California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Debbie Veale, R.Ph., Chair
Ramón Castellblanch, Ph.D., Vice Chair, Public Member
Lavanza Butler, Professional Member
Ricardo Sanchez, Public Member
Ryan Brooks, Public Member

1. Call to Order and Establishment of Quorum

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. (Government Code Sections 11125 & 11125.7(a))

3. Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire

At the July 2015 Board Meeting, the board reviewed the results of a short questionnaire made available to licensees via Survey Monkey regarding patient consultation. At the October 2015 board meeting, President Gutierrez asked the committee to develop a broader survey.

The committee discussed options within the Department of Consumer Affairs, schools of pharmacies, and associations for the survey to pharmacists. The committee discussed as possible options including UCSB graduate school, Kaiser Family Foundation, and the USC School of Business. The committee determined Dr. Castellblanch to be the point of contact for quality control.

Board staff contacted the following entities to determine interest in working with the board on a survey for pharmacists. The following entities respectfully declined working with the board: UC Davis Graduate School of Management; Kaiser Family Foundation; and Sierra Health Foundation. The board received no response from Philanthropy Dignity Health; California State University, Sacramento; and UC Santa Barbara.

Board staff contacted the Office of Professional Examination Services (OPES), housed within Department of Consumer Affairs' (DCA) Division of Programs and Policy Review.

OPES primarily provides professional psychometric expertise in examination development and validation services to DCA's regulatory entities through Intra-Agency Contract agreements. OPES follows the highest professional guidelines and technical standards in the industry and is committed to ensuring that examinations and related products are psychometrically sound and legally defensible.

OPES has experience developing and distributing surveys, including analyzing survey data. Specifically, OPES regularly constructs occupational analysis surveys to distribute to licensees for gathering critical information about occupations to then be used for licensure examination development. These projects include working with subject matter experts to develop the survey content; creating sampling plans; drafting survey communications such as introductory letters and follow up reminders; using Survey Monkey to distribute surveys; monitoring distribution; analyzing data and responses; and, writing reports documenting the survey process and results.

For the patient consultation survey project, OPES will meet with Board staff no later than June 30 to identify expectations, project tasks, potential costs, and to create a timeframe for conducting this project. Further, as part of this project, OPES can provide written updates.

At this meeting, Division of Program & Policy Review Chief Tracy A. Montez, Ph.D., Department of Consumer Affairs will be available to address the committee and answer questions on how her Division would address and handle the survey.

4. Discussion on Current Patient Consultation Practices and Actions the Board Can Take to Educate Consumers and Licensees on Appropriate Patient Consultations

At previous committee meetings the Communication and Public Education Committee has discussed the importance of educating consumers and licensees on appropriate patient consultations. At this meeting, the committee will have the opportunity to discuss current patient consultation practices. Additionally, the committee will have the opportunity to identify areas where the board can aid to the education of consumers and licensees on patient consultation.

5. Update on the Redesign of the Board's Website

Attachment 1

At the April 2016 board meeting, the committee reported the new website design will be migrated by the department and should be active approximately 2-4 weeks after final migration. The board began the process of migration the second week of May and anticipates completion in early June 2016.

Screen shots of the updated board's home page as well as the landing pages for the Consumers, Applicants, Licensees, and About Us tabs are provided in **Attachment 1**. At the July 2016 board meeting, Webmaster Victor Perez will provide a presentation and overview on the updated website.

6. Update and Discussion on Prescription Label Translations of Directions for Use

Attachments 2 and 3

a. Update on the Communication Plan

Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions.

AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Dispensers are not *required* to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use. The provisions of the bill went into effect on January 1, 2016. A copy of the chaptered bill is included in **Attachment 2**.

At the January 2016 Communication and Public Education Committee Meeting, the committee directed board staff to develop a communication plan and provide an update to the committee.

The committee directed board staff to release a public service announcement about the change in law immediately. The public service announcement was released on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall the release was sent to over 800 media outlets as indicated below:

- 499 media outlets received the English and translated press releases
- 272 media outlets received the Spanish translated press release
- 33 media outlets received the Chinese translated press release
- 17 media outlets received the Vietnamese translated press release
- 12 media outlets received the Korean translated press release
- 3 media outlets received the Russian translated press release

As part of the Communication Plan – Phase I, the information from the press release information was added to the board's website as a new topic on the homepage. Additionally, board staff contacted the Department of Consumer Affairs' (DCA) Public Affairs Office for assistance in disseminating the message through DCA's website, Facebook and Twitter account. The board wrote a newsletter article for the Spring 2016 edition of the board's newsletter, *The Script*.

A copy of the board's web page, translated press releases, DCA's webpage search function showing "label translations," DCA's Facebook post, DCA's Tweet, and the board's newsletter article are included in **Attachment 2**.

As part of the Communication Plan – Phase II, board staff recommends the following information dissemination regarding the availability of written translations as part of a specific ***Did You Know?*** Campaign:

- Flyer/Fact Sheet Development – Develop in concert with the Department of Consumer Affairs' Office of Publications, Design and Editing identifying fact sheet and tag line materials translated into the five languages identified in the law and post Flyers/Fact sheets on the board's website.
- Follow Up Press Release – Reiterate the message through a follow up Press Release with Flyer/Fact Sheet directed to audiences of the five languages identified in the law.

At this meeting, the committee will have opportunity to discuss future public education activities in relation to AB 1073.

b. Proposed Draft Regulation Language for Consideration

The committee also discussed developing draft language for regulations requiring pharmacies to post information for consumers regarding the availability of written translations. Board staff drafted language for committee consideration to require the Point to Your Language notice include a translated direction for the consumer to ask about translations available. A copy of the proposed draft regulations for committee consideration is included in **Attachment 3**.

7. Update on Development of FAQs Received From ask.inspector@dca.ca.gov

Currently, the board has available to its licensees the option to call and ask general questions to one of the board's pharmacist inspectors. This service is available Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at ask.inspector@dca.ca.gov. Emails are responded to during business days. To ensure that all licensees receive the benefits of service, the board is developing an FAQ to be posted on the board's web site concerning the most frequent questions and issues.

While the questions and answers are not intended as, nor should they be construed to be legal advice, the information is intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment to determine an appropriate course of action. Should a licensee require legal advice or detailed research, the licensee is encouraged to contact an attorney or other source.

Board staff is in the process of collecting FAQs to add to the board's website as a reference for licensees. The board will continue to develop and increase the number of FAQs, as needed. An update on the draft FAQs will be provided at the meeting.

8. Discussion and Consideration of Naloxone Related Matters

Attachment 4

a. Sample Naloxone Labels

Pursuant to title 16 CCR section 1743.6 (c)(5), the board is required to provide on the board's website sample naloxone labels. A copy of the sample naloxone labels posted on the board's website is included in **Attachment 4**.

b. Communication to the California Healing Art Boards Regarding Naloxone

At previous committee meetings, committee members have expressed interested in reaching to out to California healing arts boards regarding naloxone access, regulation and protocol. At this meeting, the committee will have the opportunity to discuss content and options for reaching out to California healing arts boards about naloxone access, regulation and protocol.

c. Need for Naloxone FAQs

At previous committee meetings, committee members have expressed the need for a naloxone FAQ. At this meeting, the committee will have the opportunity to discuss the need and content for a naloxone FAQ.

d. Naloxone Fact Sheet for Patients

Pursuant to 16 CCR 1743.6 (c)(5), the board is required approve a fact sheet for distribution to the patient by the pharmacists. The board approved the fact sheet entitled "Opioid Safety and How to Use Naloxone: A Guide for Patients and Caregivers" developed by the San Francisco Department of Public Health. A copy of the board approved fact sheet is included in **Attachment 4**.

The fact sheet is in the process of being updated by the San Francisco Department of Public Health in collaboration with California Department of Public Health. Estimated completion of the revised fact sheet is approximately July or August 2016 and will be brought to the committee when available.

At previous committee meetings, committee members have expressed interest in developing a naloxone fact sheet specific for patients. At this meeting, the committee will have the opportunity to discuss development of a naloxone fact sheet specifically for patients.

9. Update and Discussion on SB 493 Implementation

Attachment 5

a. Immunization Protocol

In July 2015, the board initiated a formal rulemaking to add section 1746.4 to Title 16 CCR to specify the requirements for a pharmacist to administer vaccinations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs on January 29, 2016, for final review. A copy of the approved regulation language is provided in **Attachment 5**.

i. Sample Administration Records for Immunizations

Pursuant to the board adopted final text, the board is required to maintain on the board's website an example of an appropriate vaccine administration record.

Board staff identified three sample immunization formats found included in **Attachment 5**:

- The California Immunization Record (yellow card) - California Department of Public Health;
- The California School Immunization Record - California Department of Public Health
- Immunization and Development Milestones for Your Child from Birth Through 6 Years Old - Centers for Disease Control and Prevention

With the assistance of a Supervising Inspector, staff reviewed the sample immunization record formats and recommends using the California Department of Public Health's yellow card. The yellow card is a widely recognized immunization record used in California and has space to write in immunizations given beyond school age (e.g., HPV, Shingles, etc.).

The California School Immunization Record by California Department of Public Health and Immunization and Development Milestones for Your Child from Birth Through 6 Years Old by Centers for Disease Control and Prevention document immunizations required from birth to six years of age, as well as immunizations required to start school, but do present limitations.

b. Self-Administered Hormonal Contraception Matters

i. Discussion and Consideration of Developing Referral Lists for Pharmacists to Give Patients When Self-Administered Hormonal Contraception is Not Furnished

Pursuant to 16 CCR 1746.1 (b)(9), the protocol for pharmacists furnishing self-administered hormonal contraception provides if self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse.

At this meeting, the committee will have the opportunity to discuss and consider the development of a referral list for pharmacists to provide to patients when self-administered hormonal contraception is not furnished to the patient.

ii. Documents Available to Memorialized Prescriptions Furnished by a Pharmacist as a Drug Order

Pursuant to 16 CCR 1746.1 (b)(11), the protocol for pharmacists furnishing self-administered hormonal contraception provides each self-administered hormonal contraception furnished by a pharmacist pursuant to the protocol shall be documented in a patient medication record as required by 16 CCR 1717 and 1707.1. These records are required to be maintained for a period of at least three years from the date of dispense.

A sample document available to memorialize and document prescriptions furnished by a pharmacist with a copy of a self-screening questionnaire is included in **Attachment 5**.

c. Nicotine Replacement Therapy Matters

i. Discussion of The DCA Page: News from the Department of Consumer Affairs Blog Article – Pharmacists Can Help You Quit Smoking

The DCA Page is the department's webpage for the latest news. On March 29, 2016, The DCA Page featured an article about the nicotine replacement therapy regulation included in **Attachment 5**.

10. Discussion on the Development of FAQs for SB 493 Related Items

Senate Bill 493 (c. 469, Hernandez) was enacted in 2013 and established a new license for an Advanced Practice Pharmacist (APP). The board is currently promulgating regulations to specify certification program requirements, as well as continuing education and other requirements. The adopted regulations are currently being reviewed by the department.

At the April 2016 board meeting, the board requested that the Communication and Public Education Committee coordinate the development of a Frequently Asked Questions (FAQs) for SB 493 related items. At this meeting, the committee will have an opportunity to discuss the development of the FAQs.

11. Update and Discussion on CURES 2.0 and Communication to Licensees

Attachment 6

The Department of Justice (DOJ) recently released a CURES 2.0 registration tip sheet to help individuals register or access the system. On April 6, 2016, the board issued a subscriber alert announcing the tip sheet as well as a reminder that all pharmacists with active California licenses need to be registered to access CURES 2.0 by July 1, 2016. Additionally, the DOJ has published on their website publications and training videos to assist in the registration process: http://oag.ca.gov/cures/publications. A copy of the board's subscriber alert, DOJ's tip sheet, and a copy of the DOJ CURES 2.0 Publication and Training Video landing page can be found in **Attachment 6**.

In February 2016, the board mailed out a reminder postcard to pharmacists to register for CURES 2.0 by July 1, 2016. Board staff is preparing a final letter to be mailed to registered pharmacists who are not registered with CURES 2.0. Any questions regarding these changes should be directed to cures@doj.ca.gov. At this meeting, the committee will have the opportunity to discuss the board's communication to its licensees about the requirement to register for CURES 2.0 by July 1, 2016.

12. Update and Discussion on Resources Available on the Board's Website

Attachment 7

a. University of California, San Diego (UCSD) on Prescription Drug Abuse

An update will be provided at this meeting.

b. Consumer Reports on Prescription Drug Abuse

The board continues to seek written approval from Consumer Reports to post their reports on prescription drug abuse.

c. *Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance* by Centers for Medicare and Medicaid Services (CMS)

The committee will have the opportunity to discuss *Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance* by Centers for Medicare and Medicaid Services (CMS). A copy of *Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance* can be found in **Attachment 7**.

13. Discussion and Consideration of the United States Access Board's Recommendations Related to Prescription Labels for Visually-Impaired and Elderly Patients

Attachment 8

As part of the Food and Drug Administration Safety and Innovation Act signed by President Obama on July 9, 2012, the Access Board was authorized to convene a stake holder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually impaired or who are elderly.

A copy of the United States Access Board's Working Group Recommendations entitled *Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly* is provided in **Attachment 8**.

14. Discussion on Federal Legislation: US Senate 524 – Comprehensive Addiction and Recovery Act of 2016

Attachment 9

At this meeting the committee will have the opportunity to discuss pending federal legislation US Senate 524 known as the Comprehensive Addiction and Recovery Act of 2016. As of March 10, 2016, the bill passed the US Senate with an amendment by Yea-Nay Vote: 94-1. A copy of US Senate 524 engrossed in Senate can be found in **Attachment 9**.

15. Proposal to Develop a Consolidated List of Drug Take Back Locations for the Board's Website

At this meeting, the committee will discuss a proposal for the board to develop a consolidated list of drug take back locations to be available on the board's website.

16. Discussion on a Possible Regulatory Change to Require the Collection of Pharmacists' Email Addresses

Attachment 10

Business and Professions Code section 4003 (c) requires the board's executive officer maintain and update records containing the names, titles, qualifications and places of business of all persons subject to the Chapter 9. Further, 16 CCR 1704 requires all persons holding a license with the board to file a proper and current residence address with the board and to notify the board within 30 days of any and all changes in residence. A copy of the statute and regulation is included in **Attachment 10**.

At the April 2016 board meeting, the board requested the Communication and Public Education Committee discuss the possible requirement to collect pharmacists' email addresses. Board staff did preliminary research and determined the fields in both the board's applicant and licensing tracking systems can accommodate the field to add the email address.

Currently, the board has on record approximately 1,500 emails of the nearly 44,000 pharmacist licensees. Updating and filing documentation of the remaining 42,500 email addresses represents approximately 3,542 hours of staff work to complete where each update takes approximately 5 minutes to complete if unilaterally mandated. If the mandate is phased in over time, assuming equal distribution of the biennial licensure renewal across 24 months, the addition of the email would represent approximately 150 hours of work a month for two years.

Additionally, ongoing workload would need to be factored. Currently, the board processes approximately 11,000 – 12,000 change of address requests from licensees annually. Assuming approximately 25% of licensed pharmacists require a change of email address each year, this represents approximately 900 additional work hours annually.

Currently, section 4013 of the Business and Professions Code requires all board licensed facilities to subscribe to the board's email notification system. The committee may wish to consider a like provision for pharmacists licensed by the board. A copy of Business and Professions Code section 4013 included in **Attachment 10**. At this meeting, the committee will have the opportunity to discuss this issue further.

17. Update on *The Script* Newsletter

The Spring 2016 edition of *The Script* newsletter was issued May 9, 2016. Board staff has begun writing articles for the Summer 2016 issue of *The Script*.

18. Update on Media Activity

The board's executive officer (unless otherwise noted) participated in the following media interviews and requests for information.

- **Ventura County Star,** April 13, 2016: Tom Kisken, Hormonal contraception regulation
- **The Verge,** April 13, 2016: Lindsey Smith, Prescription writing and filling by doctors and pharmacists using smart phone applications
- **HECHO EN CALIFORNIA on KIQI 1010 am/San Francisco & KATD 990 am/Sacramento,** April 15, 2016: Isabel Gutierrez, interview for radio program: Hormonal contraception regulation
- **One Medical Group,** May 6, 2016: Maria Hunt, hormonal contraception regulation
- **San Jose Mercury News,** May 11, 2016: Tracy Seipel, End of Life Option
- **KQED,** May 13, 2016: Kelly Dunleavy O'Mara, Self-administered hormonal contraception

19. Update on Public Outreach Activities Conducted by the Board

A list of major public outreach activities provided by the board's staff is listed below:

- April 29-30: Executive Officer Virginia Herold spoke at the CPhA Annual Meeting

- May 20: Executive Officer Virginia Herold participated in a DEA Joint Presentation at California State University, Sacramento

20. <u>Review and Discussion of News or Journal Articles</u>

Attachment 11

Attachment 11 contains several items of potential issues of interest for this committee.

21. <u>Future Meeting Dates</u>

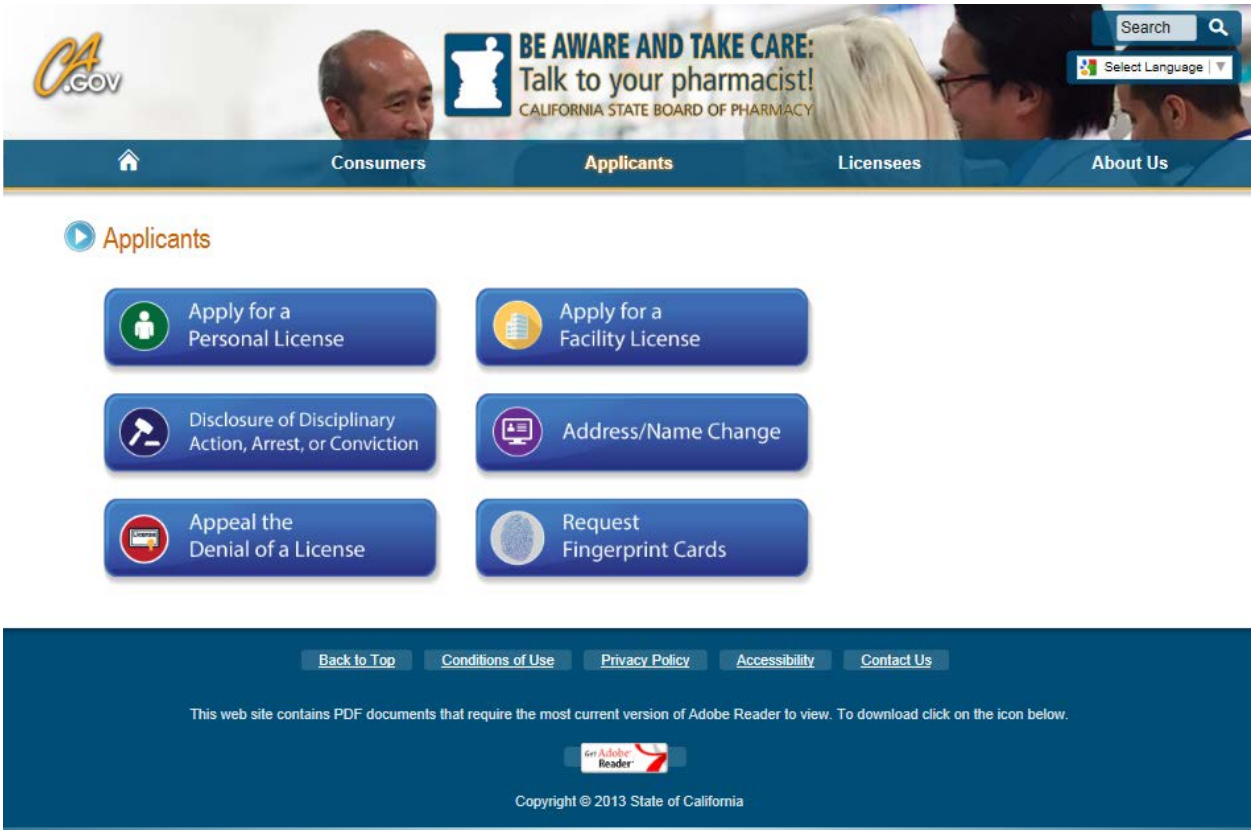
a. September 8, 2016
b. December 1, 2016

Attachment 1

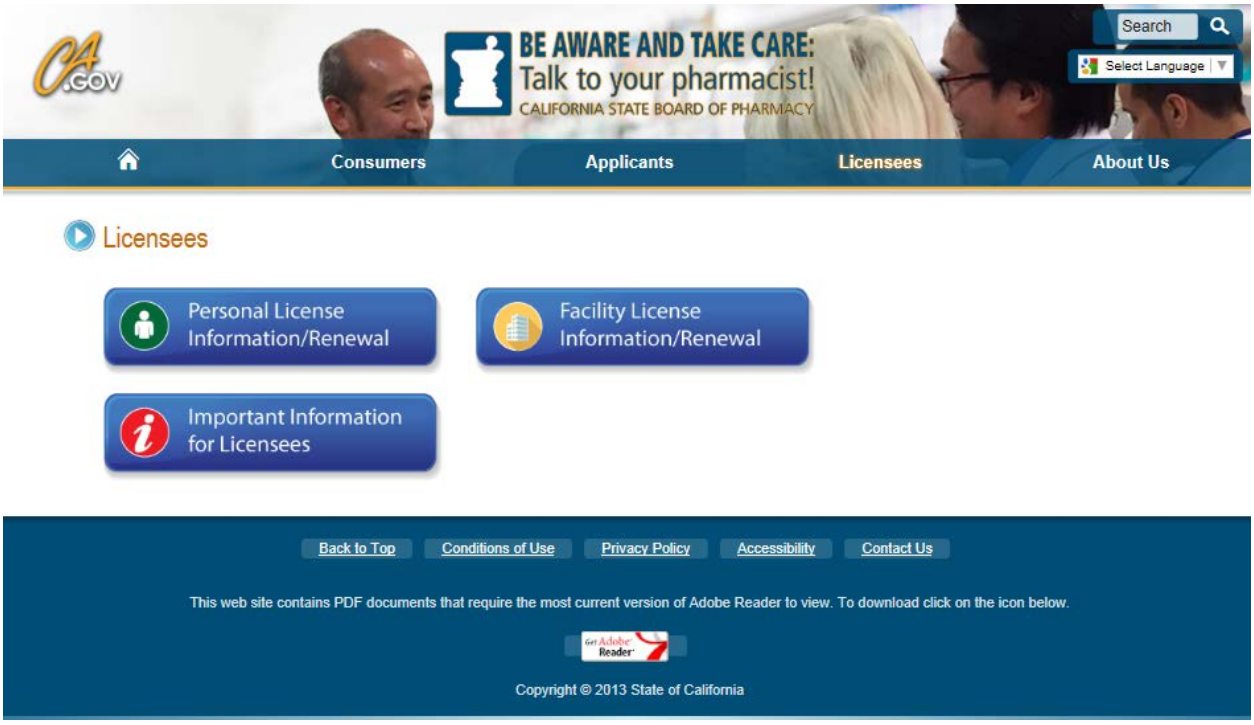
Redesigned California State Board of Pharmacy Home Page – www.pharmacy.ca.gov

