($MM)	1,315	1,156
Net present value ($MM)	729	640
Annualized net benefit—5 years ($MM)	159	156

Figures are rounded.

Executive Order 12988, Civil Justice Reform

This final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of

government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This final rule is considered an E.O. 13771 deregulatory action. The rule is an enabling rule which expands the options for opioid treatment. Details on the expected economic effects of this rule can be found in the rule's economic impact analysis.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As explained above, the DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply to this final rule.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Congressional Review Act

This rule is a major rule as defined by the Congressional Review Act. 5 U.S.C. 804. This rule will result in an annual effect on the economy of $100 million or more as a result of economic burden reductions. However, it will not cause a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign based companies in domestic and export markets. The DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501-3521

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

For the reasons set out above, the DEA amends 21 CFR part 1301 as follows:

PART 1301--REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES

- 1. The authority citation for 21 CFR part 1301 is revised to read as follows:

  Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), **875, 877, 886a, 951, 952, 956, 957, 958, 965** unless otherwise noted.

- 2. In **Sec. 1301.28**, revise paragraphs (b)(1)(i), (ii), and (iii) to read as follows:

Sec. 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

* * * * *

(b)(1) * * *

(i) The individual practitioner is registered under Sec. 1301.13 as an individual practitioner and is a "qualifying physician" as defined in section 303(g)(2)(G)(ii) of the Act (21

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U.S.C. 823(g)(2)(G)(ii)), or during the period beginning on July 22, 2016 and ending on October 1, 2021, a "qualifying other practitioner" as defined in section 303(g)(2)(G)(iv) of Act (21 U.S.C. 823(g)(2)(G)(iv)). The Secretary of Health and Human Services may, by regulation, revise the requirements for being a qualifying other practitioner.

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the individual practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary of Health and Human Services:

(A) All drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(B) Appropriate counseling and other appropriate ancillary services.

(iii)(A) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section at any one time will not exceed the applicable number. Except as provided in paragraphs (b)(1)(iii)(B) and (C) of this section, the applicable number is 30.

(B) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of Health and Human Services of the need and intent of the practitioner to treat up to 100 patients.

(C) The applicable number is 275 for a practitioner who has been approved by the Secretary of Health and Human Services under 42 CFR part 8 to treat up to 275 patients at any one time, and provided further that the practitioner has renewed such approval to the extent such renewal is required under this part of the HHS regulations.

* * * * *

Dated: January 18, 2018.

Robert W. Patterson,
Acting Administrator.

[FR Doc. 2018-01173 Filed 1-22-18; 8:45 am]

BILLING CODE 4410-09-P

Agenda Item: **Licensing Report**

Staff Note: Mr. Heaberlin will provide information on note-worthy licensing matters.

Action: None anticipated.

Criteria for this report:
License Status = Current Active, Current Inactive, Probation - Current Active, Adverse Findings - Current Active, Current Active-RN Privilege and Expiration Date >= Today or is null.

License Count Report for Medicine

Board	Occupation	State	License Status	License Count
Medicine				
	Assistant Behavior Analyst			
	Assistant Behavior Analyst	Virginia	Current Active	114
	Assistant Behavior Analyst	Out of state	Current Active	8
	Total for Assistant Behavior Analyst			122
	Athletic Trainer			
	Athletic Trainer	Virginia	Current Active	1,233
	Athletic Trainer	Virginia	Current Inactive	2
	Athletic Trainer	Out of state	Current Active	226
	Athletic Trainer	Out of state	Current Inactive	2
	Total for Athletic Trainer			1,463
	Behavior Analyst			
	Behavior Analyst	Virginia	Current Active	740
	Behavior Analyst	Virginia	Current Inactive	2
	Behavior Analyst	Out of state	Current Active	181
	Total for Behavior Analyst			923
	Chiropractor			
	Chiropractor	Virginia	Current Active	1,372
	Chiropractor	Virginia	Current Inactive	25
	Chiropractor	Out of state	Current Active	286
	Chiropractor	Out of state	Current Inactive	78
	Total for Chiropractor			1,761
	Genetic Counselor			
	Genetic Counselor	Virginia	Current Active	56
	Genetic Counselor	Out of state	Current Active	39
	Total for Genetic Counselor			95
	Interns & Residents			
	Interns & Residents	Virginia	Current Active	2,575
	Interns & Residents	Out of state	Current Active	546
	Total for Interns & Residents			3,121
	Licensed Acupuncturist			
	Licensed Acupuncturist	Virginia	Current Active	382
	Licensed Acupuncturist	Virginia	Current Inactive	1
	Licensed Acupuncturist	Out of state	Current Active	121
	Licensed Acupuncturist	Out of state	Current Inactive	8
	Total for Licensed Acupuncturist			512
	Licensed Midwife			
	Licensed Midwife	Virginia	Current Active	59
	Licensed Midwife	Out of state	Current Active	16
	Total for Licensed Midwife			75
	Limited Radiologic Technologist			
	Limited Radiologic Technologist	Virginia	Current Active	510