Redesigned Consumers' Tab Landing Page

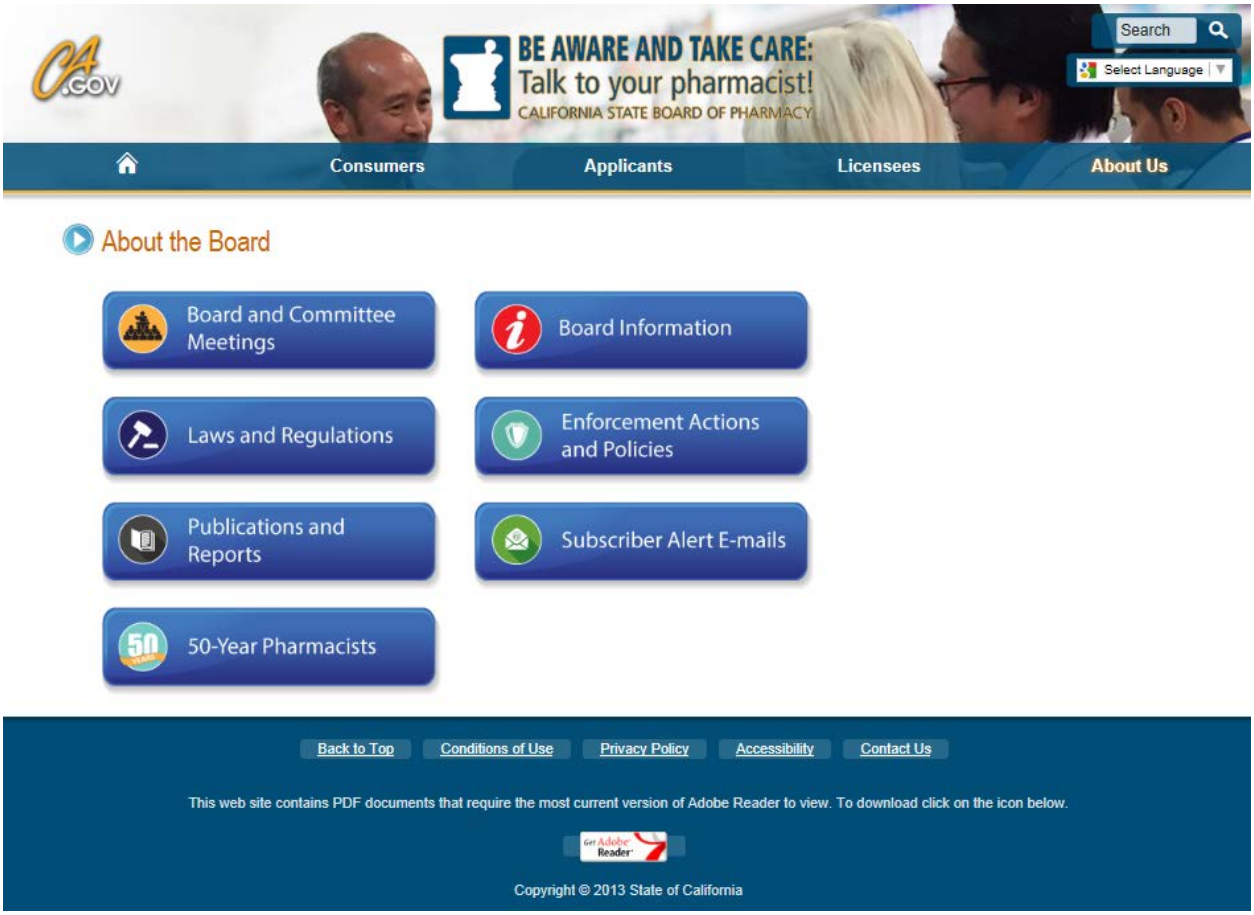
Redesigned Applicants' Tab Landing Page



Redesigned Licensees' Tab Landing Page



Redesigned About Us Tab Landing Page



Attachment 2

Assembly Bill No. 1073

CHAPTER 784

An act to amend Sections 4076 and 4199 of, and to add Section 4076.6 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 11, 2015. Filed with Secretary of State October 11, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, Ting. Pharmacy: prescription drug labels.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires a pharmacist to dispense a prescription in a container that, among other things, is correctly labeled with the directions for use of the drug, and requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that requirement, establishing standardized directions for use to be used when applicable, and requiring that the board publish on its Internet Web site translation of those directions for use into at least 5 languages other than English. A violation of that law is a crime.

This bill would require a pharmacist to use professional judgment to provide a patient with directions for use of a prescription that enhance the patient's understanding of those directions, consistent with the prescriber's instructions. The bill would also require a dispenser, excluding a veterinarian, upon the request of a patient or patient's representative, to provide translated directions for use as prescribed. The bill would authorize a dispenser to use translations made available by the board pursuant to those existing regulations. The bill would make a dispenser responsible for the accuracy of English-language directions for use provided to the patient. By imposing new requirements on dispensers, the violation of which would be a crime, this bill would impose a state-mandated local program.

The Pharmacy Law also provides for the licensure and regulation of veterinary food-animal drug retailers by the board. That law subjects to specific prescription drug labeling requirements any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food-producing animals from a veterinary food-animal drug retailer pursuant to that law.

This bill would also subject any veterinary food-animal drug so dispensed to the above drug labeling requirements relating to standardized directions for use.

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

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

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

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

SEC. 2. Section 4076.6 is added to the Business and Professions Code, to read:

4076.6. (a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.

(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.

(d) A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.

(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.

(f) For purposes of this section, a dispenser does not include a veterinarian.

SEC. 3. Section 4199 of the Business and Professions Code is amended to read:

4199. (a) Any veterinary food-animal drug dispensed pursuant to a prescription from a licensed veterinarian for food producing animals from a veterinary food-animal drug retailer pursuant to this chapter is subject to the labeling requirements of Sections 4076, 4076.6, and 4077.

(b) All prescriptions filled by a veterinary food-animal drug retailer shall be kept on file and maintained for at least three years in accordance with Section 4333.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Update on the Communication Plan

DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Patients Can Now Request Translations on the Directions for Use on Certain Prescription Labels

On February 10, 2016, the board released the press release announcing the new 2016 requirement for prescription labels. The press release was translated into Chinese, Korean, Russian, Spanish and Vietnamese. Copies of the translated press releases are available below. The press release was sent to over 800 media outlets including:

- 499 media outlets received the English and translated press releases (below)
- 272 media outlets received the Spanish translated press release
- 33 media outlets received the Chinese translated press release
- 17 media outlets received the Vietnamese translated press release
- 12 media outlets received the Korean translated press release
- 3 media outlets received the Russian translated press release

NEWS RELEASE
February 10, 2016
CONTACT: Debbie Damoth
(916) 574-7935
Debbie.Damoth@dca.ca.gov

Translations on Prescription Drug Labels
Patients Can Now Request Translations on the Directions for Use on Certain Prescriptions Labels

Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was sponsored by the California Board of Pharmacy and authored by Assembly Member Ting as AB 1073.

The law recognizes that many dispensers already provide translations on prescription containers and the enacted legislation allows this practice to continue. This law creates another opportunity for consumers to receive translations. Consumers interested in receiving such translations should request this service from their pharmacy.

In some cases, a translation may not be available for the pharmacy to provide. In such cases, the board strongly encourages consumers to use the free interpreter services available at the pharmacy to ensure they understand how to safely take medications.

Additional information about this new law as well as other changes to pharmacy law can be found on the board's website via the following link - - http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

The California Board of Pharmacy protects and promotes the health and safety of California by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.

###

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BUSINESS, CONSUMER SERVICES and HOUSING AGENCY
DEPARTAMENTO DE ASUNTOS DEL CONSUMIDOR
GOBERNADOR EDMUND G. BROWN JR.

COMUNICADO DE PRENSA
10 de febrero de 2016

CONTACTO: Debbie Damoth
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Traducción de las etiquetas de medicamentos con receta
Los pacientes ahora pueden solicitar la traducción de las instrucciones de uso de ciertos medicamentos con receta

Ser capaz de leer la etiqueta del medicamento es fundamental para poder entender cómo tomarlo de manera apropiada.

En enero de 2016 entraron en vigencia en California nuevos requisitos para las etiquetas de medicamentos con receta, los cuales establecen un mecanismo por el cual los pacientes con conocimientos limitados de inglés podrán por lo general obtener las indicaciones traducidas en las etiquetas de los envases de sus medicamentos recetados o como un suplemento a la etiqueta.

Esta ley fue patrocinada por la Junta de Farmacias de California y redactada por el miembro de la asamblea Ting como el proyecto de ley AB 1073.

La ley reconoce que muchos expendedores de medicamentos ya ofrecen traducciones en los envases y la legislación promulgada permite que esta práctica continúe. Esta ley crea una nueva oportunidad para que los consumidores reciban traducciones. Los consumidores que estén interesados en recibir este tipo de traducciones, deben solicitar este servicio a su farmacia.

En algunos casos, puede que la farmacia no cuente con una traducción disponible para proporcionarle. En tales casos, la junta recomienda encarecidamente a los consumidores que utilicen los servicios de interpretación gratuitos disponibles en la farmacia con el fin de garantizar que entiendan cómo tomar los medicamentos de forma segura.

Se puede encontrar más información acerca de esta nueva ley, así como de otros cambios en la ley de farmacias, en la página web de la junta a través del siguiente enlace:
http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

La Junta de Farmacias de California protege y promueve la salud y seguridad de California, buscando la más alta calidad de atención farmacéutica y el uso adecuado de los productos farmacéuticos a través de la educación, comunicación, concesión de licencias, legislación, regulación y aplicación de las normas.

###

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商業, 消費者服務及住家中介單位
消費者服務部門
EDMUND G. BROWN JR. 州长

新聞稿
二零一六年二月三日

聯絡人: Debbie Damoth
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處方藥標籤翻譯
患者即起可要求特定處方藥標籤中的使用說明翻譯

擁有閱讀處方藥標籤的能力是了解正確用藥方式的重要一環。

加州對處方藥標籤的新要求於二零一六年一月正式生效，其建立一個讓具備有限英語能力的患者可以在一般情況下從處方藥罐標籤中，或是在藥罐標籤外的補充信息中獲得使用說明翻譯的機制。

此法案由加州藥劑局(California Board of Pharmacy)贊助，並由丁議員以 AB 1073 法案為名提出。

目前法律認知許多藥劑師已經在處方藥罐上提供翻譯，而此法案的設定讓藥劑師們能夠繼續提供此服務。此法案為消費者提供獲取翻譯的機會。任何有意獲取翻譯的消費者皆可向藥局提出要求。

在某些情況下，藥局可能無法提供特定藥物的標籤翻譯。若遇到此情況，加州藥劑局強烈建議消費者善加利用藥局提供的免費翻譯服務以確保消費者對正確用藥的了解。

關於此法案的額外訊息及其它藥劑法的修改皆可於加州藥劑局的網站上找到，以下為連結 - - http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

加州藥劑局透過追求最高品質的藥劑師服務以及通過教育、溝通、授權、立法、條例和法規執行以確保正確用藥的方式，保護及推廣加州的健康與安全。

###

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CƠ QUAN KINH DOANH, CHĂM SÓC KHÁCH HÀNG và NHÀ Ở
PHÒNG DỊCH VỤ KHÁCH HÀNG
THỐNG ĐỐC EDMUND G. BROWN JR.

THÔNG CÁO BÁO CHÍ
10 Tháng Hai, 2016

LIÊN HỆ: Debbie Damoth
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Dịch Thuật Nhãn Thuốc Theo Toa
Bệnh Nhân Giờ Đây Có Thể Yêu Cầu Bản Dịch Hướng Dẫn Sử Dụng Trên
Nhãn Thuốc Theo Toa Nhất Định

Có khả năng đọc nhãn thuốc theo toa là một yếu tố cần thiết để có thể biết cách sử dụng thuốc thích hợp.

Trong tháng 1 năm 2016, các điều luật mới có hiệu lực tại California đối với nhãn thuốc theo toa giúp thiết lập cơ chế mà theo đó bệnh nhân với kỹ năng tiếng Anh hạn chế thường có thể được cung cấp các hướng dẫn đã được dịch trên nhãn thuốc theo toa hoặc như một bổ sung trên nhãn.

Luật này được bảo trợ bởi Hội đồng Dược California và do Thành viên Hội đồng Ting soạn thảo với tên gọi AB 1073.

Luật này nhận thấy nhiều hãng bào chế đã cung cấp bản dịch trên vỏ hộp thuốc theo toa và luật ban hành cho phép việc thực hành này được tiếp tục. Luật này cũng tạo cơ hội khác để người tiêu dùng nhận được bản dịch. Người tiêu dùng quan tâm đến việc được cung cấp bản dịch nên yêu cầu dịch vụ này từ hiệu thuốc của mình.

Trong một số trường hợp, một bản dịch có thể không có sẵn để hiệu thuốc cung cấp. Trong những trường hợp như vậy, hội đồng mạnh mẽ khuyến khích người tiêu dùng sử dụng các dịch vụ thông dịch miễn phí có sẵn tại hiệu thuốc để đảm bảo hiểu rõ cách dùng thuốc an toàn.

Thông tin thêm về điều luật mới này cũng như các thay đổi khác về luật dược có thể được tìm thấy trên trang web của hội đồng thông qua liên kết sau đây - -
http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

Hội đồng Dược California bảo vệ và thúc đẩy sức khỏe và sự an toàn của California bằng cách theo đuổi chất lượng cao nhất về sự chăm sóc của dược sĩ và việc sử dụng dược phẩm thích hợp thông qua giáo dục, truyền thông, cấp phép, pháp luật, quy định và thực thi.

###

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산업, 소비자 서비스 및 주택청
소비자부
GOVERNOR EDMUND G. BROWN JR.

보도 자료
2016 년 2 월 3 일

연락처: Debbie Damoth
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처방약 라벨에 대한 번역

지금부터 환자들은 특정 처방약 라벨에 있는 복용법에 대한 번역을 요청하실 수 있습니다.

처방약 라벨을 읽을 수 있다는 것은 약을 적절하게 복용하는 법을 이해하기위한 필수적인 요소입니다.

2016 년 1 월에, 영어를 미숙하게 이해하는 환자들이 처방약 용기 라벨이나 라벨에 추가된 부록을 통해 번역된 복용법을 자주 제공받을 수 있는 메커니즘을 수립시키는 새로운 캘리포니아 처방약 라벨 요건이 발효되었습니다.

이 법률은 캘리포니아 약사위원회의 후원을 받았으며 국회의원 팅에 의해 AB 1073 법안으로 발의되었습니다.

이 법률은 이미 많은 제약 공급자들이 처방약 용기에 번역을 제공하고 있다는 점을 인지하고 법률을 제정함으로써 이러한 관행을 유지해가고자 합니다. 이러한 법률은 소비자들이 번역을 제공받을 수 있는 새로운 기회를 창출합니다. 이러한 번역을 제공받고 싶으신 소비자는 해당 약국에 이러한 서비스를 요청하셔야 합니다.

어떤 경우 약국에서 번역을 제공하는 것이 가능하지 않을 수도 있습니다. 이러한 경우, 위원회에서는 약을 안전하게 복용하는 법을 확실히 이해할 수 있도록 해당 약국에서 제공하는 무료 통역 서비스를 이용하시기를 소비자께 강력히 권고드립니다.

약사법 개정안과 더불어 이 새로운 법률에 대한 추가적인 정보를 원하시면 다음 링크를 통해서 위원회의 웹싸이트에서 찾아보실 수 있습니다- - http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

캘리포니아 약사위원회는 고품질의 약사 서비스와 교육, 커뮤니케이션, 인허가, 법률의 제정, 규제와 집행을 통한 제약의 적절한 사용을 추구함으로써 캘리포니아의 건강과 안전을 보호하고 촉진하고 있습니다.

###

Фармацевтическое управление
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АГЕНТСТВО ПО ВЕДЕНИЮ БИЗНЕСА, ОБСЛУЖИВАНИЮ ПОТРЕБИТЕЛЕЙ И НЕДВИЖИМОСТИ
УПРАВЛЕНИЕ ПО ДЕЛАМ ПОТРЕБИТЕЛЕЙ
УПРАВЛЯЮЩИЙ ЭДМУНД Г. БРАУН МЛ.

ПРЕСС-РЕЛИЗ
от 10 февраля 2016 года

КОНТАКТНОЕ ЛИЦО: Дебби Дамос
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Перевод инструкций по применению лекарственных препаратов, отпускаемых по рецепту
Теперь пациенты могут запросить перевод инструкций по применению определенных лекарственных средств рецептурного отпуска

Умение правильно прочесть инструкцию к лекарственному препарату – это залог верного понимания способа его применения.

В январе 2016 года вступили в силу новые требования штата Калифорния в отношении инструкций к лекарственным препаратам рецептурного отпуска. Согласно указанным требованиям, пациенты, не владеющие английским языком, могут получить перевод инструкции к лекарственному средству прямо на его упаковке или в качестве приложения к нему.

Автором Закона под номером AB 1073 стал Член Ассамблеи Фил Тинг при поддержке Фармацевтического управления штата Калифорния.

Закон признает тот факт, что многие фармацевты уже предлагают своим клиентам оригинальные упаковки с переводом инструкций, а веденный в действие Закон позволяет и в дальнейшем поддерживать эту практику. Этот Закон дает потребителю еще одну возможность получить перевод. Он может попросить перевод лекарственного средства в своей аптеке.

В некоторых случаях аптека не может предоставить клиенту готовый перевод. В данной ситуации Управление настоятельно рекомендует воспользоваться бесплатными услугами перевода, предоставляемыми аптекой, для правильного и безопасного приема лекарственного препарата.

Более подробно о новом Законе, а также законодательных изменениях в фармацевтической области, можно прочитать на сайте Управления по адресу:
http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

Фармацевтическое управление штата Калифорния обеспечивает здоровье и безопасность жителей Калифорнии благодаря использованию высоких стандартов качества в фармацевтической области. Для осведомленности населения о надлежащем использовании лекарственных препаратов используются образовательные программы, информационные материалы, лицензии, законодательная база, различные методы регулирования и контроля соблюдения.

###

Department of Consumer Affairs Search Results

About 397 results (0.28 seconds)

Patient-Centered Labels Information, Translations, and Sample Labels
Patient-Centered **Labels** Information, **Translations**, and Sample **Labels** ... the new **labels** on **prescription medication** containers you received from pharmacies?
www.pharmacy.ca.gov/publications/**labels**_info.shtml

Patients Can Now Request Translations on the Directions for Use on ...
Feb 10, 2016 **...** The press release was **translated** into Chinese, Korean, Russian, Spanish and Vietnamese. Copies ... **Translations** on **Prescription** Drug **Labels**
www.pharmacy.ca.gov/publications/**label**_press_release.shtml

Translations of Pill Directions
Translations of Pill Directions. Press Release Announcing the New 2016 Requirement for **Prescription Labels**. Disclaimer. The California Endowment, in an ...
www.pharmacy.ca.gov/publications/**translations**.shtml

Meeting Materials
File Format: PDF/Adobe Acrobat
Jan 13, 2015 **...** Translation of Labels and the Use of Translated Directions Available ... proposal to require on a **prescription label translated** "directions for use".
www.pharmacy.ca.gov/meetings/agendas/.../15_jan_pub_mat.pdf

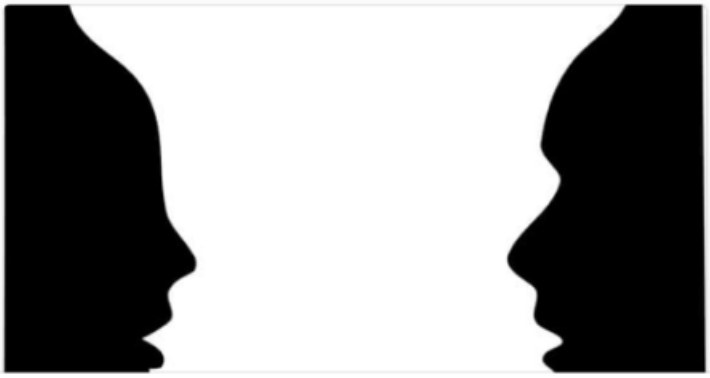
AT&T LTE 7:34 PM 46%

California Depart...

California Department of Consumer Affairs

February 11 ·

Patients can now request translations in five languages on the directions for use on certain prescription labels. The request can be made for Spanish, Russian, Chinese, Korean and Vietnamese. Check out the Board of Pharmacy's latest news releases here:



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Patients can now request translations in five languages on the directions for use on certain prescription labels.
pharmacy.ca.gov/publications/l…

RETWEETS
2

3:20 PM - 11 Feb 2016

Translation on Prescription Drug Labels

AB 1073 (Ting), Chapter 784, Statutes of 2015

Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was authored by Assembly Member Ting as AB 1073, and amends Business and Professions Code sections 4076 and 4199, and creates new section 4076.6. The text of the new requirements can be viewed from this link: *http://www.pharmacy.ca.gov/publications/labels_info.shtml*

The law recognizes that many dispensers already provide translations on prescription containers. The enacted legislation allows this practice to continue.