License Count Report for Medicine

Board	Occupation	State	License Status	License Count
Medicine				
	Limited Radiologic Technologist			
	Limited Radiologic Technologist	Virginia	Current Inactive	29
	Limited Radiologic Technologist	Out of state	Current Active	27
	Limited Radiologic Technologist	Out of state	Current Inactive	1
	Total for Limited Radiologic Technologist			567
	Medicine & Surgery			
	Medicine & Surgery	Virginia	Current Active	22,106
	Medicine & Surgery	Virginia	Current Inactive	315
	Medicine & Surgery	Virginia	Probation - Currei	3
	Medicine & Surgery	Out of state	Current Active	14,784
	Medicine & Surgery	Out of state	Current Inactive	1,084
	Total for Medicine & Surgery			38,292
	Occupational Therapist			
	Occupational Therapist	Virginia	Current Active	3,238
	Occupational Therapist	Virginia	Current Inactive	38
	Occupational Therapist	Out of state	Current Active	816
	Occupational Therapist	Out of state	Current Inactive	40
	Total for Occupational Therapist			4,132
	Occupational Therapy Assistant			
	Occupational Therapy Assistant	Virginia	Current Active	1,278
	Occupational Therapy Assistant	Virginia	Current Inactive	9
	Occupational Therapy Assistant	Out of state	Current Active	279
	Occupational Therapy Assistant	Out of state	Current Inactive	3
	Total for Occupational Therapy Assistant			1,569
	Osteopathy & Surgery			
	Osteopathy & Surgery	Virginia	Current Active	1,726
	Osteopathy & Surgery	Virginia	Current Inactive	4
	Osteopathy & Surgery	Out of state	Current Active	1,637
	Osteopathy & Surgery	Out of state	Current Inactive	53
	Total for Osteopathy & Surgery			3,420
	Physician Assistant			
	Physician Assistant	Virginia	Current Active	2,843
	Physician Assistant	Virginia	Current Inactive	4
	Physician Assistant	Out of state	Current Active	762
	Physician Assistant	Out of state	Current Inactive	21
	Total for Physician Assistant			3,630
	Podiatry			
	Podiatry	Virginia	Current Active	388
	Podiatry	Virginia	Current Inactive	5
	Podiatry	Virginia	Probation - Currei	1
	Podiatry	Out of state	Current Active	119
	Podiatry	Out of state	Current Inactive	27
	Total for Podiatry			540
	Polysomnographic Technologist			
	Polysomnographic Technologist	Virginia	Current Active	361
	Polysomnographic Technologist	Out of state	Current Active	102