The requirements of the new law implement the following key components:

1. A pharmacist must use professional judgment when selecting the wording of directions that appear on a prescription container label in any language.

   The specific requirement is:
   4076(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions. (Business and Professions Code section 4076(e))

2. A dispenser must provide translated directions for use on a prescription container when requested by the patient or a patient's representative, provided:

   a) The dispenser believes that a standardized direction for use (as listed in the board's patient-centered regulation) is appropriate for the patient's prescribed medication (this list also appears on page 5 of this newsletter). If so the board has translated the 15 standardized directions for use into five languages -- Spanish, Vietnamese, Korean, Russian and Chinese. These translation are available from: *http://www.pharmacy.ca.gov/publications/translations.shtml*

      Translations into additional languages or translations of additional directions are not required.

   b) The dispenser may provide his/her/its own translations in place of the translations available from the board,

      And

   c) The dispenser is responsible for the accuracy of the **English** directions provided to the patient.

3. The translated direction should, whenever possible, appear in the patient-centered area of the prescription container or label. When this occurs the English version should appear, whenever possible, on the prescription container or label in or outside the patient-centered area. When the English translation cannot be printed on the prescription container or label, the English translation may be provided on a supplemental sheet.

   A translated direction may be provided on a supplemental sheet when it cannot be added to the prescription container or label. In this case, the label shall contain the English version of the direction. (Per existing law, such direction should be in the patient centered portion of the container or label.)

*See **Translation on Rx Label** Page 5*

Translation on Rx Label

Continued from Page 4

Where can I find the translated directions for use?

Pharmacies may use translated directions for use that are available on the board's website when appropriate. The translations of certain standardized directions for use are found in Board regulation 1707.5(a)(1) and are available in multiple languages on the Board's website at *http://www.pharmacy.ca.gov/publications/translations.shtml*. The English version of the standardized directions are:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and I [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

Attachment 3

Proposed Draft Regulation Language for Consideration

Proposed Draft Regulations for Consideration - 16 CCR § 1707.6

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost. <u>Ask about what translations for prescription labels may be available.</u>

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

Attachment 4

Sample Naloxone Labels

Sample Naloxone Labels

http://www.pharmacy.ca.gov/licensing/naloxone_labels.shtml

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Provider: Roger Brown RPH
Single Dose Vial
Quantity: 2 Vials

JOHNSON, JUDITH
Naloxone, Injection 0.4mg/1mL,
Single Dose Vial
Manufacturer: Hospira
Call 911. Inject 1mL into upper arm or thigh muscle for opioid overdose. May repeat after 3 minutes if patient not breathing.

Expires: 04/01/2016

Rx# 06197 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Judith Johnson
5873 EVERGREEN AVE
DAVIS, CA 95615
(555) 555-7889

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Provider: Roger Brown RPH
Syringe
Quantity: 2 Syringes

JOHNSON, JUDITH
3mL syringe with 25G x 1" needle
Manufacturer: BD
Call 911. Use to withdraw naloxone from vial and inject 1mL into upper arm or thigh muscle for opioid overdose. Use a new syringe for each dose.

Expires: 04/01/2016

Rx# 06198 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Judith Johnson
5873 EVERGREEN AVE
DAVIS, CA 95615
(555) 555-7889

SMITH, ADAM
Naloxone, Intranasal 1mg/1mL,
2mL Needleless Syringe
Manufacturer: Amphastar
Call 911. Attach white cone. Spray ½ of syringe (1mL) into each nostril for opioid overdose. May repeat in 3 minutes if patient not breathing.

Provider: Roger Brown RPH Quantity: 2 Syringes
Prefilled Needleless Syringe
Expires: 04/01/2016

Rx# 06197 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Adam Smith
73 Main St.
Sacramento, CA 95835
(555) 555-6789

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

SMITH, ADAM
Mucosal Atomization Device (MAD)
Manufacturer: LMA
Call 911. Screw onto naloxone needleless syringe to administer drug into nose. Then insert white cone into nostril. Spray ½ of syringe (1mL) into each nostril.

Provider: Roger Brown RPH Quantity: 2 MAD
Mucosal Atomization Device
Expires: 04/01/2016

Rx# 06198 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Adam Smith
73 Main St.
Sacramento, CA 95835
(555) 555-6789

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Rx# 06197 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

SAMANATHA GONZALEZ
4200 ELM STREET
ELK GROVE, CA 95758
(555) 555-1234

GONZALEZ, SAMANTHA
Evzio 0.4mg/0.4mL, 2 auto-injectors
Manufacturer: Kaleo
Call 911. For opioid overdose, remove cover and red cap. Press black end firmly against outer thigh to inject. May repeat in 3 minutes if patient is not breathing.

Provider: Roger Brown RPH Quantity: 2 auto-injectors
Auto-Injector
Expires: 04/01/2016

CAMP, DENNIS
Narcan Nasal Spray
4mg/ 0.1ml sprayer
Manufacturer: Adapt Pharma
Call 911. Administer a single spray intranasally into one nostril for opiod overdose. May repeat in 3 minutes if patient is not breathing.

Provider: Roger Brown RPH Quantity: 2 Nasal Sprays
Prefilled Nasal Spray
Expires: 04/01/2016

Rx# 06198 1234567
DATE FILLED: 04/01/2015
ORIG RX DATE: 04/01/2015
RPH: RB
Store DEA# BT5555555

Dennis Camp
73 Main St.
Sacramento, CA 95835
(555) 555-6789

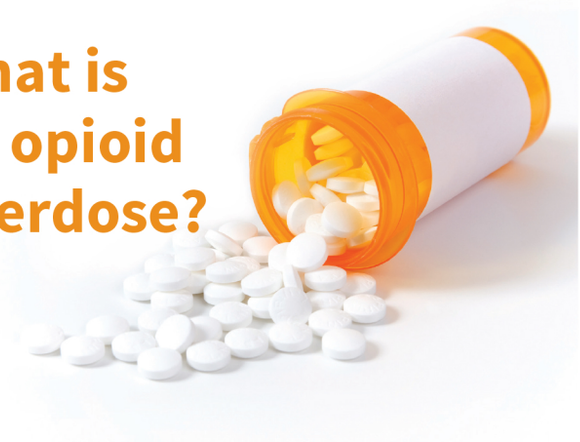
Victor's Pharmacy
1625 N. Market Blvd.
Sacramento, CA 95834
(555) 555-9810

Naloxone

Fact Sheet

for Patients

What is an opioid overdose?



Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone...

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit **www.prescribetoprevent.org**

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH
CALIFORNIA STATE BOARD OF PHARMACY

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

DEVELOPED BY
SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

How to identify an opioid overdose:

Look for these common signs:

- The person won't wake up even if you shake them or say their name
- Breathing slows or even stops
- Lips and fingernails turn blue or gray
- Skin gets pale, clammy

In case of overdose:

1 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

2 Do rescue breathing or chest compressions

Follow 911 dispatcher instructions

3 After naloxone

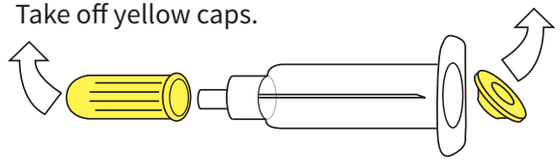
Stay with person for at least 3 hours or until help arrives

How to give naloxone:

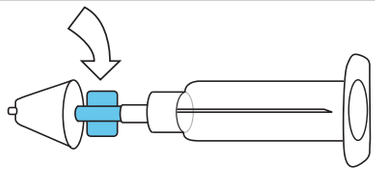
There are 3 ways to give naloxone. Follow the instructions for the type you have.

Nasal spray naloxone

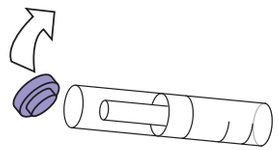
1 Take off yellow caps.

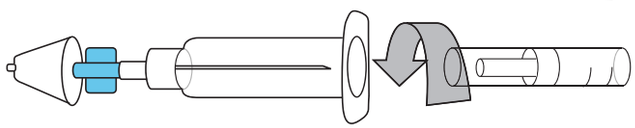


2 Screw on white cone.

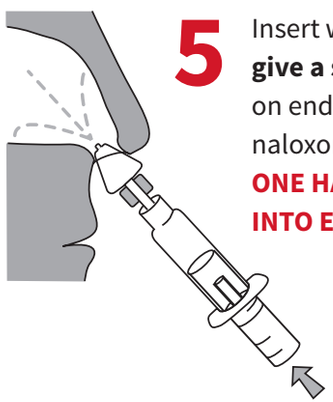


3 Take purple cap off capsule of naloxone.





4 Gently screw capsule of naloxone into barrel of syringe.



5 Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**

Push to spray.

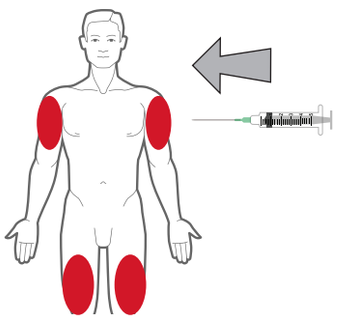
6 If no reaction in 3 minutes, give second dose.

Injectable naloxone

1 Remove cap from naloxone vial and uncover the needle.

2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.

3 Inject 1 ml of naloxone into an upper arm or thigh muscle.



4 If no reaction in 3 minutes, give second dose.

Auto-injector

The naloxone auto-injector is FDA approved for use by anyone in the community. It contains a speaker that provides instructions to inject naloxone into the outer thigh, through clothing if needed.

Attachment 5

Immunization Protocol

BOARD OF PHARMACY

Order of Adoption

Add and Adopt §1746.4, which is new regulation text as follows:

§1746.4 Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:
(1) Completion of an approved immunization training program, and
(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a

vaccine administration record, which fully documents the vaccines administered by the pharmacist. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

Sample Administration Records for Immunizations

Sample California Immunization Record

VACCINE		DATE GIVEN	DOCTOR OFFICE OR CLINIC	DATE NEXT DOSE DUE
PNEUMOCOCCAL (Conjugate=PCV) (Polysaccharide=PPV23)	1		☐ Conj ☐ Poly	
	2		☐ Conj ☐ Poly	
	3		☐ Conj ☐ Poly	
	4		☐ Conj ☐ Poly	

TB SKIN TESTS* *Pruebas de la Tuberculosis*	Type**	Date given	Given by	Date read	Read by	mm indur	Interpretation
	☐ PPD-Mantoux ☐ Other____	/ /		/ /			☐ Pos ☐ Neg
	☐ PPD-Mantoux ☐ Other____	/ /		/ /			☐ Pos ☐ Neg
	☐ PPD-Mantoux ☐ Other____	/ /		/ /			☐ Pos ☐ Neg

* A chest x-ray may be indicated if skin test is positive.
** If required for school entry, must be Mantoux unless exception granted by local health department.

CHEST X-RAY *[Radiografía]* (Necessary if skin test positive.)
Film date: ____/____/____ Interpretation: ☐ normal ☐ abnormal
Person is free of communicable tuberculosis: ☐ yes ☐ no
Signature/Agency: _____

Parents: Your child must meet California's immunization requirements to be enrolled in school and child care. Keep this Record as proof of immunization.
Padres: Su niño debe cumplir con los requisitos de vacunas para asistir a la escuela y a la guardería. Mantenga este Comprobante: lo necesitará.

IMMUNIZATION RECORD

Comprobante de Inmunización

Name
nombre

Birthdate
fecha de nacimiento

Allergies
alergias

Vaccine Reactions
reacciones a cualquier vacuna

RETAIN THIS DOCUMENT — *CONSERVE ESTE DOCUMENTO*

Name Sex Birthdate

PROVIDERS: If using combination vaccines, remember to record dose in all appropriate spaces.

VACCINE *vacuna*		DATE GIVEN *fecha de vacunación*	DOCTOR OFFICE OR CLINIC *médico o clínica*		DATE NEXT DOSE DUE *próxima vacuna*
POLIO	1		☐ IPV ☐ OPV		
	2		☐ IPV ☐ OPV		
	3		☐ IPV ☐ OPV		
	4		☐ IPV ☐ OPV		
DTaP DTP Td DT	1		☐ DTaP/DTP ☐ DT/Td		
	2		☐ DTaP/DTP ☐ DT/Td		
	3		☐ DTaP/DTP ☐ DT/Td		
	4		☐ DTaP/DTP ☐ DT/Td		
	5		☐ DTaP/DTP ☐ DT/Td		
			☐ Td		
HIB	1				
	2				
	3				
	4				
MMR	1				
	2				
HEPATITIS B	1				
	2				
	3				
VARICELLA (chickenpox) ☐ Had disease					
HEPATITIS A	1				
	2				

DT = diphtheria, tetanus *[difteria, tétano]*
DTaP = diphtheria, tetanus, pertussis (whooping cough) *[difteria, tétano y tos ferina]*
FLU = influenza
Hep A = Hepatitis A, **Hep B** = Hepatitis B
HIB = Hib meningitis (Haemophilus influenzae type B) *[meningitis Hib]*
IPV = inactivated polio *[poliomielitis inactivado]*, **OPV** = oral polio *[vacuna oral contra la polio]*
MMR = measles, mumps, rubella *[sarampión, paperas y rubéola (sarampión alemán)]*
PCV = pneumococcal conjugate vaccine *[neumocócica conjugada]*
PPV = pneumococcal polysaccharide vaccine *[vacuna polisacárida contra el neumococo]*
Td = tetanus, diphtheria *[tétano, difteria]*
VAR = varicella (chickenpox) *[varicela]*

PM 298 (8/02) WM-75

Note: Not shown at actual size. The California Immunization Record (yellow card) can be folded to fit into the plastic holder.

CALIFORNIA SCHOOL IMMUNIZATION RECORD

This record is part of the student's permanent record (cumulative folder) as defined in Section 49068 of the Education Code and shall transfer with that record. Local health departments shall have access to this record in schools, child care facilities, and family day care homes.

This record must be completed by school and child care personnel from an immunization record provided by parent or guardian. See reverse side for instructions.

dent Name _____ Sex: M ☐ F ☐ Birthdate _____ Place of Birth _____

me of Parent or Guardian _____ Race/Ethnicity: ☐ White, not Hispanic ☐ Hispanic ☐ Black ☐ Other: _____ Address _____

ephone _____ Daytime _____ Nighttime City _____ ZIP _____

VACCINE	DATE EACH DOSE WAS GIVEN					
	1st	2nd	3rd	4th	5th	Booster
POLIO (OPV or IPV)						
DTP/DTaP/DT/Td (Diphtheria, tetanus and [acellular] pertussis OR tetanus and diphtheria only)						
MMR (Measles, mumps, and rubella)						
HIB (Required only for child care and preschool)						
HEPATITIS B						
VARICELLA (Chickenpox)						
HEPATITIS A (Not required)						

TB SKIN TESTS	Type*	Date given	Date read	mm indur	Impression
	☐ PPD-Mantoux ☐ Other				☐ Pos ☐ Neg
	☐ PPD-Mantoux ☐ Other				☐ Pos ☐ Neg

*If required for school entry, must be Mantoux unless exception granted by local health department.

CHEST X-RAY (Necessary if skin test positive)

Film date: _____ Impression: ☐ normal ☐ abnormal

Person is free of communicable tuberculosis: ☐ yes ☐ no

I. DOCUMENTATION

I certify that I reviewed a record of this child's immunizations and transcribed it accurately:

Date _____

Staff Signature _____

Record Presented was:

☐ Yellow California Immunization Record
☐ Out-of-state school record
☐ Other immunization record
Specify: _____

II. STATUS OF REQUIREMENTS

☐ A. All Requirements are met.
Date _____

☐ B. Currently up-to-date, but more doses are due later. Needs follow-up.

Exemption was granted for:

☐ C. Medical Reasons—Permanent
☐ D. Medical Reasons—Temporary
☐ E. Personal Beliefs

III. 7th GRADE ENTRY

☐ A. All Requirements are met.
Name _____ Date _____

☐ B. Currently up-to-date, but more doses are due later. Needs follow-up.
Name _____ Date _____

nmunizations and Developmental Milestones or Your Child from Birth Through 6 Years Old

Child's Name _____ Birth Date _____

		Birth	1 MONTH	2 MONTHS	4 MONTHS	6 MONTHS
Recommended Immunizations	Hepatitis B	○ **HepB**	○ **HepB**[1]			○ **HepB**
	Rotavirus			○ **RV**	○ **RV**	○ **RV**
	Diphtheria, Tetanus, Pertussis			○ **DTaP**	○ **DTaP**	○ **DTaP**
	Haemophilus influenzae type b			○ **Hib**	○ **Hib**	○ **Hib**
	Pneumococcal			○ **PCV**	○ **PCV**	○ **PCV**
	Inactivated Poliovirus			○ **IPV**	○ **IPV**	○ **IPV**
	Influenza (Flu)					○ **Influenza**, first dose[2] ○ second dose
Milestones*	Milestones should be achieved by the age indicated. Talk to your child's doctor about age-appropriate milestones if your child was born prematurely.	○ Recognizes caregiver's voice ○ Turns head toward breast or bottle ○ Communicates through body language, fussing or crying	○ Starts to smile ○ Raises head when on tummy ○ Calms down when rocked, cradled or sung to	○ Begins to smile at people ○ Coos, makes gurgling sounds ○ Begins to follow things with eyes ○ Can hold head up	○ Babbles with expression ○ Likes to play with people ○ Reaches for toy with one hand ○ Brings hands to mouth	○ Knows familiar faces ○ Responds to own name ○ Brings things to mouth ○ Rolls over in both directions
Growth	At each well child visit, enter date, length, weight, and percentile information to keep track of your child's progress.	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE
	Shaded boxes indicate the vaccine can be given during shown age range.	VISIT DATE	VISIT DATE	VISIT DATE	VISIT DATE	VISIT DATE

continues on back page

[1] The second dose of HepB may be given either at the 1 month or 2 month visit.

[2] Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time and for some other children in this age group.

* Milestones adapted from Caring for your baby and young child: Birth to age 5, Fifth Edition, edited by Steven Shelov and Tanya Remer Altmann © 1991, 1993, 1998, 2004, 2009 by the American Academy of Pediatrics and Bright Futures: Guidelines for health supervision of infants, children, and adolescents, Third Edition, edited by Joseph Hagan, Jr., Judith S. Shaw, and Paula M. Duncan, 2008, Elk Grove Village, IL: American Academy of Pediatrics.

If your child has any medical conditions that put him at risk for infections or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html (Immunization) or http://www.cdc.gov/ncbddd/actearly/milestones/index.html (Milestones)

Last updated on January 2016 • CS261834-C

mmunizations and Developmental Milestones or Your Child from Birth Through 6 Years Old

Child's Name _____ Birth Date _____

		12 MONTHS	15 MONTHS	18 MONTHS	19–23 MONTHS	2–3 YEARS	4–6 YEARS
Recommended Immunizations	Hepatitis B	○ **HepB** (Final dose administered between 6 and 18 months)					
	Diphtheria, Tetanus, Pertussis		○ **DTaP**				○ **DTaP**
	Haemophilus influenzae type b	○ **Hib**					
	Pneumococcal	○ **PCV**					
	Inactivated Poliovirus	○ **IPV**					○ **IPV**
	Influenza (Flu)	○ **Influenza,** first dose[2] ○ second dose (if needed)				Age 2 Age 3 ○○ **Influenza**, first dose[2] ○○ second dose (if needed)	Age 4 Age 5 Age 6 ○○○ **Influenza**, first dose[2] ○○○ second dose (if needed)
	Measles, Mumps, Rubella	○ **MMR**					○ **MMR**
	Varicella	○ **Varicella**					○ **Varicella**
	Hepatitis A	○○ **Hep A**[3]					
Milestones*	Milestones should be achieved by the age indicated. Talk to your child's doctor about age-appropriate milestones if your child was born prematurely.	○ Cries when mom or dad leaves ○ Says "mama" and "dada" ○ Copies gestures (for example, waves "bye bye") ○ May stand alone	○ Imitates what you are doing ○ Drinks from a cup ○ Scribbles on his own ○ Walks well	○ Points to show others something interesting ○ Says several single words ○ Points to one body part ○ May walk up steps and run	○ Plays mainly beside other children ○ Follows two-step commands ○ Plays simple make-believe games ○ Throws ball overhand	○ Can name most familiar things ○ Shows affection for friends without prompting ○ Turns book pages one at a time ○ Kicks a ball	○ Speaks very clearly ○ Tells stories ○ Can print some letters or numbers ○ Hops; may be able to skip
Growth	At each well child visit, enter date, length, weight, and percentile information to keep track of your child's progress.	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT / PERCENTILE LENGTH / PERCENTILE HEAD CIRCUMFERENCE	WEIGHT HEIGHT BMI	WEIGHT HEIGHT BMI
		VISIT DATE	VISIT DATE	VISIT DATE	VISIT DATE	VISIT DATE	VISIT DATE

☐ Shaded boxes indicate the vaccine can be given during shown age range.

[2] Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time and for some other children in this age group.

[3] Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 to 18 months later. HepA vaccination may be given to any child 12 months and older to protect against HepA. Children and adolescents who did not receive the HepA vaccine and are at high-risk, should be vaccinated against HepA.

* Milestones adapted from *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents* Third Edition, edited by Joseph Hagan, Jr., Judith S. Shaw, and Paula M. Duncan, 2008, Elk Grove Village, IL: *American Academy of Pediatrics*.