License Count Report for Medicine

Board	Occupation	State	License Status	License Count
Medicine				
	Total for Polysomnographic Technologist			463
	Radiologic Technologist			
	Radiologic Technologist	Virginia	Current Active	3,261
	Radiologic Technologist	Virginia	Current Inactive	30
	Radiologic Technologist	Out of state	Current Active	765
	Radiologic Technologist	Out of state	Current Inactive	7
	Total for Radiologic Technologist			4,063
	Radiologist Assistant			
	Radiologist Assistant	Virginia	Current Active	10
	Radiologist Assistant	Out of state	Current Active	1
	Total for Radiologist Assistant			11
	Respiratory Therapist			
	Respiratory Therapist	Virginia	Current Active	3,014
	Respiratory Therapist	Virginia	Current Inactive	71
	Respiratory Therapist	Out of state	Current Active	702
	Respiratory Therapist	Out of state	Current Inactive	29
	Total for Respiratory Therapist			3,816
	Restricted Volunteer			
	Restricted Volunteer	Virginia	Current Active	69
	Restricted Volunteer	Out of state	Current Active	25
	Total for Restricted Volunteer			94
	Surgical Assistant			
	Surgical Assistant	Virginia	Current Active	247
	Surgical Assistant	Out of state	Current Active	22
	Total for Surgical Assistant			269
	Surgical Technologist			
	Surgical Technologist	Virginia	Current Active	354
	Surgical Technologist	Out of state	Current Active	8
	Total for Surgical Technologist			362
	University Limited License			
	University Limited License	Virginia	Current Active	19
	University Limited License	Out of state	Current Active	1
	Total for University Limited License			20
Total for Medicine				69,320

This report has been modified on 10-27-2017 by adding Reinstatement licenses to the Count during the time range selected.

Issued License Count for Medicine between 07/01/2017 and 02/07/2018

Board	License Type	Obtained By	Count
Medicine			
	Assistant Behavior Analyst		
		Application	14
	Athletic Trainer		
		Application	112
		Reinstatement	2
	Behavior Analyst		
		Application	107
		Reinstatement	1
	Chiropractor		
		Application	48
		Reinstatement	3
	Genetic Counselor		
		Application	92
	Interns & Residents		
		Application	206
		Reinstatement	11
	Licensed Acupuncturist		
		Application	14
		Reinstatement	2
	Licensed Midwife		
		Examination	8
	Limited Radiologic Technologist		
		Application	27
		Reinstatement	2
	Medicine & Surgery		
		Application	421
		Application (american)	573

Issued License Count for Medicine between 07/01/2017 and 02/07/2018

Board	License Type	Obtained By	Count
		Application (non american)	173
		Reinstatement	64
	Occupational Therapist		
		Application	192
		Reinstatement	11
	Occupational Therapy Assistant		
		Application	141
		Reinstatement	1
	Osteopathy & Surgery		
		Application	232
		Reinstatement	2
	Physician Assistant		
		Application	242
		Reinstatement	7
	Podiatry		
		Application	17
		Reinstatement	1
	Polysomnographic Technologist		
		Application	23
	Radiologic Technologist		
		Application	242
		Reinstatement	24
	Respiratory Therapist		
		Application	155
		Reinstatement	9
	Restricted Volunteer		
		Application	9
	Surgical Assistant		
		Application	11

Issued License Count for Medicine between 07/01/2017 and 02/07/2018

Board	License Type	Obtained By	Count
	Surgical Technologist		
		Application	5
	University Limited License		
		Application	7
Total for Medicine			3,211
Grand Total:			**3,211**

Agenda Item: **Discipline Report**

Staff Note: Ms. Deschenes will provide information on discipline matters.

Action: None anticipated.

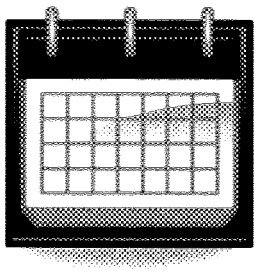
Agenda Item: **Appointment of Nominating Committee**

Staff Note: A Nominating Committee needs to be constituted to prepare a slate of officers for the June Board meeting.

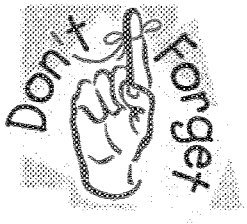
Action: The President will ask for volunteers that he can appoint to the Nominating Committee.

Next Meeting Date of the Full Board is

June 14-16, 2018



Please check your calendars and advise staff of any known conflicts that may affect your attendance.



The travel regulations require that "travelers must submit the Travel Expense Reimbursement Voucher with 30 days after completion of their trip". (CAPP Topic 20335, State Travel Regulations, p.7)

In order for the agency to be in compliance with the state travel regulations, please submit your request for today's meeting no later than

March 15, 2018