If your child has any medical conditions that put him at risk for infections or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

For more information, call toll free **1-800-CDC-INFO** (**1-800-232-4636**) or visit **http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html** (Immunization) or **http://www.cdc.gov/ncbddd/actearly/milestones/index.html** (Milestones)

Self-Administered Hormonal Contraception

Documents Available to Memorialize Prescriptions Furnished by a Pharmacist as a Drug Order

Hormonal Contraceptive Self-Screening Questionnaire

Name: _____ Date of Birth_____

Address: _____ Phone: _____

Allergies to Medications? □ Yes □ No If yes, list them here: _____

Are you interested in a starting/changing to a new contraceptive □ Yes □ No □ Maybe

Do you have a preferred method of birth control that you would like to use? □ Continue my current method

□ A pill taken daily □ A patch changed weekly □ A vaginal ring changed monthly □ A shot every 3 months

□ Other Long term method like an IUD or implant □ Not sure

Do you want your health care provider to receive a notice regarding this visit? □ Yes □ No If yes who:_____

1	Do you think you might be pregnant now?	Yes □ No□
2	What was the first day of your last menstrual period?	___/ _/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?	Yes □ No□
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No□
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No□
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No□
5	Do you smoke cigarettes?	Yes □ No□

Medical History:

6	Have you given birth within the past 6 weeks?	Yes □ No□
7	Are you currently breastfeeding an infant less than 1 month of age?	Yes □ No□
8	Do you have diabetes?	Yes □ No□
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes □ No□
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes □ No□
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No□
12	Have you ever had a blood clot in your leg or lung?	Yes □ No□
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes □ No□
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No□
15	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No□
16	Do you have or have you ever had breast cancer?	Yes □ No□
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes □ No□
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No□
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No□
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No□
	- If yes, list them here:	

Signature: _____ Date: _____

Pharmacy use only

☐ Eligible for pharmacist services ☐ BP Reading_____/_____

☐ Refer Patient to:

Pharmacist Name_____Pharmacist Signature _____

Notes:

Pharmacy 123
456 Main Street
My Town, California
(XXX) 333-4444

Name: _____ Date:_____

ADDRESS: _____

Contraceptive selected: _____

Sig:

Refills:

_____ _____

Furnishing pharmacist printed name Signature of furnishing pharmacist

NPI number: _____:

The DCA Page: News from the Department of Consumer Affairs Blog Article

Pharmacists Can Help You Quit Smoking

Pharmacists Can Help You Quit Smoking

Posted on **March 29, 2016** by **DCAStaffWriter**

It just got a lot easier to kick the nicotine habit now that products to help you quit smoking are available from your local pharmacy without a prescription.

“Quitting smoking is difficult to do, but important to patient health. Pharmacists can now offer greater assistance to individuals who have decided to quit smoking,” said Virginia Herold, California State Board of Pharmacy executive officer.

Board of Pharmacy regulations went into effect in late January that allow pharmacists to furnish smoking cessation products without a prescription. Before they can provide the products, pharmacists are required to complete two hours of approved continuing education on nicotine replacement therapy and must then receive ongoing training.

Before dispensing, your pharmacist must ask questions to determine if nicotine replacement products are safe for you. Your pharmacist will ask about your current tobacco use and attempts to quit; if you’ve suffered a recent heart attack; if you have a history of heart problems; if you have frequent chest pain or unstable angina; or if you have nasal allergies or have been diagnosed with temporal mandibular joint (TMJ). Women will be asked if they are pregnant or plan to become pregnant.

Follow

A pharmacist will use his or her professional judgment and the responses to your questions to determine whether to furnish the products or refer you to a health care professional.

According to the Centers for Disease Control (CDC), in 2014 nearly 17 out of every 100 Americans – or 40 million people – smoked cigarettes. The CDC says cigarette smoking kills 480,000 in the U.S. every year and is the leading cause of preventable disease and death. Along with those deaths, more than 16 million Americans live with smoking-related diseases. Quitting smoking is an important step to improving your health and life expectancy.

Pharmacists received authority to provide nicotine replacement products with the passage of SB 493 (Hernandez). The Board of Pharmacy and Medical Board of California then developed protocols for pharmacists to follow. Ask your pharmacist if he or she can work with you to help you kick the smoking habit and start on a path to better health.

Click here to view the regulation:
http://www.pharmacy.ca.gov/laws_regs/1746_2_ooa.pdf.

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Follow

Attachment 6

California State Board of Pharmacy Subscriber Alert - Message (HTML)

You forwarded this message on 4/11/2016 11:18 AM.

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV> Sent: Wed 4/6/2016 10:51 AM

To: PHARM-GENERAL@DCALISTS.CA.GOV

Cc:

Subject: California State Board of Pharmacy Subscriber Alert

The Department of Justice recently released a CURES 2.0 registration tip sheet to help individuals register or access the system. Pharmacists would be included under "All Applicants" on page 2.

As a reminder, all pharmacists with active California licenses need to be registered to access CURES by July 1, 2016.

The tip sheet can be accessed at: http://www.pharmacy.ca.gov/licensing/cures_tips.pdf

Information about CURES registration can also be obtained from: http://www.pharmacy.ca.gov/licensing/cures.shtml

---------- To unsubscribe from this email list please click on the link below and follow the instructions on the web page.

https://www.dca.ca.gov/webapps/pharmacy/subscribe.php

CURES 2.0

Registration Tips to Successfully Register

Medical Doctors

License Type

Your license type is the letter in front of your license number on your license wallet card.

For example, if your wallet card reads G12345,
select "Medical Doctor (MD) - Type G" as your license type.

Osteopathic Doctors

License Type

Your license type is "Osteopathic Doctor (DO) – Type A."

License Number

The prefix "20A" reflects your license type. It is not part of your license number and should not be included in the license number field.

For example, if your wallet card reads 20A1234,
enter "1234" as your license number.

Podiatric Doctors

License Board

Select the "Board of Podiatric Medicine" as your licensing board, NOT "Medical Board of California."

Nurse Midwives / Nurse Practitioners

License Number

Make sure to register using your Nurse Midwife Furnishing license number or your Nurse Practitioner Furnishing license number and NOT your Registered Nurse license number.

The Nurse Midwife Furnishing license or Nurse Practitioner Furnishing license is your qualifying license for access to the CURES database.

Physician Assistants

License Board

Select the "Physician Assistant Committee" as your licensing board, NOT "Medical Board of California."

All Applicants

Social Security Number (SSN) and Individual Tax Identification Number (ITIN)

Choose between these options based upon **what is on file with your licensing board**.

To be approved, the information you enter into the CURES online registration form must **EXACTLY** match records on file with your licensing board.

A business ITIN number should never be used, because it will not match records on file for you.

Prescriber Name Validation

For prescribers to be approved, their last name, as entered into the CURES online registration form, must match their name on file with the Drug Enforcement Agency.

Security Questions and Answers

Please make a note of your security question answers for later retrieval.

The answer CANNOT be part of the question (a word, part of a word, or a single letter.)

For example, if the security question contains the word **PET**, an answer of **PET** will not be accepted.
If the security question contains the word **WHERE**, an answer of **ER** will not be accepted.
Do not use abbreviations or single letter answers.

Reapplying after Denial

Once denied, applicants must reapply.

The CURES program cannot edit information submitted by applicants.

Upon receipt of a denial, review your User Registration Confirmation page printout for accuracy and compliance with these tips before reapplying.

If the information you entered is correct, contact your licensing board to verify that the date of birth and SSN or ITIN it has on file for you is accurate.

Approval/Denial Timeframe

Applicants should receive an approval or denial within 48 hours.

If you have not received an email by then, check your spam/junk email folder before contacting the CURES program.

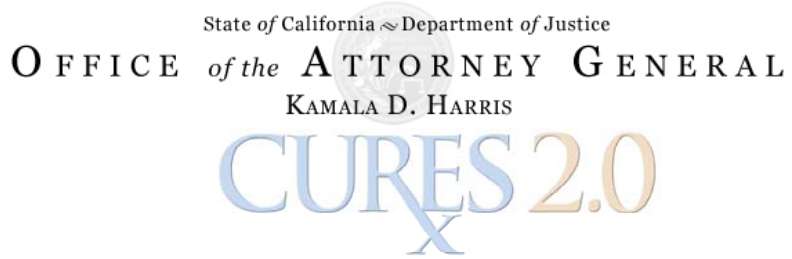
First-Time Login Tips

Entering Primary Address

To enter the address, **CLICK THE PENCIL ICON**.
After inserting address, **CLICK THE CHECKMARK** to confirm address entry.

Entering Phone Type – (Required Field)

Make sure to select phone type (home, office, or cell.)



PUBLICATIONS AND TRAINING VIDEOS

CURES 2.0 (Controlled Substance Utilization Review and Evaluation System) is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. CURES 2.0 is committed to the reduction of prescription drug abuse and diversion without affecting legitimate medical practice or patient care.

Publications

Annual Report to the California Legislature

- CURES 2.0 Annual Grant Report for 2015, pdf
- CURES 2.0 Annual Private Donations Report for 2015, pdf

CURES 2.0 User Training Documents

- CURES 2.0 Prescriber and Dispenser User Guide, pdf
- CURES Registration Instructions for Prescribers and Dispensers, pdf
- CURES 2.0 Registration Tips and Tricks, pdf

CURES 2.0 Training Videos

Prescriber and Dispenser Users:

- Registration Part 1
- Registration Part 2
- Patient Activity Report (PAR) Search
- Update User Profile
- Manage Delegates
- Patient Treatment Exclusivity Compact
- Peer-to-Peer Communication

All Users:

- Log-In and Navigation
- Change Password
- Forgot Password
- Forgot User ID

Attachment 7

Drug Diversion Toolkit

Patient Counseling—A Pharmacist's Responsibility to Ensure Compliance

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Content Summary

This booklet educates pharmacy personnel about the requirements surrounding patient counseling standards. Pharmacists will understand the Federal requirement under the Omnibus Budget Reconciliation Act of 1990 to offer patient counseling to Medicaid patients. Pharmacists will understand that laws established by each State may differ and will recognize the importance of complying with State regulations. This booklet provides guidance on when counseling may not be required as well as alternative methods to offer counseling when a patient is not present in the pharmacy or when language barriers exist. Finally, this booklet discusses the provision of written materials to supplement patient counseling and the importance of documentation to demonstrate compliance with the requirement.

A patient's complete understanding of how to use a prescription medication is critical to following medication therapy. An effective counseling session between patient and pharmacist ensures that the patient receives essential educational information related to the medication and provides an opportunity for the patient to ask questions. Not only is patient counseling the right thing to do, it is mandated by law in most States. It is vital to document this care provision to validate compliance.

The Omnibus Budget Reconciliation Act

Federal lawmakers enacted Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to ensure fiscally responsible spending of Federal funding while ensuring safe and effective therapeutic outcomes for Medicaid patients. OBRA '90 includes three key drug utilization review components that affect pharmacy practice: prospective drug utilization review, record-keeping requirements, and a requirement to offer counsel.[1] OBRA '90 further outlines specific information that the pharmacist, while exercising professional judgment, should discuss with the patient when he or she accepts the offer to counsel, such as:

- Name of the drug (brand name, generic, or other descriptive information);
- Intended use and expected action;
- Route, dosage form, dosage, and administration schedule;
- Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them and the action required if they occur;
- Techniques for self-monitoring of drug therapy;
- Proper storage;
- Potential drug-drug interactions or drug-disease contraindications;
- Prescription refill information; and
- Action to take in the event of a missed dose.[2]

OBRA '90 and regulations adopted by Centers for Medicare & Medicaid Services (CMS)[3] require States to establish standards regarding implementation of patient counseling requirements to participate in and to receive continued Federal funding for State Medicaid programs. Although the original Federal requirements of OBRA '90 were intended to apply only to Medicaid beneficiaries, States established unique patient counseling regulations for both Medicaid and non-Medicaid beneficiaries. As a result, all patients are entitled to the benefits associated with patient counseling standards of care. For links to State Boards of Pharmacy and their rules and regulations regarding patient counseling, refer to http://www.nabp.net/boards-of-pharmacy on the National Association of Boards of Pharmacy website.

Counseling When the Patient Is Not Present

When pharmacies deliver or mail prescriptions to patients, they are not exempt from the patient counseling provision of care. Pharmacies should establish a process to offer patient counseling services when a patient is not present. One method to ensure compliance is to provide printed drug information that includes pharmacy business hours as well as a toll-free telephone number for patients to speak with a pharmacist. Mail order pharmacies commonly use this method. It is common to require the pharmacy to provide information that includes a toll-free phone number on the prescription bottle or label as well as the pharmacy's business hours. In addition, States may

have specific regulations that require a mail order pharmacy to be open a certain number of hours (and sometimes a certain number of days) per week to be compliant.

Limited English Proficient Patient

Depending on local and regional demographics, pharmacies may interact with different degrees of non-English speaking patients. The largest numbers of limited English proficient (LEP) patients speaking Spanish, Chinese, Korean, Vietnamese, or Tagalog who spoke English "less than very well" lived in the States of New York, California, Texas, and Florida, according to the 2011 language mapper from the U.S. Census Bureau.[4] New York has passed a law that requires language services to LEP patients. Any pharmacy that is part of a group of eight or more pharmacies located within New York State and owned by the same corporate entity is required to provide, at no charge, LEP individuals with oral language translation services for medication labels, associated warning labels, and other written materials.[5] It is important to become familiar with the regulations in your State and establish a means to safely provide medications and counseling to LEP patients in your pharmacy to ensure compliance.

Providing Written Information

Providing written information to a patient as a supplement to oral counseling ensures patient access to important medication information after they leave the pharmacy. States may have laws that require pharmacies to provide written information to a patient under specific circumstances. Several States have requirements or an option for providing written materials in certain circumstances. More information on the implementation of these requirements, including translation of certain materials into other languages, is summarized in a 2010 study by the National Health Law Program.[6]

California has a number of written materials regulations. One of these regulations requires provision of an emergency contraception fact sheet when dispensing emergency contraception to any patient.[7] To accommodate the large number of LEP individuals in the State, PDF versions are available to pharmacies in seven different languages through the California Board of Pharmacy website for patient distribution.[8] California also requires

the provision of culturally sensitive patient information, which is printed in certain languages, to participate in the State's HIV treatment program (Cal. Health & Safety Code Section 125092).[9]

Oral Counseling Exclusions

Circumstances may exist when a State does not require patient counseling or the patient does not desire it. States may exempt pharmacists from patient counseling requirements when drugs are dispensed to patients as part of institutional care.[10] For example, patient counseling requirements may not apply when a health care professional administers the medication to the patient during an inpatient hospital admission, in a long-term care facility, or in another institutional setting. In addition, not every patient may want counseling on his or her medication therapy. OBRA '90 mandates that pharmacists make an "offer to counsel;" however, pharmacists are not required to provide counseling to a patient (or patient's caregiver) who refuses the offer.[11] Pharmacists, pharmacy interns, and pharmacy technicians should consult their State statutes to determine when oral counseling exclusions are applicable.

Comparison of State Requirements

All States require pharmacists to counsel or at least offer to counsel Medicaid patients.[12] Other requirements for counseling compliance in each State vary widely depending on the payer; new or refill prescription; face-to-face, written, or telephonic interaction; or mail-order or in-store delivery. Rules for documenting patient counseling or refusal to accept counseling vary widely as well. Pharmacists, pharmacy interns, and pharmacy technicians should consult their State Medicaid agency and Board of Pharmacy to ensure that pharmacy personnel understand and are complying with State regulations. For a comprehensive overview and comparison of the finer points of State pharmacy law, refer to the National Association of Boards of Pharmacy's (NABP's) Survey of Pharmacy Law, updated annually and available for a fee from https://www.nabp.net/publications/survey-of-pharmacy-law/ on the Internet.

Documentation Requirements

Documenting that patient counseling was offered and indicating whether it was accepted or declined is critical to ensuring compliance with State statutes. Social Security Act Section 1927(g)(2)(A), amended by the Deficit Reduction Act of 2005, says pharmacists are not required to provide documentation of an offer to counsel or of the refusal of the patient to accept counseling, but many States require such documentation anyway.[13] The patient (or patient caregiver) may simply mark a "yes" or "no" checkbox when the prescription is picked up to satisfy the documentation requirement in most instances.

Key Points

Pharmacists, pharmacy interns, and pharmacy technicians should consider the following aspects of patient counseling to ensure compliance:

- Understand the patient counseling components of OBRA '90;
- Be familiar with State patient counseling regulations;
- Establish a process to ensure compliance when the patient is not present in the pharmacy;
- Understand when oral counseling is not required;

- Provide written materials to supplement oral counseling;
- Establish processes to accommodate LEP individuals; and
- Comply with State documentation requirements for acceptance or refusal of the counseling offer.

Resources

American Pharmacists Association. http://www.pharmacist.com

American Society of Health-System Pharmacists Guidelines on Pharmacist-Conducted Patient Education and Counseling. http://www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx

National Association of Boards of Pharmacy. http://nabp.net

Conclusion

Providing quality patient counseling requires much more than having effective communication skills. It entails understanding the patient counseling requirements as outlined in OBRA ’90 as well as complying with State-specific regulations. In addition, there needs to be processes for providing counseling when the patient is not present or when the patient is non-English speaking, as well as for the provision of written materials to supplement oral counseling. Finally, establishing a process to document the acceptance or refusal of the counseling offer is critical. If there is no documentation that patient counseling was offered, there is no proof to demonstrate compliance with documentation requirements.

To see the electronic version of this booklet and the other products included in the “Drug Diversion” Toolkit, visit the Medicaid Program Integrity Education page at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html on the CMS website.

Follow us on Twitter #MedicaidIntegrity

References

1 Omnibus Budget Reconciliation Act of 1990. Pub. L. 101-508, § 4401, 104 Stat. 143. Retrieved January 12, 2016, from https://www.ssa.gov/OP_Home/comp2/F101-508.html

2 Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(g). Retrieved January 12, 2016, from http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/pdf/USCODE-2008-title42-chap7-subchapXIX-sec1396r-8.pdf

3 Prospective Drug Review, 42 C.F.R. § 456.705. Retrieved January 12, 2016, from http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=40186ffdc8d94276897981632b944bc0&n=pt42.4.456&r=PART&ty=HTML#se42.4.456_1705

4 United States Census Bureau. U.S. Department of Commerce. 2011 Language Mapper. Retrieved January 12, 2016, from http://www.census.gov/hhes/socdemo/language/data/language_map.html

5 N.Y. Comp. Codes R. & Regs. tit. 8, § 63.11 (2014). Retrieved January 12, 2016, from https://govt.westlaw.com/nycrr/Document/Ib6ca32d5cea011e282c80000845b8d3e?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)

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9 Cal. Health & Safety Code § 125092. Retrieved January 12, 2016, from http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=125001-126000&file=125050-125119.5

10 Drug Use Review Program. 42 C.F.R. § 456.703(b), (c). Retrieved January 12, 2016, from http://www.ecfr.gov/cgi-bin/text-idx?SID=6550376a840cc4495b16f1fa802ebbac&mc=true&node=se42.4.456_1703&rgn=div8

11 Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(g). Retrieved January 12, 2016, from http://www.gpo.gov/fdsys/pkg/USCODE-2008-title42/html/USCODE-2008-title42-chap7-subchapXIX-sec1396r-8.htm

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13 Social Security Act § 1927(g)(2)(A). Retrieved January 12, 2016, from https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

Disclaimer

This booklet was current at the time it was published or uploaded onto the web. Medicaid and Medicare policies change frequently so links to the source documents have been provided within the document for your reference.

This booklet was prepared as a service to the public and is not intended to grant rights or impose obligations. This booklet may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. Use of this material is voluntary. Inclusion of a link does not constitute CMS endorsement of the material. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

February 2016

February 2016

Attachment 8

Working Group Recommendations

Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly

Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

Table of Contents

- Legislative Background
- Working Group Participant Organizations
- Why Are Best Practices Needed?
- What Is a Prescription Drug Container Label?
- Delivery Methods for Providing Accessible Prescription Drug Container Labels
- Best Practices to Use for All Formats
- Format-Specific Best Practices
- Resources

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Legislative Background:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, 126 Stat. 993). The law includes measures to promote drug safety and to improve FDA procedures for reviewing new medicines and medical devices.

A provision of the Act, **Section 904**, authorizes the Access Board to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly. (See 29 U.S.C. 792.) Under the law, representation within the working group must be divided equally between consumer and industry advocates. The Act exempts the working group from the Federal Advisory Committee Act.

The law calls for the working group to develop, no later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

According to Section 904, the best practices are not mandatory. They are not to be construed as accessibility guidelines or standards of the Access Board, nor do they confer any rights or impose any obligations on working group participants or other persons. The law makes it clear that nothing in Section 904 is to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

The law also provides that the working group may make this best practices report publicly available through the internet websites of working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities. The National Council on Disability will conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. The Government Accountability Office will undertake a review beginning 18 months after the date of this report to assess the extent to which pharmacies are following the best practices and to what extent barriers to information on prescription drug container labels remain.

Working Group Participant Organizations

In October 2012, the Access Board formed an 18-member working group with representation from national organizations advocating for individuals who are blind, visually-impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

The working group is comprised of representatives of the following organizations:

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Federation of the Blind (NFB)
- National Council on Patient Information and Education (NCPIE)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

The working group met in person in Washington, DC, on January 10 and11, 2013, and subsequently via five teleconferences. The working group explored various alternatives, including braille, large print labels, and various auditory technologies such as "talking bottles" and radio frequency identification devices. The working group also considered whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices.

Why Are Best Practices Needed?

Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.

In recent years, various organizations, including US Pharmacopeia (USP), the National Association of Boards of Pharmacy, and the National Council on Patient Information and Education, have recommended the adoption of patient-centered pharmacy practices to improve patient understanding and safe, effective use of prescription medication. Inherently inclusive, patient-centered pharmacy practices promote accessibility, while a one-size-fits-all approach typically creates barriers.

In the context of this report, the term "best practice" refers to a set of working methods that the working group believes is most effective in providing access to prescription drug container label information to customers with blindness and visual impairments, including older adults.

The goal of the best practices for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

What Is a Prescription Drug Container Label?

A prescription drug container label is a legal document that must be prepared by the pharmacist filling the prescription. The pharmacist must ensure the accuracy of the prescription drug container label, and include on the label all elements required by applicable state law.

In 2009, USP determined optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription drug container label instructions. USP created universal prescription drug container label standards for format, appearance, content, and language (see: **U.S. Pharmacopeial Convention**). The best practices in this report build upon the USP universal patient-centered prescription drug container label standards.

Delivery Methods for Providing Accessible Prescription Drug Container Labels

A variety of delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats. Delivery methods include:

- Hard copy braille and large print: A pharmacist filling prescriptions produces hard copy braille and large print labels upon request, and affixes the accessible labels to the prescription drug containers.
- Dedicated electronic equipment: Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include:
  - Digital Voice or Text-to-Speech Recorder: This is a small electronic device that a pharmacist affixes to a prescription drug container. When activated by pushing a button on the device, the patient hears the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
  - Radio Frequency Identification Device (RFID): A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that, when a container with an RFI Tag is placed over the device, audibly announces the text on the prescription drug container label. This technology may also provide prescription drug container label information in large print, and has a USB drive.
  - Smart devices and computers: Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug container a QR code, RFI tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in electronic braille, large print, or audible format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

Some electronic prescription drug container label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate prescription drug container label information into several languages.

The key to providing accessible prescription drug container labels is patient-centered communication between pharmacists and patients with blindness and visual impairment and patient representatives. Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

Best Practices to Use for All Formats

The following best practices promote access to prescription drug container label information in all formats, including audible, braille, and large print labels.

- One of the best things pharmacists can do is to encourage patients and patient representatives to communicate their needs to pharmacists:
  - Advertise a local or, when possible, a toll-free telephone number to promote communication between patients and pharmacists;
  - If pharmacy websites and applications (apps) are made available to patients, ensure website and app accessibility; and
  - When a pharmacist observes a patient or patient representative having reading difficulty, offer education and counseling in a setting that maintains patient privacy.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print formats via methods using, for example, hard copy, dedicated devices, and computers or smart devices.
- Explain to the patient the available accessible prescription drug container label format options, and provide the prescription drug container label in the format option selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription drug container label.
- Subject accessible prescription drug container labels to the same quality control processes used for print labels to ensure accuracy and patient safety.

- Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.
- In advance, make arrangements to provide accessible prescription drug container labels. For example, maintain a sufficient inventory of supplies necessary to support timely provision of prescription drug container labels in accessible label formats.
- Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments.
- Do not impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label.
- Select a container that best supports the type of accessible label provided.
- For all accessible label formats, including audible formats, ensure that all required information contained on the print prescription drug container label is provided on the accessible label in the same sequence as the print label.
- Include in accessible prescription drug container labels the information on warning labels added to the container at the pharmacist's discretion.

Format-Specific Best Practices

In addition to the best practices listed above, please note the following format-specific best practices.

Audible Prescription Drug Labels

For dedicated equipment, select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.

If using a voice recorder:

- speak in a clear voice;
- record information in a setting that minimizes background noise and maintains patient privacy.

Offer to show the patient how to operate the audible prescription drug container label.

Braille Prescription Drug Container Labels

Electronic delivery method: Acquire an electronic delivery method using RFI tags, QR codes, or other processes to provide electronic text of the prescription drug container label upon request. Consumers with electronic braille equipment may then access electronic text in braille format.

Note that, as required, the working group considered significant challenges that pharmacies may face in producing drug labels in accessible formats, such as hard copy braille. The working group recognizes that mail order and online pharmacies, because of their centralized structure, large volume, and mail delivery process, may be better equipped than local stores to provide hard copy braille prescription drug container labels. Many mail order and online pharmacies have established a unit with the necessary computer software and braille embossers to produce hard copy braille labels and a protocol to develop pharmacists' proficiency in printing accurate braille labels.

- If a local pharmacy store has a high demand for hard copy braille prescription drug container labels, acquire on-site braille embosser capacity and proficiency.
- If a local pharmacy store receives infrequent or occasional requests for hard copy braille prescription drug container labels, partner with a pharmacy that has braille prescription drug container labeling capacity to provide a hard copy braille prescription drug container label.

When embossing hard copy braille prescription drug container labels:

- Use contracted (Grade 2) braille.
- Emboss braille labels on transparent material in order to preserve the legibility of print container labels. Affix braille label to the prescription drug container with strong adhesive.
- Do not fold braille labels.

Printing Large Print Labels (hard copy):

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, san-serif font, such as Arial.
- Provide 1.5 line spacing.
- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.

- When covering a large print label with protective tape, use non-glossy, transparent tape.

Resources

USP Patient-Centered Prescription Label Standards

UMS White Paper, The National Council for Prescription Drug Programs Work Group (WG), 2013

Working Group Participant Organizations

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Council on Patient Information and Education (NCPIE)
- National Federation of the Blind (NFB)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

Attachment 9

114TH CONGRESS
2D SESSION

S. 524

AN ACT

To authorize the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. **SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the "Comprehensive Addiction and Recovery Act of 2016".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Definitions.

TITLE I—PREVENTION AND EDUCATION

Sec. 101. Development of best practices for the prescribing of prescription opioids.
Sec. 102. Awareness campaigns.
Sec. 103. Community-based coalition enhancement grants to address local drug crises.

TITLE II—LAW ENFORCEMENT AND TREATMENT

Sec. 201. Treatment alternative to incarceration programs.
Sec. 202. First responder training for the use of drugs and devices that rapidly reverse the effects of opioids.

Sec. 203. Prescription drug take back expansion.
Sec. 204. Heroin and methamphetamine task forces.

TITLE III—TREATMENT AND RECOVERY

Sec. 301. Evidence-based prescription opioid and heroin treatment and interventions demonstration.
Sec. 302. Criminal justice medication assisted treatment and interventions demonstration.
Sec. 303. National youth recovery initiative.
Sec. 304. Building communities of recovery.

TITLE IV—ADDRESSING COLLATERAL CONSEQUENCES

Sec. 401. Correctional education demonstration grant program.
Sec. 402. National Task Force on Recovery and Collateral Consequences.

TITLE V—ADDICTION AND TREATMENT SERVICES FOR WOMEN, FAMILIES, AND VETERANS

Sec. 501. Improving treatment for pregnant and postpartum women.
Sec. 502. Report on grants for family-based substance abuse treatment.
Sec. 503. Veterans' treatment courts.

TITLE VI—INCENTIVIZING STATE COMPREHENSIVE INITIATIVES TO ADDRESS PRESCRIPTION OPIOID AND HEROIN ABUSE

Sec. 601. State demonstration grants for comprehensive opioid abuse response.

TITLE VII—MISCELLANEOUS

Sec. 701. GAO report on IMD exclusion.
Sec. 702. Funding.
Sec. 703. Conforming amendments.
Sec. 704. Grant accountability.
Sec. 705. Programs to prevent prescription drug abuse under the Medicare program.

TITLE VIII—TRANSNATIONAL DRUG TRAFFICKING ACT

Sec. 801. Short title.
Sec. 802. Possession, manufacture or distribution for purposes of unlawful importations.
Sec. 803. Trafficking in counterfeit goods or services.

SEC. 2. **FINDINGS.**

Congress finds the following:

(1) The abuse of heroin and prescription opioid painkillers is having a devastating effect on public health and safety in communities across the United States. According to the Centers for Disease Control and Prevention, drug overdose deaths now surpass traffic accidents in the number of deaths caused by injury in the United States. In 2014, an average of more than 120 people in the United States died from drug overdoses every day.

(2) According to the National Institute on Drug Abuse (commonly known as "NIDA"), the number of prescriptions for opioids increased from approximately 76,000,000 in 1991 to nearly 207,000,000 in 2013, and the United States is the biggest consumer of opioids globally, accounting for almost 100 percent of the world total for hydrocodone and 81 percent for oxycodone.

(3) Opioid pain relievers are the most widely misused or abused controlled prescription drugs (commonly referred to as "CPDs") and are involved in most CPD-related overdose incidents. According to the Drug Abuse Warning Network (commonly known as "DAWN"), the estimated number of emergency department visits involving nonmedical use of prescription opiates or opioids increased by 112 percent between 2006 and 2010, from 84,671 to 179,787.

(4) The use of heroin in the United States has also spiked sharply in recent years. According to the most recent National Survey on Drug Use and Health, more than 900,000 people in the United States reported using heroin in 2014, nearly a 35 percent increase from the previous year. Heroin overdose deaths more than tripled from 2010 to 2014.

(5) The supply of cheap heroin available in the United States has increased dramatically as well, largely due to the activity of Mexican drug trafficking organizations. The Drug Enforcement Administration (commonly known as the "DEA") estimates that heroin seizures at the Mexican border have more than doubled since 2010, and heroin production in Mexico increased 62 percent from 2013 to 2014. While only 8 percent of State and local law enforcement officials across the United States identified heroin as the greatest drug threat in their area in 2008, that number rose to 38 percent in 2015.

(6) Law enforcement officials and treatment experts throughout the country report that many people who have misused prescription

opioids have turned to heroin as a cheaper or more easily obtained alternative to prescription opioids.

(7) According to a report by the National Association of State Alcohol and Drug Abuse Directors (commonly referred to as "NASADAD"), 37 States reported an increase in admissions to treatment for heroin use during the past 2 years, while admissions to treatment for prescription opiates increased 500 percent from 2000 to 2012.

(8) Research indicates that combating the opioid crisis, including abuse of prescription painkillers and, increasingly, heroin, requires a multipronged approach that involves prevention, education, monitoring, law enforcement initiatives, reducing drug diversion and the supply of illicit drugs, expanding delivery of existing treatments (including medication assisted treatments), expanding access to overdose medications and interventions, and the development of new medications for pain that can augment the existing treatment arsenal.

(9) Substance use disorders are a treatable disease. Discoveries in the science of addiction have led to advances in the treatment of substance use disorders that help people stop abusing drugs and prescription medications and resume their productive lives.

(10) According to the National Survey on Drug Use and Health, approximately 22,700,000 people in the United States needed substance use disorder treatment in 2013, but only 2,500,000 people received it. Furthermore, current treatment services are not adequate to meet demand. According to a report commissioned by the Substance Abuse and Mental Health Services Administration (commonly known as "SAMHSA"), there are approximately 32 providers for every 1,000 individuals needing substance use disorder treatment. In some States, the ratio is much lower.

(11) The overall cost of drug abuse, from health care- and criminal justice-related costs to lost productivity, is steep, totaling more than $700,000,000,000 a year, according to NIDA. Effective substance abuse prevention can yield major economic dividends.

(12) According to NIDA, when schools and communities properly implement science-validated substance abuse prevention programs, abuse of alcohol, tobacco, and illicit drugs is reduced. Such

programs help teachers, parents, and healthcare professionals shape the perceptions of youths about the risks of drug abuse.

(13) Diverting certain individuals with substance use disorders from criminal justice systems into community-based treatment can save billions of dollars and prevent sizeable numbers of crimes, arrests, and re-incarcerations over the course of those individuals' lives.

(14) According to the DEA, more than 2,700 tons of expired, unwanted prescription medications have been collected since the enactment of the Secure and Responsible Drug Disposal Act of 2010 (Public Law 111–273; 124 Stat. 2858).

(15) Faith-based, holistic, or drug-free models can provide a critical path to successful recovery for a number of people in the United States. The 2015 membership survey conducted by Alcoholics Anonymous (commonly known as "AA") found that 73 percent of AA members were sober longer than 1 year and attended 2.5 meetings per week.

(16) Research shows that combining treatment medications with behavioral therapy is an effective way to facilitate success for some patients. Treatment approaches must be tailored to address the drug abuse patterns and drug-related medical, psychiatric, and social problems of each individual. Different types of medications may be useful at different stages of treatment or recovery to help a patient stop using drugs, stay in treatment, and avoid relapse. Patients have a range of options regarding their path to recovery and many have also successfully addressed drug abuse through the use of faith-based, holistic, or drug-free models.

(17) Individuals with mental illness, especially severe mental illness, are at considerably higher risk for substance abuse than the general population, and the presence of a mental illness complicates recovery from substance abuse.

(18) Rural communities are especially susceptible to heroin and opioid abuse. Individuals in rural counties have higher rates of drug poisoning deaths, including deaths from opioids. According to the American Journal of Public Health, "[O]pioid poisonings in nonmetropolitan counties have increased at a rate greater than threefold the increase in metropolitan counties." According to a

February 19, 2016, report from the Maine Rural Health Research Center, "[M]ultiple studies document a higher prevalence [of abuse] among specific vulnerable rural populations, particularly among youth, women who are pregnant or experiencing partner violence, and persons with co-occurring disorders."

SEC. 3. **DEFINITIONS.**

In this Act—

(1) the term "first responder" includes a firefighter, law enforcement officer, paramedic, emergency medical technician, or other individual (including an employee of a legally organized and recognized volunteer organization, whether compensated or not), who, in the course of professional duties, responds to fire, medical, hazardous material, or other similar emergencies;

(2) the term "medication assisted treatment" means the use, for problems relating to heroin and other opioids, of medications approved by the Food and Drug Administration in combination with counseling and behavioral therapies;

(3) the term "opioid" means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability; and

(4) the term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and any territory or possession of the United States.

TITLE I—PREVENTION AND EDUCATION

SEC. 101. **DEVELOPMENT OF BEST PRACTICES FOR THE PRESCRIBING OF PRESCRIPTION OPIOIDS.**

(a) DEFINITIONS.—In this section—

(1) the term "Secretary" means the Secretary of Health and Human Services; and

(2) the term "task force" means the Pain Management Best Practices Interagency Task Force convened under subsection (b).

(b) INTERAGENCY TASK FORCE.—Not later than December 14, 2018, the Secretary, in cooperation with the Secretary of Veterans Affairs, the Secretary of Defense, and the Administrator of the Drug Enforcement Administration, shall convene a Pain Management Best Practices Interagency Task Force to review, modify, and update, as appropriate, best practices for pain management (including chronic and acute pain) and prescribing pain medication.

(c) MEMBERSHIP.—The task force shall be comprised of—

(1) representatives of—

(A) the Department of Health and Human Services;

(B) the Department of Veterans Affairs;

(C) the Food and Drug Administration;

(D) the Department of Defense;

(E) the Drug Enforcement Administration;

(F) the Centers for Disease Control and Prevention;

(G) the National Academy of Medicine;

(H) the National Institutes of Health;

(I) the Office of National Drug Control Policy; and

(J) the Office of Rural Health Policy of the Department of Health and Human Services;

(2) physicians, dentists, and nonphysician prescribers;

(3) pharmacists;

(4) experts in the fields of pain research and addiction research;

(5) representatives of—

(A) pain management professional organizations;

(B) the mental health treatment community;

(C) the addiction treatment community;

(D) pain advocacy groups; and

(E) groups with expertise around overdose reversal; and

(6) other stakeholders, as the Secretary determines appropriate.

(d) DUTIES.—The task force shall—

(1) not later than 180 days after the date on which the task force is convened under subsection (b), review, modify, and update, as appropriate, best practices for pain management (including chronic and acute pain) and prescribing pain medication, taking into consideration—

(A) existing pain management research;

(B) recommendations from relevant conferences and existing relevant evidence-based guidelines;

(C) ongoing efforts at the State and local levels and by medical professional organizations to develop improved pain management strategies, including consideration of alternatives to opioids to reduce opioid monotherapy in appropriate cases;

(D) the management of high-risk populations, other than populations who suffer pain, who—

(i) may use or be prescribed benzodiazepines, alcohol, and diverted opioids; or

(ii) receive opioids in the course of medical care; and

(E) the Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention (80 Fed. Reg. 77351 (December 14, 2015)) and any final guidelines issued by the Centers for Disease Control and Prevention;

(2) solicit and take into consideration public comment on the practices developed under paragraph (1), amending such best practices if appropriate; and

(3) develop a strategy for disseminating information about the best practices to stakeholders, as appropriate.

(e) LIMITATION.—The task force shall not have rulemaking authority.

(f) REPORT.—Not later than 270 days after the date on which the task force is convened under subsection (b), the task force shall submit to Congress a report that includes—

(1) the strategy for disseminating best practices for pain management (including chronic and acute pain) and prescribing pain medication, as reviewed, modified, or updated under subsection (d); and

(2) recommendations for effectively applying the best practices described in paragraph (1) to improve prescribing practices at medical facilities, including medical facilities of the Veterans Health Administration.

SEC. 102. **AWARENESS CAMPAIGNS.**

(a) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the Attorney General, shall advance the education and awareness of the public, providers, patients, consumers, and other appropriate entities regarding the risk of abuse of prescription opioid drugs if such products are not taken as prescribed, including opioid and methadone abuse. Such education and awareness campaigns shall include information on the dangers of opioid abuse, how to prevent opioid abuse including through safe disposal of prescription medications and other safety precautions, and detection of early warning signs of addiction.

(b) DRUG-FREE MEDIA CAMPAIGN.—

(1) IN GENERAL.—The Office of National Drug Control Policy, in coordination with the Secretary of Health and Human Services and the Attorney General, shall establish a national drug awareness campaign.

(2) REQUIREMENTS.—The national drug awareness campaign required under paragraph (1) shall—

(A) take into account the association between prescription opioid abuse and heroin use;

(B) emphasize the similarities between heroin and prescription opioids and the effects of heroin and prescription opioids on the human body; and

(C) bring greater public awareness to the dangerous effects of fentanyl when mixed with heroin or abused in a similar manner.

SEC. 103. **COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO ADDRESS LOCAL DRUG CRISES.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.) is amended by striking section 2997 and inserting the following:

"SEC. 2997. COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO ADDRESS LOCAL DRUG CRISES.

"(a) DEFINITIONS.—In this section—

"(1) the term 'Drug-Free Communities Act of 1997' means chapter 2 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.);

"(2) the term 'eligible entity' means an organization that—

"(A) on or before the date of submitting an application for a grant under this section, receives or has received a grant under the Drug-Free Communities Act of 1997; and

"(B) has documented, using local data, rates of abuse of opioids or methamphetamines at levels that are—

"(i) significantly higher than the national average as determined by the Secretary (including appropriate consideration of the results of the Monitoring the Future Survey published by the National Institute on Drug Abuse and the National Survey on Drug Use and Health published by the Substance Abuse and Mental Health Services Administration); or

"(ii) higher than the national average, as determined by the Secretary (including appropriate consideration of the results of the surveys described in clause (i)), over a sustained period of time;

"(3) the term 'local drug crisis' means, with respect to the area served by an eligible entity—

"(A) a sudden increase in the abuse of opioids or methamphetamines, as documented by local data;

"(B) the abuse of prescription medications, specifically opioids or methamphetamines, that is significantly higher than the national average, over a sustained period of time, as documented by local data; or

"(C) a sudden increase in opioid-related deaths, as documented by local data;

"(4) the term 'opioid' means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability; and

"(5) the term 'Secretary' means the Secretary of Health and Human Services.

"(b) PROGRAM AUTHORIZED.—The Secretary, in coordination with the Director of the Office of National Drug Control Policy, may make grants to eligible entities to implement comprehensive community-wide strategies that address local drug crises within the area served by the eligible entity.

"(c) APPLICATION.—

"(1) IN GENERAL.—An eligible entity seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

"(2) CRITERIA.—As part of an application for a grant under this section, the Secretary shall require an eligible entity to submit a

detailed, comprehensive, multisector plan for addressing the local drug crisis within the area served by the eligible entity.

"(d) USE OF FUNDS.—An eligible entity shall use a grant received under this section—

"(1) for programs designed to implement comprehensive community-wide prevention strategies to address the local drug crisis in the area served by the eligible entity, in accordance with the plan submitted under subsection (c)(2); and

"(2) to obtain specialized training and technical assistance from the organization funded under section 4 of Public Law 107–82 (21 U.S.C. 1521 note).

"(e) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds.

"(f) EVALUATION.—A grant under this section shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on the recipient of a grant under the Drug-Free Communities Act of 1997, and may also include an evaluation of the effectiveness at reducing abuse of opioids, methadone, or methamphetamines.

"(g) LIMITATION ON ADMINISTRATIVE EXPENSES.—Not more than 8 percent of the amounts made available to carry out this section for a fiscal year may be used by the Secretary to pay for administrative expenses.".

TITLE II—LAW ENFORCEMENT AND TREATMENT

SEC. 201. **TREATMENT ALTERNATIVE TO INCARCERATION PROGRAMS.**

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means a State, unit of local government, Indian tribe, or nonprofit organization.

(2) ELIGIBLE PARTICIPANT.—The term "eligible participant" means an individual who—

(A) comes into contact with the juvenile justice system or criminal justice system or is arrested or charged with an offense that is not—

(i) a crime of violence, as defined under applicable State law or section 3156 of title 18, United States Code; or

(ii) a serious drug offense, as defined under section 924 (e)(2)(A) of title 18, United States Code;

(B) has been screened by a qualified mental health professional and determined to suffer from a substance use disorder, or co-occurring mental illness and substance use disorder, that there is a reasonable basis to believe is related to the commission of the offense; and

(C) has been, after consideration of any potential risk of violence to any person in the program or the public if the individual were selected to participate in the program, unanimously approved for participation in a program funded under this section by, as applicable depending on the stage of the criminal justice process—

(i) the relevant law enforcement agency;

(ii) the prosecuting attorney;

(iii) the defense attorney;

(iv) the pretrial, probation, or correctional officer;

(v) the judge; and

(vi) a representative from the relevant mental health or substance abuse agency.

(b) PROGRAM AUTHORIZED.—The Secretary of Health and Human Services, in coordination with the Attorney General, may make grants to eligible entities to—

(1) develop, implement, or expand a treatment alternative to incarceration program for eligible participants, including—

(A) pre-booking, including pre-arrest, treatment alternative to incarceration programs, including—

(i) law enforcement training on substance use disorders and co-occurring mental illness and substance use disorders;

(ii) receiving centers as alternatives to incarceration of eligible participants;

(iii) specialized response units for calls related to substance use disorders and co-occurring mental illness and substance use disorders; and

(iv) other pre-arrest or pre-booking treatment alternative to incarceration models; and

(B) post-booking treatment alternative to incarceration programs, including—

(i) specialized clinical case management;

(ii) pretrial services related to substance use disorders and co-occurring mental illness and substance use disorders;

(iii) prosecutor and defender based programs;

(iv) specialized probation;

(v) programs utilizing the American Society of Addiction Medicine patient placement criteria;

(vi) treatment and rehabilitation programs and recovery support services; and

(vii) drug courts, DWI courts, and veterans treatment courts; and

(2) facilitate or enhance planning and collaboration between State criminal justice systems and State substance abuse systems in order to more efficiently and effectively carry out programs described

in paragraph (1) that address problems related to the use of heroin and misuse of prescription drugs among eligible participants.

(c) APPLICATION.—

(1) IN GENERAL.—An eligible entity seeking a grant under this section shall submit an application to the Secretary of Health and Human Services—

(A) that meets the criteria under paragraph (2); and

(B) at such time, in such manner, and accompanied by such information as the Secretary of Health and Human Services may require.

(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

(A) provide extensive evidence of collaboration with State and local government agencies overseeing health, community corrections, courts, prosecution, substance abuse, mental health, victims services, and employment services, and with local law enforcement agencies;

(B) demonstrate consultation with the Single State Authority for Substance Abuse (as defined in section 201(e) of the Second Chance Act of 2007 (42 U.S.C. 17521(e)));

(C) demonstrate consultation with the Single State criminal justice planning agency;

(D) demonstrate that evidence-based treatment practices, including if applicable the use of medication assisted treatment, will be utilized; and

(E) demonstrate that evidenced-based screening and assessment tools will be utilized to place participants in the treatment alternative to incarceration program.

(d) REQUIREMENTS.—Each eligible entity awarded a grant for a treatment alternative to incarceration program under this section shall—

(1) determine the terms and conditions of participation in the program by eligible participants, taking into consideration the collateral consequences of an arrest, prosecution, or criminal conviction;

(2) ensure that each substance abuse and mental health treatment component is licensed and qualified by the relevant jurisdiction;

(3) for programs described in subsection (b)(2), organize an enforcement unit comprised of appropriately trained law enforcement professionals under the supervision of the State, tribal, or local criminal justice agency involved, the duties of which shall include—

(A) the verification of addresses and other contacts of each eligible participant who participates or desires to participate in the program; and

(B) if necessary, the location, apprehension, arrest, and return to court of an eligible participant in the program who has absconded from the facility of a treatment provider or has otherwise violated the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

(4) notify the relevant criminal justice entity if any eligible participant in the program absconds from the facility of the treatment provider or otherwise violates the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

(5) submit periodic reports on the progress of treatment or other measured outcomes from participation in the program of each eligible participant in the program to the relevant State, tribal, or local criminal justice agency;

(6) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program, and specifically explain how such measurements will provide valid measures of the impact of the program; and

(7) describe how the program could be broadly replicated if demonstrated to be effective.

(e) USE OF FUNDS.—An eligible entity shall use a grant received under this section for expenses of a treatment alternative to incarceration program, including—

(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including the enforcement unit;

(2) payments for treatment providers that are approved by the relevant State or tribal jurisdiction and licensed, if necessary, to provide needed treatment to eligible participants in the program, including medication assisted treatment, aftercare supervision, vocational training, education, and job placement;

(3) payments to public and nonprofit private entities that are approved by the State or tribal jurisdiction and licensed, if necessary, to provide alcohol and drug addiction treatment and mental health treatment to eligible participants in the program; and

(4) salaries, personnel costs, and other costs related to strategic planning among State and local government agencies.

(f) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds.

(g) GEOGRAPHIC DISTRIBUTION.—The Secretary of Health and Human Services shall ensure that, to the extent practicable, the geographical distribution of grants under this section is equitable and includes a grant to an eligible entity in—

(1) each State;

(2) rural, suburban, and urban areas; and

(3) tribal jurisdictions.

(h) PRIORITY CONSIDERATION WITH RESPECT TO STATES.—In awarding grants to States under this section, the Secretary of Health and Human Services shall give priority to—

(1) a State that submits a joint application from the substance abuse agencies and criminal justice agencies of the State that proposes to use grant funds to facilitate or enhance planning and collaboration between the agencies, including coordination to better address the needs of incarcerated populations; and

(2) a State that—

(A) provides civil liability protection for first responders, health professionals, and family members who have received appropriate training in the administration of naloxone in administering naloxone to counteract opioid overdoses; and

(B) submits to the Secretary a certification by the attorney general of the State that the attorney general has—

(i) reviewed any applicable civil liability protection law to determine the applicability of the law with respect to first responders, health care professionals, family members, and other individuals who—

(I) have received appropriate training in the administration of naloxone; and

(II) may administer naloxone to individuals reasonably believed to be suffering from opioid overdose; and

(ii) concluded that the law described in subparagraph (A) provides adequate civil liability protection applicable to such persons.

(i) REPORTS AND EVALUATIONS.—

(1) IN GENERAL.—Each fiscal year, each recipient of a grant under this section during that fiscal year shall submit to the Secretary of Health and Human Services a report on the outcomes of activities carried out using that grant in such form, containing such information, and on such dates as the Secretary of Health and Human Services shall specify.

(2) CONTENTS.—A report submitted under paragraph (1) shall—

(A) describe best practices for treatment alternatives; and

(B) identify training requirements for law enforcement officers who participate in treatment alternative to incarceration programs.

(j) FUNDING.—During the 5-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services may carry out this section using not more than $5,000,000 each fiscal year of amounts appropriated to the Substance Abuse and Mental Health Services Administration for Criminal Justice Activities. No additional funds are authorized to be appropriated to carry out this section.

SEC. 202. **FIRST RESPONDER TRAINING FOR THE USE OF DRUGS AND DEVICES THAT RAPIDLY REVERSE THE EFFECTS OF OPIOIDS.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 103, is amended by adding at the end the following:

"SEC. 2998. FIRST RESPONDER TRAINING FOR THE USE OF DRUGS AND DEVICES THAT RAPIDLY REVERSE THE EFFECTS OF OPIOIDS.

"(a) DEFINITION.—In this section—

"(1) the terms 'drug' and 'device' have the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

"(2) the term 'eligible entity' means a State, a unit of local government, or an Indian tribal government;

"(3) the term 'first responder' includes a firefighter, law enforcement officer, paramedic, emergency medical technician, or other individual (including an employee of a legally organized and recognized volunteer organization, whether compensated or not), who, in the course of professional duties, responds to fire, medical, hazardous material, or other similar emergencies;

"(4) the term 'opioid' means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability; and

"(5) the term 'Secretary' means the Secretary of Health and Human Services.

"(b) PROGRAM AUTHORIZED.—The Secretary, in coordination with the Attorney General, may make grants to eligible entities to allow appropriately trained first responders to administer an opioid overdose reversal drug to an individual who has—

"(1) experienced a prescription opioid or heroin overdose; or

"(2) been determined to have likely experienced a prescription opioid or heroin overdose.

"(c) APPLICATION.—

"(1) IN GENERAL.—An eligible entity seeking a grant under this section shall submit an application to the Secretary—

"(A) that meets the criteria under paragraph (2); and

"(B) at such time, in such manner, and accompanied by such information as the Secretary may require.

"(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

"(A) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program funded with a grant under this section, and specifically explain how such measurements will provide valid measures of the impact of the program;

"(B) describe how the program could be broadly replicated if demonstrated to be effective;

"(C) identify the governmental and community agencies that the program will coordinate; and

"(D) describe how law enforcement agencies will coordinate with their corresponding State substance abuse and mental health agencies to identify protocols and resources that are available to overdose victims and families, including information on treatment and recovery resources.

"(d) USE OF FUNDS.—An eligible entity shall use a grant received under this section to—

"(1) make such opioid overdose reversal drugs or devices that are approved by the Food and Drug Administration, such as naloxone, available to be carried and administered by first responders;

"(2) train and provide resources for first responders on carrying an opioid overdose reversal drug or device approved by the Food and Drug Administration, such as naloxone, and administering the drug or device to an individual who has experienced, or has been determined to have likely experienced, a prescription opioid or heroin overdose; and

"(3) establish processes, protocols, and mechanisms for referral to appropriate treatment, which may include an outreach coordinator or team to connect individuals receiving opioid overdose reversal drugs to follow-up services.

"(e) TECHNICAL ASSISTANCE GRANTS.—The Secretary shall make a grant for the purpose of providing technical assistance and training on the use of an opioid overdose reversal drug, such as naloxone, to respond to an individual who has experienced, or has been determined to have likely experienced, a prescription opioid or heroin overdose, and mechanisms for referral to appropriate treatment for an eligible entity receiving a grant under this section.

"(f) EVALUATION.—The Secretary shall conduct an evaluation of grants made under this section to determine—

"(1) the number of first responders equipped with naloxone, or another opioid overdose reversal drug, for the prevention of fatal opioid and heroin overdose;

"(2) the number of opioid and heroin overdoses reversed by first responders receiving training and supplies of naloxone, or another opioid overdose reversal drug, through a grant received under this section;

"(3) the number of calls for service related to opioid and heroin overdose;

"(4) the extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions; and

"(5) the research, training, and naloxone, or another opioid overdose reversal drug, supply needs of first responder agencies, including those agencies that are not receiving grants under this section.

"(g) RURAL AREAS WITH LIMITED ACCESS TO EMERGENCY MEDICAL SERVICES.—In making grants under this section, the Secretary shall ensure that not less than 25 percent of grant funds are awarded to eligible entities that are not located in metropolitan statistical areas, as defined by the Office of Management and Budget.".

SEC. 203. **PRESCRIPTION DRUG TAKE BACK EXPANSION.**

(a) DEFINITION OF COVERED ENTITY.—In this section, the term "covered entity" means—

(1) a State, local, or tribal law enforcement agency;

(2) a manufacturer, distributor, or reverse distributor of prescription medications;

(3) a retail pharmacy;

(4) a registered narcotic treatment program;

(5) a hospital or clinic with an onsite pharmacy;

(6) an eligible long-term care facility; or

(7) any other entity authorized by the Drug Enforcement Administration to dispose of prescription medications.

(b) PROGRAM AUTHORIZED.—The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

SEC. 204. **HEROIN AND METHAMPHETAMINE TASK FORCES.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 202, is amended by adding at the end the following:

"SEC. 2999. HEROIN AND METHAMPHETAMINE TASK FORCES.

"(a) DEFINITION OF OPIOID.—In this section, the term 'opioid' means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

"(b) AUTHORITY.—The Attorney General may make grants to State law enforcement agencies for investigative purposes—

"(1) to locate or investigate illicit activities through statewide collaboration, including activities related to—

"(A) the distribution of heroin or fentanyl, or the unlawful distribution of prescription opioids; or

"(B) unlawful heroin, fentanyl, and prescription opioid traffickers; and

"(2) to locate or investigate illicit activities, including precursor diversion, laboratories, or methamphetamine traffickers.".

TITLE III—TREATMENT AND RECOVERY

SEC. 301. **EVIDENCE-BASED PRESCRIPTION OPIOID AND HEROIN TREATMENT AND INTERVENTIONS DEMONSTRATION.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 204, is amended by adding at the end the following:

"SEC. 2999A. EVIDENCE-BASED PRESCRIPTION OPIOID AND HEROIN TREATMENT AND INTERVENTIONS DEMONSTRATION.

"(a) DEFINITIONS.—In this section—

"(1) the terms 'Indian tribe' and 'tribal organization' have the meaning given those terms in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603));

"(2) the term 'medication assisted treatment' means the use, for problems relating to heroin and other opioids, of medications approved by the Food and Drug Administration in combination with counseling and behavioral therapies;

"(3) the term 'opioid' means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability;

"(4) the term 'Secretary' means the Secretary of Health and Human Services; and

"(5) the term 'State substance abuse agency' means the agency of a State responsible for the State prevention, treatment, and recovery system, including management of the Substance Abuse Prevention and Treatment Block Grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.).

"(b) GRANTS.—

"(1) AUTHORITY TO MAKE GRANTS.—The Secretary, acting through the Director of the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration, and in coordination with the Attorney General and other departments or agencies, as appropriate, may award grants to State substance abuse agencies, units of local government, nonprofit organizations, and Indian tribes or tribal organizations that have a high rate, or have had a rapid increase, in the use of heroin or other opioids, in order to permit such entities to expand activities, including an expansion in the availability of medication assisted treatment and other clinically appropriate services, with respect to the treatment of addiction in the specific geographical areas of such entities where there is a high rate or rapid increase in the use of heroin or other opioids.

"(2) NATURE OF ACTIVITIES.—The grant funds awarded under paragraph (1) shall be used for activities that are based on reliable scientific evidence of efficacy in the treatment of problems related to heroin or other opioids.

"(c) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that grants awarded under subsection (b) are distributed equitably among

the various regions of the United States and among rural, urban, and suburban areas that are affected by the use of heroin or other opioids.

"(d) ADDITIONAL ACTIVITIES.—In administering grants under subsection (b), the Secretary shall—

"(1) evaluate the activities supported by grants awarded under subsection (b);

"(2) disseminate information, as appropriate, derived from the evaluation as the Secretary considers appropriate;

"(3) provide States, Indian tribes and tribal organizations, and providers with technical assistance in connection with the provision of treatment of problems related to heroin and other opioids; and

"(4) fund only those applications that specifically support recovery services as a critical component of the grant program.".

SEC. 302. **CRIMINAL JUSTICE MEDICATION ASSISTED TREATMENT AND INTERVENTIONS DEMONSTRATION.**

(a) DEFINITIONS.—In this section—

(1) the term "criminal justice agency" means a State, local, or tribal—

(A) court;

(B) prison;

(C) jail; or

(D) other agency that performs the administration of criminal justice, including prosecution, pretrial services, and community supervision;

(2) the term "eligible entity" means a State, unit of local government, or Indian tribe; and

(3) the term "Secretary" means the Secretary of Health and Human Services.

(b) PROGRAM AUTHORIZED.—The Secretary, in coordination with the Attorney General, may make grants to eligible entities to implement medication assisted treatment programs through criminal justice agencies.

(c) APPLICATION.—

(1) IN GENERAL.—An eligible entity seeking a grant under this section shall submit an application to the Secretary—

(A) that meets the criteria under paragraph (2); and

(B) at such time, in such manner, and accompanied by such information as the Secretary may require.

(2) CRITERIA.—An eligible entity, in submitting an application under paragraph (1), shall—

(A) certify that each medication assisted treatment program funded with a grant under this section has been developed in consultation with the Single State Authority for Substance Abuse (as defined in section 201(e) of the Second Chance Act of 2007 (42 U.S.C. 17521(e))); and

(B) describe how data will be collected and analyzed to determine the effectiveness of the program described in subparagraph (A).

(d) USE OF FUNDS.—An eligible entity shall use a grant received under this section for expenses of—

(1) a medication assisted treatment program, including the expenses of prescribing medications recognized by the Food and Drug Administration for opioid treatment in conjunction with psychological and behavioral therapy;

(2) training criminal justice agency personnel and treatment providers on medication assisted treatment;

(3) cross-training personnel providing behavioral health and health services, administration of medicines, and other administrative expenses, including required reports; and

(4) the provision of recovery coaches who are responsible for providing mentorship and transition plans to individuals reentering society following incarceration or alternatives to incarceration.

(e) PRIORITY CONSIDERATION WITH RESPECT TO STATES.—In awarding grants to States under this section, the Secretary shall give priority to a State that—

(1) provides civil liability protection for first responders, health professionals, and family members who have received appropriate training in the administration of naloxone in administering naloxone to counteract opioid overdoses; and

(2) submits to the Secretary a certification by the attorney general of the State that the attorney general has—

(A) reviewed any applicable civil liability protection law to determine the applicability of the law with respect to first responders, health care professionals, family members, and other individuals who—

(i) have received appropriate training in the administration of naloxone; and

(ii) may administer naloxone to individuals reasonably believed to be suffering from opioid overdose; and

(B) concluded that the law described in subparagraph (A) provides adequate civil liability protection applicable to such persons.

(f) TECHNICAL ASSISTANCE.—The Secretary, in coordination with the Director of the National Institute on Drug Abuse and the Attorney General, shall provide technical assistance and training for an eligible entity receiving a grant under this section.

(g) REPORTS.—

(1) IN GENERAL.—An eligible entity receiving a grant under this section shall submit a report to the Secretary on the outcomes of each grant received under this section for individuals receiving medication assisted treatment, based on—

(A) the recidivism of the individuals;

(B) the treatment outcomes of the individuals, including maintaining abstinence from illegal, unauthorized, and unprescribed or undispensed opioids and heroin;

(C) a comparison of the cost of providing medication assisted treatment to the cost of incarceration or other participation in the criminal justice system;

(D) the housing status of the individuals; and

(E) the employment status of the individuals.

(2) CONTENTS AND TIMING.—Each report described in paragraph (1) shall be submitted annually in such form, containing such information, and on such dates as the Secretary shall specify.

(h) FUNDING.—During the 5-year period beginning on the date of enactment of this Act, the Secretary may carry out this section using not more than $5,000,000 each fiscal year of amounts appropriated to the Substance Abuse and Mental Health Services Administration for Criminal Justice Activities. No additional funds are authorized to be appropriated to carry out this section.

SEC. 303. **NATIONAL YOUTH RECOVERY INITIATIVE.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 301, is amended by adding at the end the following:

"SEC. 2999B. NATIONAL YOUTH RECOVERY INITIATIVE.

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means—

"(A) a high school that has been accredited as a recovery high school by the Association of Recovery Schools;

"(B) an accredited high school that is seeking to establish or expand recovery support services;

"(C) an institution of higher education;

"(D) a recovery program at a nonprofit collegiate institution; or

"(E) a nonprofit organization.

"(2) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given the term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

"(3) RECOVERY PROGRAM.—The term 'recovery program'—

"(A) means a program to help individuals who are recovering from substance use disorders to initiate, stabilize, and maintain healthy and productive lives in the community; and

"(B) includes peer-to-peer support and communal activities to build recovery skills and supportive social networks.

"(b) GRANTS AUTHORIZED.—The Secretary of Health and Human Services, in coordination with the Secretary of Education, may award grants to eligible entities to enable the entities to—

"(1) provide substance use disorder recovery support services to young people in high school and enrolled in institutions of higher education;

"(2) help build communities of support for young people in recovery through a spectrum of activities such as counseling and health- and wellness-oriented social activities; and

"(3) encourage initiatives designed to help young people achieve and sustain recovery from substance use disorders.

"(c) USE OF FUNDS.—Grants awarded under subsection (b) may be used for activities to develop, support, and maintain youth recovery support services, including—

"(1) the development and maintenance of a dedicated physical space for recovery programs;

"(2) dedicated staff for the provision of recovery programs;

"(3) health- and wellness-oriented social activities and community engagement;

"(4) establishment of recovery high schools;

"(5) coordination of recovery programs with—

"(A) substance use disorder treatment programs and systems;

"(B) providers of mental health services;

"(C) primary care providers and physicians;

"(D) the criminal justice system, including the juvenile justice system;

"(E) employers;

"(F) housing services;

"(G) child welfare services;

"(H) high schools and institutions of higher education; and

"(I) other programs or services related to the welfare of an individual in recovery from a substance use disorder;

"(6) the development of peer-to-peer support programs or services; and

"(7) additional activities that help youths and young adults to achieve recovery from substance use disorders.".

SEC. 304. **BUILDING COMMUNITIES OF RECOVERY.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 303, is amended by adding at the end the following:

"SEC. 2999C. BUILDING COMMUNITIES OF RECOVERY.

"(a) DEFINITION.—In this section, the term 'recovery community organization' means an independent nonprofit organization that—

"(1) mobilizes resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery from substance use disorders; and

"(2) is wholly or principally governed by people in recovery for substance use disorders who reflect the community served.

"(b) GRANTS AUTHORIZED.—The Secretary of Health and Human Services may award grants to recovery community organizations to enable such organizations to develop, expand, and enhance recovery services.

"(c) FEDERAL SHARE.—The Federal share of the costs of a program funded by a grant under this section may not exceed 50 percent.

"(d) USE OF FUNDS.—Grants awarded under subsection (b)—

"(1) shall be used to develop, expand, and enhance community and statewide recovery support services; and

"(2) may be used to—

"(A) advocate for individuals in recovery from substance use disorders;

"(B) build connections between recovery networks, between recovery community organizations, and with other recovery support services, including—

"(i) substance use disorder treatment programs and systems;

"(ii) providers of mental health services;

"(iii) primary care providers and physicians;

"(iv) the criminal justice system;

"(v) employers;

"(vi) housing services;

"(vii) child welfare agencies; and

"(viii) other recovery support services that facilitate recovery from substance use disorders;

"(C) reduce the stigma associated with substance use disorders;

"(D) conduct public education and outreach on issues relating to substance use disorders and recovery, including—

"(i) how to identify the signs of addiction;

"(ii) the resources that are available to individuals struggling with addiction and families who have a family member struggling with or being treated for addiction, including programs that mentor and provide support services to children;

"(iii) the resources that are available to help support individuals in recovery; and

"(iv) information on the medical consequences of substance use disorders, including neonatal abstinence syndrome and potential infection with human immunodeficiency virus and viral hepatitis; and

"(E) carry out other activities that strengthen the network of community support for individuals in recovery.".

TITLE IV—ADDRESSING COLLATERAL CONSEQUENCES

SEC. 401. **CORRECTIONAL EDUCATION DEMONSTRATION GRANT PROGRAM.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 304, is amended by adding at the end the following:

"SEC. 2999D. CORRECTIONAL EDUCATION DEMONSTRATION GRANT PROGRAM.

"(a) DEFINITION.—In this section, the term 'eligible entity' means a State, unit of local government, nonprofit organization, or Indian tribe.

"(b) GRANT PROGRAM AUTHORIZED.—The Attorney General may make grants to eligible entities to design, implement, and expand educational programs for offenders in prisons, jails, and juvenile facilities, including to pay for—

"(1) basic education, secondary level academic education, high school equivalency examination preparation, career technical education, and English language learner instruction at the basic, secondary, or post-secondary levels, for adult and juvenile populations;

"(2) screening and assessment of inmates to assess education level and needs, occupational interest or aptitude, risk level, and other needs, and case management services;

"(3) hiring and training of instructors and aides, reimbursement of non-corrections staff and experts, reimbursement of stipends paid to inmate tutors or aides, and the costs of training inmate tutors and aides;

"(4) instructional supplies and equipment, including occupational program supplies and equipment to the extent that the supplies and equipment are used for instructional purposes;

"(5) partnerships and agreements with community colleges, universities, and career technology education program providers;

"(6) certification programs providing recognized high school equivalency certificates and industry recognized credentials; and

"(7) technology solutions to—

"(A) meet the instructional, assessment, and information needs of correctional populations; and

"(B) facilitate the continued participation of incarcerated students in community-based education programs after the students are released from incarceration.

"(c) APPLICATION.—An eligible entity seeking a grant under this section shall submit to the Attorney General an application in such form and manner, at such time, and accompanied by such information as the Attorney General specifies.

"(d) PRIORITY CONSIDERATIONS.—In awarding grants under this section, the Attorney General shall give priority to applicants that—

"(1) assess the level of risk and need of inmates, including by—

"(A) assessing the need for English language learner instruction;

"(B) conducting educational assessments; and

"(C) assessing occupational interests and aptitudes;

"(2) target educational services to assessed needs, including academic and occupational at the basic, secondary, or post-secondary level;

"(3) target career and technology education programs to—

"(A) areas of identified occupational demand; and

"(B) employment opportunities in the communities in which students are reasonably expected to reside post-release;

"(4) include a range of appropriate educational opportunities at the basic, secondary, and post-secondary levels;

"(5) include opportunities for students to attain industry recognized credentials;

"(6) include partnership or articulation agreements linking institutional education programs with community sited programs provided by adult education program providers and accredited institutions of higher education, community colleges, and vocational training institutions; and

"(7) explicitly include career pathways models offering opportunities for incarcerated students to develop academic skills, in-demand occupational skills and credentials, occupational experience in institutional work programs or work release programs, and linkages with employers in the community, so that incarcerated students have opportunities to embark on careers with strong prospects for both post-release employment and advancement in a career ladder over time.

"(e) REQUIREMENTS.—An eligible entity seeking a grant under this section shall—

"(1) describe the evidence-based methodology and outcome measurements that will be used to evaluate each program funded with a grant under this section, and specifically explain how such measurements will provide valid measures of the impact of the program; and

"(2) describe how each program described in paragraph (1) could be broadly replicated if demonstrated to be effective.

"(f) CONTROL OF INTERNET ACCESS.—An entity that receives a grant under this section may restrict access to the Internet by prisoners, as appropriate and in accordance with Federal and State law, to ensure public safety.".

SEC. 402. **NATIONAL TASK FORCE ON RECOVERY AND COLLATERAL CONSEQUENCES.**

(a) DEFINITION.—In this section, the term "collateral consequence" means a penalty, disability, or disadvantage imposed on an individual who is in recovery for a substance use disorder (including by an administrative agency, official, or civil court) as a result of a Federal or State conviction for a drug-related offense but not as part of the judgment of the court that imposes the conviction.

(b) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Attorney General shall establish a bipartisan task force to be known as the Task Force on Recovery and Collateral Consequences (in this section referred to as the "Task Force").

(2) MEMBERSHIP.—

(A) TOTAL NUMBER OF MEMBERS.—The Task Force shall include 10 members, who shall be appointed by the Attorney General in accordance with subparagraphs (B) and (C).

(B) MEMBERS OF THE TASK FORCE.—The Task Force shall include—

(i) members who have national recognition and significant expertise in areas such as health care, housing, employment, substance use disorders, mental health, law enforcement, and law;

(ii) not fewer than 2 members—

(I) who have personally experienced a substance abuse disorder or addiction and are in recovery; and

(II) not fewer than 1 of whom has benefitted from medication assisted treatment; and

(iii) to the extent practicable, members who formerly served as elected officials at the State and Federal levels.

(C) TIMING.—The Attorney General shall appoint the members of the Task Force not later than 60 days after the date on which the Task Force is established under paragraph (1).

(3) CHAIRPERSON.—The Task Force shall select a chairperson or co-chairpersons from among the members of the Task Force.

(c) DUTIES OF THE TASK FORCE.—

(1) IN GENERAL.—The Task Force shall—

(A) identify collateral consequences for individuals with Federal or State convictions for drug-related offenses who are in recovery for substance use disorder; and

(B) examine any policy basis for the imposition of collateral consequences identified under subparagraph (A) and the effect of the collateral consequences on individuals in recovery in resuming their personal and professional activities.

(2) RECOMMENDATIONS.—Not later than 180 days after the date of the first meeting of the Task Force, the Task Force shall develop recommendations, as it considers appropriate, for proposed legislative and regulatory changes related to the collateral consequences identified under paragraph (1).

(3) COLLECTION OF INFORMATION.—The Task Force shall hold hearings, require the testimony and attendance of witnesses, and secure information from any department or agency of the United States in performing the duties under paragraphs (1) and (2).

(4) REPORT.—

(A) SUBMISSION TO EXECUTIVE BRANCH.—Not later than 1 year after the date of the first meeting of the Task Force, the Task Force shall submit a report detailing the findings and recommendations of the Task Force to—

(i) the head of each relevant department or agency of the United States;

(ii) the President; and

(iii) the Vice President.

(B) SUBMISSION TO CONGRESS.—The individuals who receive the report under subparagraph (A) shall submit to Congress such legislative recommendations, if any, as those individuals consider appropriate based on the report.

TITLE V—ADDICTION AND TREATMENT SERVICES FOR WOMEN, FAMILIES, AND VETERANS

SEC. 501. **IMPROVING TREATMENT FOR PREGNANT AND POSTPARTUM WOMEN.**

(a) IN GENERAL.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) is amended—

(1) in subsection (a), by inserting "(referred to in this section as the 'Director')" after "Director of the Center for Substance Abuse Treatment"; and

(2) in subsection (p), in the first sentence—

(A) by striking "Committee on Labor and Human Resources" and inserting "Committee on Health, Education, Labor, and Pensions"; and

(B) by inserting "(other than subsection (r))" after "this section".

(b) PILOT PROGRAM GRANTS FOR STATE SUBSTANCE ABUSE AGENCIES.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) is amended—

(1) by striking subsection (r); and

(2) by inserting after subsection (q) the following:

"(r) PILOT PROGRAM FOR STATE SUBSTANCE ABUSE AGENCIES.—

"(1) IN GENERAL.—The Director shall carry out a pilot program under which the Director makes competitive grants to State substance abuse agencies to—

"(A) enhance flexibility in the use of funds designed to support family-based services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

"(B) help State substance abuse agencies address identified gaps in services furnished to such women along the continuum of care, including services provided to women in non-residential based settings; and

"(C) promote a coordinated, effective, and efficient State system managed by State substance abuse agencies by encouraging new approaches and models of service delivery that are evidence-based, including effective family-based programs for women involved with the criminal justice system.

"(2) REQUIREMENTS.—In carrying out the pilot program under this subsection, the Director—

"(A) shall require State substance abuse agencies to submit to the Director applications, in such form and manner and

containing such information as specified by the Director, to be eligible to receive a grant under the program;

"(B) shall identify, based on such submitted applications, State substance abuse agencies that are eligible for such grants;

"(C) shall require services proposed to be furnished through such a grant to support family-based treatment and other services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

"(D) notwithstanding subsection (a)(1), shall not require that services furnished through such a grant be provided solely to women that reside in facilities; and

"(E) shall not require that grant recipients under the program make available all services described in subsection (d).

"(3) REQUIRED SERVICES.—

"(A) IN GENERAL.—The Director shall specify minimum services required to be made available to eligible women through a grant awarded under the pilot program under this subsection. Such minimum services—

"(i) shall include the requirements described in subsection (c);

"(ii) may include any of the services described in subsection (d);

"(iii) may include other services, as appropriate; and

"(iv) shall be based on the recommendations submitted under subparagraph (B)

"(B) STAKEHOLDER INPUT.—The Director shall convene and solicit recommendations from stakeholders, including State substance abuse agencies, health care providers, persons in recovery from a substance use disorder, and other appropriate individuals, for the minimum services described in subparagraph (A).

"(4) DURATION.—The pilot program under this subsection shall not exceed 5 years.

"(5) EVALUATION AND REPORT TO CONGRESS.—

"(A) IN GENERAL.—Out of amounts made available to the Center for Behavioral Health Statistics and Quality, the Director of the Center for Behavioral Health Statistics and Quality, in cooperation with the recipients of grants under this subsection, shall conduct an evaluation of the pilot program under this subsection, beginning 1 year after the date on which a grant is first awarded under this subsection. The Director of the Center for Behavioral Health Statistics and Quality, in coordination with the Director of the Center for Substance Abuse Treatment, not later than 120 days after completion of such evaluation, shall submit to the relevant Committees of the Senate and the House of Representatives a report on such evaluation.

"(B) CONTENTS.—The report to Congress under subparagraph (A) shall include, at a minimum, outcomes information from the pilot program, including any resulting reductions in the use of alcohol and other drugs, engagement in treatment services, retention in the appropriate level and duration of services, increased access to the use of drugs approved by the Food and Drug Administration for the treatment of substance use disorders in combination with counseling, and other appropriate measures.

"(6) DEFINITION OF STATE SUBSTANCE ABUSE AGENCY.—For purposes of this subsection, the term 'State substance abuse agency' means, with respect to a State, the agency in such State that manages the substance abuse prevention and treatment block grant program under part B of title XIX.

"(s) FUNDING.—

"(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $15,900,000 for each of fiscal years 2016 through 2020.

"(2) LIMITATION.—Of the amounts made available under paragraph (1) to carry out this section, not more than 25 percent may be used each fiscal year to carry out subsection (r).".

SEC. 502. **REPORT ON GRANTS FOR FAMILY-BASED SUBSTANCE ABUSE TREATMENT.**

Section 2925 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797s–4) is amended—

(1) by striking "An entity" and inserting "(a) ENTITY REPORTS.—An entity"; and

(2) by adding at the end the following:

"(b) ATTORNEY GENERAL REPORT ON FAMILY-BASED SUBSTANCE ABUSE TREATMENT.—The Attorney General shall submit to Congress an annual report that describes the number of grants awarded under section 2921(1) and how such grants are used by the recipients for family-based substance abuse treatment programs that serve as alternatives to incarceration for custodial parents to receive treatment and services as a family.".

SEC. 503. **VETERANS' TREATMENT COURTS.**

Section 2991(j)(1)(B)(ii) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(j)(1)(B)(ii)), as amended by the Comprehensive Justice and Mental Health Act of 2015 (S. 993, 114th Congress), is amended—

(1) by inserting "(I)" after "(ii)";

(2) in subclause (I), as so designated, by striking the period and inserting "; or"; and

(3) by adding at the end the following:

"(II) was discharged or released from such service under dishonorable conditions, if the reason for that discharge or release, if known, is attributable to a substance use disorder.".

TITLE VI—INCENTIVIZING STATE COMPREHENSIVE INITIATIVES TO ADDRESS PRESCRIPTION OPIOID AND HEROIN ABUSE

SEC. 601. **STATE DEMONSTRATION GRANTS FOR COMPREHENSIVE OPIOID ABUSE RESPONSE.**

(a) DEFINITIONS.—In this section—

(1) the term "dispenser" has the meaning given the term in section 102 of the Controlled Substances Act (21 U.S.C. 802);

(2) the term "prescriber" means a dispenser who prescribes a controlled substance, or the agent of such a dispenser;

(3) the term "prescriber of a schedule II, III, or IV controlled substance" does not include a prescriber of a schedule II, III, or IV controlled substance that dispenses the substance—

(A) for use on the premises on which the substance is dispensed;

(B) in a hospital emergency room, when the substance is in short supply;

(C) for a certified opioid treatment program; or

(D) in other situations as the Attorney General may reasonably determine; and

(4) the term "schedule II, III, or IV controlled substance" means a controlled substance that is listed on schedule II, schedule III, or schedule IV of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

(b) PLANNING AND IMPLEMENTATION GRANTS.—

(1) IN GENERAL.—The Attorney General, in coordination with the Secretary of Health and Human Services and in consultation with the Director of the Office of National Drug Control Policy, may award grants to States, and combinations thereof, to prepare a comprehensive plan for and implement an integrated opioid abuse response initiative.

(2) PURPOSES.—A State receiving a grant under this section shall establish a comprehensive response to opioid abuse, which shall include—

(A) prevention and education efforts around heroin and opioid use, treatment, and recovery, including education of residents, medical students, and physicians and other prescribers of schedule II, III, or IV controlled substances on relevant prescribing guidelines and the prescription drug monitoring program of the State;

(B) a comprehensive prescription drug monitoring program to track dispensing of schedule II, III, or IV controlled substances, which shall—

(i) provide for data sharing with other States by statute, regulation, or interstate agreement; and

(ii) allow for access to all individuals authorized by the State to write prescriptions for schedule II, III, or IV controlled substances on the prescription drug monitoring program of the State;

(C) developing, implementing, or expanding prescription drug and opioid addiction treatment programs by—

(i) expanding programs for medication assisted treatment of prescription drug and opioid addiction, including training for treatment and recovery support providers;

(ii) developing, implementing, or expanding programs for behavioral health therapy for individuals who are in treatment for prescription drug and opioid addiction;

(iii) developing, implementing, or expanding programs to screen individuals who are in treatment for prescription drug and opioid addiction for hepatitis C and HIV, and provide treatment for those individuals if clinically appropriate; or

(iv) developing, implementing, or expanding programs that provide screening, early intervention, and referral to

treatment (commonly known as "SBIRT") to teenagers and young adults in primary care, middle schools, high schools, universities, school-based health centers, and other community-based health care settings frequently accessed by teenagers or young adults; and

(D) developing, implementing, and expanding programs to prevent overdose death from prescription medications and opioids.

(3) PLANNING GRANT APPLICATIONS.—

(A) APPLICATION.—

(i) IN GENERAL.—A State seeking a planning grant under this section to prepare a comprehensive plan for an integrated opioid abuse response initiative shall submit to the Attorney General an application in such form, and containing such information, as the Attorney General may require.

(ii) REQUIREMENTS.—An application for a planning grant under this section shall, at a minimum, include—

(I) a budget and a budget justification for the activities to be carried out using the grant;

(II) a description of the activities proposed to be carried out using the grant, including a schedule for completion of such activities;

(III) outcome measures that will be used to measure the effectiveness of the programs and initiatives to address opioids; and

(IV) a description of the personnel necessary to complete such activities.

(B) PERIOD; NONRENEWABILITY.—A planning grant under this section shall be for a period of 1 year. A State may not receive more than 1 planning grant under this section.

(C) STRATEGIC PLAN AND PROGRAM IMPLEMENTATION PLAN.—A State receiving a planning grant under this section shall develop a strategic plan and a program implementation plan.

(4) IMPLEMENTATION GRANTS.—

(A) APPLICATION.—A State seeking an implementation grant under this section to implement a comprehensive strategy for addressing opioid abuse shall submit to the Attorney General an application in such form, and containing such information, as the Attorney General may require.

(B) USE OF FUNDS.—A State that receives an implementation grant under this section shall use the grant for the cost of carrying out an integrated opioid abuse response program in accordance with this section, including for technical assistance, training, and administrative expenses.

(C) REQUIREMENTS.—An integrated opioid abuse response program carried out using an implementation grant under this section shall—

(i) require that each prescriber of a schedule II, III, or IV controlled substance in the State—

(I) registers with the prescription drug monitoring program of the State; and

(II) consults the prescription drug monitoring program database of the State before prescribing a schedule II, III, or IV controlled substance;

(ii) require that each dispenser of a schedule II, III, or IV controlled substance in the State—

(I) registers with the prescription drug monitoring program of the State;

(II) consults the prescription drug monitoring program database of the State before dispensing a schedule II, III, or IV controlled substance; and

(III) reports to the prescription drug monitoring program of the State, at a minimum, each instance in which a schedule II, III, or IV controlled substance is dispensed, with limited exceptions, as defined by the State, which shall indicate the prescriber by name and National Provider Identifier;

(iii) require that, not fewer than 4 times each year, the State agency or agencies that administer the prescription drug monitoring program of the State prepare and provide to each prescriber of a schedule II, III, or IV controlled substance an informational report that shows how the prescribing patterns of the prescriber compare to prescribing practices of the peers of the prescriber and expected norms;

(iv) if informational reports provided to a prescriber under clause (iii) indicate that the prescriber is repeatedly falling outside of expected norms or standard practices for the prescriber's field, direct the prescriber to educational resources on appropriate prescribing of controlled substances;

(v) ensure that the prescriber licensing board of the State receives a report describing any prescribers that repeatedly fall outside of expected norms or standard practices for the prescriber's field, as described in clause (iii);

(vi) require consultation with the Single State Authority for Substance Abuse (as defined in section 201(e) of the Second Chance Act of 2007 (42 U.S.C. 17521(e))); and

(vii) establish requirements for how data will be collected and analyzed to determine the effectiveness of the program.

(D) PERIOD.—An implementation grant under this section shall be for a period of 2 years.

(5) PRIORITY CONSIDERATIONS.—In awarding planning and implementation grants under this section, the Attorney General shall give priority to a State that—

(A) (i) provides civil liability protection for first responders, health professionals, and family members who have received appropriate training in the administration of naloxone in administering naloxone to counteract opioid overdoses; and

(ii) submits to the Attorney General a certification by the attorney general of the State that the attorney general has—

(I) reviewed any applicable civil liability protection law to determine the applicability of the law with respect to first responders, health care professionals, family members, and other individuals who—

(aa) have received appropriate training in the administration of naloxone; and

(bb) may administer naloxone to individuals reasonably believed to be suffering from opioid overdose; and

(II) concluded that the law described in subclause (I) provides adequate civil liability protection applicable to such persons;

(B) has in effect legislation or implements a policy under which the State shall not terminate, but may suspend, enrollment under the State plan for medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for an individual who is incarcerated for a period of fewer than 2 years;

(C) has a process for enrollment in services and benefits necessary by criminal justice agencies to initiate or continue treatment in the community, under which an individual who is incarcerated may, while incarcerated, enroll in services and benefits that are necessary for the individual to continue treatment upon release from incarceration;

(D) ensures the capability of data sharing with other States, such as by making data available to a prescription monitoring hub;

(E) ensures that data recorded in the prescription drug monitoring program database of the State is available within 24 hours, to the extent possible; and

(F) ensures that the prescription drug monitoring program of the State notifies prescribers and dispensers of schedule II, III, or IV controlled substances when overuse or misuse of such controlled substances by patients is suspected.

(c) AUTHORIZATION OF FUNDING.—For each of fiscal years 2016 through 2020, the Attorney General may use, from any unobligated balances made available under the heading "GENERAL ADMINISTRATION" to the Department of Justice in an appropriation Act, such amounts as are necessary to carry out this section, not to exceed $5,000,000 per fiscal year.

TITLE VII—MISCELLANEOUS

SEC. 701. **GAO REPORT ON IMD EXCLUSION.**

(a) DEFINITION.—In this section, the term "Medicaid Institutions for Mental Disease exclusion" means the prohibition on Federal matching payments under Medicaid for patients who have attained age 22, but have not attained age 65, in an institution for mental diseases under subparagraph (B) of the matter following subsection (a) of section 1905 of the Social Security Act (42 U.S.C. 1396d) and subsection (i) of such section.

(b) REPORT REQUIRED.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the impact that the Medicaid Institutions for Mental Disease exclusion has on access to treatment for individuals with a substance use disorder.

(c) ELEMENTS.—The report required under subsection (b) shall include a review of what is known regarding—

(1) Medicaid beneficiary access to substance use disorder treatments in institutions for mental disease; and

(2) the quality of care provided to Medicaid beneficiaries treated in and outside of institutions for mental disease for substance use disorders.

SEC. 702. **FUNDING.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.), as amended by section 401, is amended by adding at the end the following:

"SEC. 2999E. FUNDING.

"There are authorized to be appropriated to the Attorney General and the Secretary of Health and Human Services to carry out this part $62,000,000 for each of fiscal years 2016 through 2020.".

SEC. 703. **CONFORMING AMENDMENTS.**

Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.) is amended—

(1) in the part heading, by striking "**CONFRONTING USE OF METHAMPHETAMINE**" and inserting "**COMPREHENSIVE ADDICTION AND RECOVERY**"; and

(2) in section 2996(a)(1), by striking "this part" and inserting "this section".

SEC. 704. **GRANT ACCOUNTABILITY.**

(a) GRANTS UNDER PART II OF TITLE I OF THE OMNIBUS CRIME CONTROL AND SAFE STREETS ACT OF 1968.—Part II of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.); as amended by section 702, is amended by adding at the end the following:

"SEC. 2999F. GRANT ACCOUNTABILITY.

"(a) DEFINITIONS.—In this section—

"(1) the term 'applicable committees'—

"(A) with respect to the Attorney General and any other official of the Department of Justice, means—

"(i) the Committee on the Judiciary of the Senate; and

"(ii) the Committee on the Judiciary of the House of Representatives; and

"(B) with respect to the Secretary of Health and Human Services and any other official of the Department of Health and Human Services, means—

"(i) the Committee on Health, Education, Labor, and Pensions of the Senate; and

"(ii) the Committee on Energy and Commerce of the House of Representatives;

"(2) the term 'covered agency' means—

"(A) the Department of Justice; and

"(B) the Department of Health and Human Services; and

"(3) the term 'covered official' means—

"(A) the Attorney General; and

"(B) the Secretary of Health and Human Services.

"(b) ACCOUNTABILITY.—All grants awarded by a covered official under this part shall be subject to the following accountability provisions:

"(1) AUDIT REQUIREMENT.—

"(A) DEFINITION.—In this paragraph, the term 'unresolved audit finding' means a finding in the final audit report of the Inspector General of a covered agency that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months after the date on which the final audit report is issued.

"(B) AUDIT.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of a covered agency shall conduct audits of recipients of grants awarded by the applicable covered official under this part to prevent waste, fraud, and abuse

of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

"(C) MANDATORY EXCLUSION.—A recipient of grant funds under this part that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this part during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

"(D) PRIORITY.—In awarding grants under this part, a covered official shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this part.

"(E) REIMBURSEMENT.—If an entity is awarded grant funds under this part during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the covered official that awarded the grant funds shall—

"(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

"(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

"(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

"(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

"(B) PROHIBITION.—A covered official may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

"(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this part and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the applicable covered official, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, a covered official shall make the information disclosed under this subparagraph available for public inspection.

"(3) CONFERENCE EXPENDITURES.—

"(A) LIMITATION.—No amounts made available to a covered official under this part may be used by the covered official, or by any individual or entity awarded discretionary funds through a cooperative agreement under this part, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the covered official, unless the covered official provides prior written authorization that the funds may be expended to host the conference.

"(B) WRITTEN AUTHORIZATION.—Written authorization under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

"(C) REPORT.—

"(i) DEPARTMENT OF JUSTICE.—The Deputy Attorney General shall submit to the applicable committees an annual report on all conference expenditures approved by the Attorney General under this paragraph.

"(ii) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Deputy Secretary of Health and Human Services shall submit to the applicable committees an annual report on all conference expenditures approved by

the Secretary of Health and Human Services under this paragraph.

"(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this section, each covered official shall submit to the applicable committees an annual certification—

"(A) indicating whether—

"(i) all audits issued by the Office of the Inspector General of the applicable agency under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director, or the appropriate official of the Department of Health and Human Services, as applicable;

"(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

"(iii) all reimbursements required under paragraph (1)(E) have been made; and

"(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

"(c) PREVENTING DUPLICATIVE GRANTS.—

"(1) IN GENERAL.—Before a covered official awards a grant to an applicant under this part, the covered official shall compare potential grant awards with other grants awarded under this part by the covered official to determine if duplicate grant awards are awarded for the same purpose.

"(2) REPORT.—If a covered official awards duplicate grants to the same applicant for the same purpose, the covered official shall submit to the applicable committees a report that includes—

"(A) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

"(B) the reason the covered official awarded the duplicate grants.".

(b) OTHER GRANTS.—

(1) DEFINITIONS.—In this subsection—

(A) the term "applicable committees"—

(i) with respect to the Attorney General and any other official of the Department of Justice, means—

(I) the Committee on the Judiciary of the Senate; and

(II) the Committee on the Judiciary of the House of Representatives; and

(ii) with respect to the Secretary of Health and Human Services and any other official of the Department of Health and Human Services, means—

(I) the Committee on Health, Education, Labor, and Pensions of the Senate; and

(II) the Committee on Energy and Commerce of the House of Representatives;

(B) the term "covered agency" means—

(i) the Department of Justice; and

(ii) the Department of Health and Human Services;

(C) the term "covered grant" means a grant under section 201, 302, or 601 of this Act or section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) (as amended by section 501 of this Act); and

(D) the term "covered official" means—

(i) the Attorney General; and

(ii) the Secretary of Health and Human Services.

(2) ACCOUNTABILITY.—All covered grants awarded by a covered official shall be subject to the following accountability provisions:

(A) AUDIT REQUIREMENT.—

(i) DEFINITION.—In this subparagraph, the term "unresolved audit finding" means a finding in the final audit report of the Inspector General of a covered agency that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months after the date on which the final audit report is issued.

(ii) AUDIT.—Beginning in the first fiscal year beginning after the date of enactment of this Act, and in each fiscal year thereafter, the Inspector General of a covered agency shall conduct audits of recipients of covered grants awarded by the applicable covered official to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

(iii) MANDATORY EXCLUSION.—A recipient of covered grant funds that is found to have an unresolved audit finding shall not be eligible to receive covered grant funds during the first 2 fiscal years beginning after the end of the 12-month period described in clause (i).

(iv) PRIORITY.—In awarding covered grants, a covered official shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a covered grant.

(v) REIMBURSEMENT.—If an entity is awarded covered grant funds during the 2-fiscal-year period during which the entity is barred from receiving grants under clause (iii), the covered official that awarded the funds shall—

(I) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

(II) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

(B) NONPROFIT ORGANIZATION REQUIREMENTS.—

(i) DEFINITION.—For purposes of this subparagraph and the covered grant programs, the term "nonprofit organization" means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

(ii) PROHIBITION.—A covered official may not award a covered grant to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

(iii) DISCLOSURE.—Each nonprofit organization that is awarded a covered grant and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the applicable covered official, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, a covered official shall make the information disclosed under this clause available for public inspection.

(C) CONFERENCE EXPENDITURES.—

(i) LIMITATION.—No amounts made available to a covered official under a covered grant program may be used by the covered official, or by any individual or entity awarded discretionary funds through a cooperative

agreement under a covered grant program, to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the covered official, unless the covered official provides prior written authorization that the funds may be expended to host the conference.

(ii) WRITTEN AUTHORIZATION.—Written authorization under clause (i) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

(iii) REPORT.—

(I) DEPARTMENT OF JUSTICE.—The Deputy Attorney General shall submit to the applicable committees an annual report on all conference expenditures approved by the Attorney General under this subparagraph.

(II) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Deputy Secretary of Health and Human Services shall submit to the applicable committees an annual report on all conference expenditures approved by the Secretary of Health and Human Services under this subparagraph.

(D) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this Act, each covered official shall submit to the applicable committees an annual certification—

(i) indicating whether—

(I) all audits issued by the Office of the Inspector General of the applicable agency under subparagraph (A) have been completed and reviewed by the appropriate Assistant Attorney General or Director, or the appropriate official of the Department of Health and Human Services, as applicable;

(II) all mandatory exclusions required under subparagraph (A)(iii) have been issued; and

(III) all reimbursements required under subparagraph (A)(v) have been made; and

(ii) that includes a list of any grant recipients excluded under subparagraph (A) from the previous year.

(3) PREVENTING DUPLICATIVE GRANTS.—

(A) IN GENERAL.—Before a covered official awards a covered grant to an applicant, the covered official shall compare potential grant awards with other covered grants awarded by the covered official to determine if duplicate grant awards are awarded for the same purpose.

(B) REPORT.—If a covered official awards duplicate grants to the same applicant for the same purpose, the covered official shall submit to the applicable committees a report that includes—

(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

(ii) the reason the covered official awarded the duplicate grants.

SEC. 705. **PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER THE MEDICARE PROGRAM.**

(a) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(1) IN GENERAL.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended by adding at the end the following:

"(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

"(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may,

in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by a prescriber (or prescribers) selected under subparagraph (D), and dispensed for such beneficiary by a pharmacy (or pharmacies) selected under such subparagraph.

"(B) REQUIREMENT FOR NOTICES.—

"(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

"(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

"(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse, as described in subparagraph (C)(iv).

"(ii) INITIAL NOTICE.—An initial written notice described in this clause is a notice that provides to the beneficiary—

"(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

"(II) information, when possible, describing State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary may have access, including substance use disorder treatment services, addiction treatment services, mental health services, and other counseling services;

"(III) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and

pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

"(IV) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

"(V) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor;

"(VI) contact information for other organizations that can provide the beneficiary with information regarding drug management program for at-risk beneficiaries (similar to the information provided by the Secretary in other standardized notices to part D eligible individuals enrolled in prescription drug plans under this part); and

"(VII) notice that the beneficiary has a right to an appeal pursuant to subparagraph (E).

"(iii) SECOND NOTICE.—A second written notice described in this clause is a notice that provides to the beneficiary notice—

"(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

"(II) that such beneficiary has been sent, or informed of, such identification in the initial notice and is now subject to the requirements of the drug

management program for at-risk beneficiaries established by such PDP sponsor for such plan;

"(III) of the prescriber and pharmacy selected for such individual under subparagraph (D);

"(IV) of, and information about, the right of the beneficiary to a reconsideration and an appeal under subsection (h) of such identification and the prescribers and pharmacies selected;

"(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

"(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (V).

"(iv) TIMING OF NOTICES.—

"(I) IN GENERAL.—Subject to subclause (II), a second written notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

"(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (II), the PDP sponsor may provide such second notice on such earlier date.

"(III) FORM OF NOTICE.—The written notices under clauses (ii) and (iii) shall be in a format determined appropriate by the Secretary, taking into account beneficiary preferences.

"(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

"(i) IN GENERAL.—For purposes of this paragraph, the term 'at-risk beneficiary for prescription drug abuse' means a part D eligible individual who is not an exempted individual described in clause (ii) and—

"(I) who is identified through criteria developed by the Secretary in consultation with PDP sponsors and other stakeholders described in subsection section __ (g)(2)(A) of the Comprehensive Addiction and Recovery Act of 2016 based on clinical factors indicating misuse or abuse of prescription drugs described in subparagraph (G), including dosage, quantity, duration of use, number of and reasonable access to prescribers, and number of and reasonable access to pharmacies used to obtain such drug; or

"(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under a prescription drug plan in which such individual was previously enrolled and such identification has not been terminated under subparagraph (F).

"(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

"(I) receives hospice care under this title;

"(II) resides in a long-term care facility, a facility described in section 1905(d), or other facility under contract with a single pharmacy; or

"(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

"(iii) PROGRAM SIZE.—The Secretary shall establish policies, including the criteria developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

"(iv) CLINICAL CONTACT.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

"(D) SELECTION OF PRESCRIBERS.—

"(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(III) and (iii)(V) of subparagraph (B) if applicable, select—

"(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a 'prescriber') who may write prescriptions for such drugs for such beneficiary; and

"(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

"(ii) REASONABLE ACCESS.—In making the selection under this subparagraph, a PDP sponsor shall ensure, taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time, that the beneficiary continues to have reasonable access to drugs described in subparagraph (G), including—

"(I) for individuals with multiple residences; and

"(II) in the case of natural disasters and similar emergency situations.

"(iii) BENEFICIARY PREFERENCES.—

"(I) IN GENERAL.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

"(aa) review such preferences;

"(bb) select or change the selection of a prescriber or pharmacy for the beneficiary based on such preferences; and

"(cc) inform the beneficiary of such selection or change of selection.

"(II) EXCEPTION.—In the case that the PDP sponsor determines that a change to the selection of a prescriber or pharmacy under item (bb) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of a prescriber or pharmacy for the beneficiary. If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

"(aa) at least 30 days written notice of the change of selection; and

"(bb) a rationale for the change.

"(III) TIMING.—An at-risk beneficiary for prescription drug abuse may choose to express their prescriber and pharmacy preference and communicate such preference to their PDP sponsor at any date while enrolled in the program, including after a second notice under subparagraph (B)(iii) has been provided.

"(iv) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

"(E) APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of a prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to an expedited reconsideration and appeal pursuant to subsection (h).

"(F) TERMINATION OF IDENTIFICATION.—

"(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

"(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); or

"(II) the end of such maximum period of identification as the Secretary may specify.

"(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

"(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term 'frequently abused drug' means a drug that is determined by the Secretary to be frequently abused or diverted and that is—

"(i) a Controlled Drug Substance in Schedule CII; or

"(ii) within the same class or category of drugs as a Controlled Drug Substance in Schedule CII, as determined through notice and comment rulemaking.

"(H) DATA DISCLOSURE.—

"(i) DATA ON DECISION TO IMPOSE LIMITATION.—In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require such PDP sponsor to disclose data, including necessary individually identifiable health information, about the decision to impose such limitations and the limitations imposed by the PDP sponsor under this part.

"(ii) DATA TO REDUCE FRAUD, ABUSE, AND WASTE.—The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

"(I) SHARING OF INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

"(J) PRIVACY ISSUES.—Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

"(K) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

"(i) provided through the improper payment outreach and education program described in section 1874A(h); and

"(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

"(L) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.".

(2) INFORMATION FOR CONSUMERS.—Section 1860D–4(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–104(a)(1)(B)) is amended by adding at the end the following:

"(v) The drug management program for at-risk beneficiaries under subsection (c)(5).".

(3) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D)) is amended by inserting ", subject to such limits as the Secretary may establish for individuals identified pursuant to section 1860D–4(c)(5)" after "the Secretary".

(b) UTILIZATION MANAGEMENT PROGRAMS.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as amended by subsection (a)(1), is amended—

(1) in paragraph (1), by inserting after subparagraph (D) the following new subparagraph:

"(E) A utilization management tool to prevent drug abuse (as described in paragraph (5)(A)).”; and

(2) by adding at the end the following new paragraph:

"(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

"(A) IN GENERAL.—A tool described in this paragraph is any of the following:

"(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

"(ii) Retrospective utilization review to identify—

"(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

"(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

"(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

"(B) REPORTING.—A PDP sponsor offering a prescription drug plan in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

"(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor during the 30-day period before such report is submitted; and

"(ii) the name and prescription records of individuals described in paragraph (5)(C).

"(C) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that plan sponsor annual compliance reviews and program audits include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.".

(c) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

"(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.".

(d) SENSE OF CONGRESS REGARDING USE OF TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Congress that MA organizations and PDP sponsors should consider using e-prescribing and other health information technology tools to support combating fraud under MA–PD plans and prescription drug plans under parts C and D of the Medicare Program.

(e) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the implementation of the amendments made by this section, including the effectiveness of the at-risk beneficiaries for prescription drug abuse drug management programs authorized by section 1860D–4(c)(5) of the Social Security Act (42 U.S.C. 1395w–10(c)(5)), as added by subsection (a)(1). Such study shall include an analysis of—

(A) the impediments, if any, that impair the ability of individuals described in subparagraph (C) of such section 1860D–4(c)(5) to access clinically appropriate levels of prescription drugs;

(B) the effectiveness of the reasonable access protections under subparagraph (D)(ii) of such section 1860D–4(c)(5), including the impact on beneficiary access and health;

(C) how best to define the term "designated pharmacy", including whether the definition of such term should include an entity that is comprised of a number of locations that are under common ownership and that electronically share a real-time, online database and whether such a definition would help to protect and improve beneficiary access;

(D) the types of—

(i) individuals who, in the implementation of such section, are determined to be individuals described in such subparagraph; and

(ii) prescribers and pharmacies that are selected under subparagraph (D) of such section;

(E) the extent of prescription drug abuse beyond Controlled Drug Substances in Schedule CII in parts C and D of the Medicare program; and

(F) other areas determined appropriate by the Comptroller General.

(2) REPORT.—Not later than July 1, 2019, the Comptroller General of the United States shall submit to the appropriate committees of jurisdiction of Congress a report on the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines to be appropriate.

(f) REPORT BY SECRETARY.—

(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of Congress a report on ways to improve upon the appeals process for Medicare beneficiaries with respect to prescription drug coverage under part D of title XVIII of the Social Security Act. Such report shall include an analysis comparing appeals processes under parts C and D of such title XVIII.

(2) FEEDBACK.—In development of the report described in paragraph (1), the Secretary of Health and Human Services shall solicit feedback on the current appeals process from stakeholders, such as beneficiaries, consumer advocates, plan sponsors, pharmacy benefit managers, pharmacists, providers, independent review entity evaluators, and pharmaceutical manufacturers.

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in subsection (d)(2), the amendments made by this section shall apply to prescription drug plans for plan years beginning on or after January 1, 2018.

(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2017, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part

A of title XVIII of the Social Security Act or enrolled under part B of such title of such Act, advocacy groups representing such individuals, clinicians, plan sponsors, pharmacists, retail pharmacies, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B). The input described in the preceding sentence shall be provided to the Secretary in sufficient time in order for the Secretary to take such input into account in promulgating the regulations pursuant to subparagraph (C).

(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

(i) the impact on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors who are at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)));

(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk beneficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act);

(iii) the types of enrollees that should be treated as exempted individuals, as described in clause (ii) of such paragraph;

(iv) the manner in which terms and definitions in paragraph (5) of such section 1860D–4(c) should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph (5);

(v) the information to be included in the notices described in subparagraph (B) of such section and the standardization of such notices;

(vi) with respect to a PDP sponsor that establishes a drug management program for at-risk beneficiaries under such paragraph (5), the responsibilities of such PDP sponsor with respect to the implementation of such program;

(vii) notices for plan enrollees at the point of sale that would explain why an at-risk beneficiary has been prohibited from receiving a prescription at a location outside of the designated pharmacy;

(viii) evidence-based prescribing guidelines for opiates; and

(ix) the sharing of claims data under parts A and B with PDP sponsors.

(C) RULEMAKING.—The Secretary of Health and Human Services shall, taking into account the input gathered pursuant to subparagraph (A) and after providing notice and an opportunity to comment, promulgate regulations to carry out the provisions of, and amendments made by subsections (a) and (b).

TITLE VIII—TRANSNATIONAL DRUG TRAFFICKING ACT

SEC. 801. SHORT TITLE.

This title may be cited as the "Transnational Drug Trafficking Act of 2015".

SEC. 802. **POSSESSION, MANUFACTURE OR DISTRIBUTION FOR PURPOSES OF UNLAWFUL IMPORTATIONS.**

Section 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 959) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) in subsection (a), by striking "It shall" and all that follows and inserting the following: "It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II or flunitrazepam or a listed chemical intending, knowing, or having

reasonable cause to believe that such substance or chemical will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States.

"(b) It shall be unlawful for any person to manufacture or distribute a listed chemical—

"(1) intending or knowing that the listed chemical will be used to manufacture a controlled substance; and

"(2) intending, knowing, or having reasonable cause to believe that the controlled substance will be unlawfully imported into the United States.".

SEC. 803. **TRAFFICKING IN COUNTERFEIT GOODS OR SERVICES.**

Chapter 113 of title 18, United States Code, is amended—

(1) in section 2318(b)(2), by striking "section 2320(e)" and inserting "section 2320(f)"; and

(2) in section 2320—

(A) in subsection (a), by striking paragraph (4) and inserting the following:

"(4) traffics in a drug and knowingly uses a counterfeit mark on or in connection with such drug,";

(B) in subsection (b)(3), in the matter preceding subparagraph (A), by striking "counterfeit drug" and inserting "drug that uses a counterfeit mark on or in connection with the drug"; and

(C) in subsection (f), by striking paragraph (6) and inserting the following:

"(6) the term 'drug' means a drug, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).".

Passed the Senate March 10, 2016.

Attest:

Secretary

114TH
CONGRESS
2D
SESSION

S. 524

AN ACT

To authorize the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use.

Attachment 10

State of California

BUSINESS AND PROFESSIONS CODE

Section 4003

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) This section shall remain in effect only until January 1, 2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2017, deletes or extends that date.

(Amended by Stats. 2012, Ch. 332, Sec. 84. (SB 1236) Effective January 1, 2013. Repealed as of January 1, 2017, by its own provisions.)

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§ 1704. Change of Address.

Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4100, Business and Professions Code.

HISTORY

1. Amendment filed 7-21-66; effective thirtieth day thereafter (Register 66, No. 23).

2. Amendment filed 6-24-71; effective thirtieth day thereafter (Register 71, No. 26).

3. Amendment filed 5-18-78; effective thirtieth day thereafter (Register 78, No. 20).

4. Amendment filed 12-8-80; effective thirtieth day thereafter (Register 80, No. 50).

5. Change without regulatory effect amending Note filed 9-11-2002 pursuant to section 100, title 1, California Code of Regulations (Register 2002, No. 37).

This database is current through 4/29/16 Register 2016, No. 18

16 CCR § 1704, 16 CA ADC § 1704

END OF DOCUMENT

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State of California

BUSINESS AND PROFESSIONS CODE

Section 4013

4013. (a) Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail notification list within 30 days of a change in the facility's e-mail address.

(c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single e-mail address to the board's e-mail notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an e-mail notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board by July 1, 2011, or within 60 days of initial licensure, whichever is later, informing the board of the single e-mail address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its e-mail address with the board's e-mail notification list within 30 days of any change in the owner's e-mail address.

(d) This section shall become operative on July 1, 2010.

(Amended by Stats. 2010, Ch. 653, Sec. 19. (SB 1489) Effective January 1, 2011.)

Attachment 11

ORANGE COUNTY REGISTER

Fatal drug overdoses reach 10-year high in Orange County

By JENNA CHANDLER
2016-05-15 22:30:18

The number of people dying of drug overdoses in Orange County has soared to the highest levels in at least a decade.

According to preliminary coroner data, fatal drug overdoses climbed to at least 400 last year, a 6 percent increase from 2014 – and a nearly 63 percent jump compared with 2005, when the number stood at 246.

The latest figures punctuate a problem that has rapidly multiplied in Orange County and the U.S. In the past five years, drug overdoses have killed 1,769 people in the county.

The coroner's office has cases awaiting toxicology results, so the 400 figure could rise.

More than two-thirds of last year's cases – 286 – involved opioids, a class of drug that includes heroin and prescription painkillers such as Percocet, OxyContin and Vicodin.

That's not unusual: A 2014 report from the county Health Care Agency found that from 2011 to 2013, 70 percent of all drug and alcohol overdose deaths investigated by the coroner involved opioids.

The Centers for Disease Control and Prevention considers the spike in opioid abuse and death a national epidemic, claiming 78 lives daily in the U.S.

"Frankly, we're still under-resourced. I think the public doesn't fully appreciate yet the scope of the problem," President Barack Obama said in March at the National Rx Drug Abuse & Heroin Summit in Atlanta, where his administration announced it would spend $11 million to expand access to naloxone, a fast-acting opioid overdose-reversal medicine.

Obama also is asking Congress to spend an extra $1.1 billion to expand treatment and programs to prevent prescription drug and heroin overdoses.

It's been only within the past few months that such efforts have escalated to curb the death toll.

"We have a community at risk," said Dr. Padma Gulur, a pain specialist at UC Irvine Health. "It's so concerning."

Gulur is leading a new coalition of health insurance companies, law enforcement agencies, hospitals and public health agencies that has collected drug overdose data from 2013 on every California county.

The numbers show Orange County has one of the higher rates of prescription opioid deaths in the state, 17th out of 58 counties.

The coalition is encouraging physicians to scale back the amount of opioids they prescribe and to know the signs of addiction. It's also coming up with ways to expand access to naloxone.

"Naloxone saves lives; it just does," Gulur sad. "Looking at the data from the coroner's office, these are preventable deaths."

Two local mothers whose children died of overdoses are on a mission to distribute naloxone, also known under the brand name Narcan. It can be sprayed into the nose or jabbed into arm or leg muscles to kick-start the lungs of someone who has stopped breathing after overdosing on opioids.

The mothers, Aimee Dunkle and Margie Fleitman, are taking the antidote to sober-living homes and putting it in the hands of users and their families.

The mothers also are working with UCI medical students who in February won approval from the state health department to hand out clean needles to users on Saturdays in downtown Santa Ana.

They've given out hundreds of vials of naloxone, and 48 clients have reported successfully using it to revive a person who overdosed, Orange County Needle Exchange Program founder Kyle Barbour said.

A proposal in the Legislature would take the needle exchange concept a step further by making it legal for local public health departments to set up clean, safe places for users to inject and ride out their highs under medical supervision.

Drug use via needles is so pervasive in Orange County that in 2½ months, Barbour's group distributed 40,000 clean needles and collected 23,928 dirty ones – numbers they anticipated hitting over a full year.

"There's a huge need – much greater than we initially expected," he said.

But, he added, "As large as we feel our statistics are, there are surely people in Anaheim, Fullerton, Huntington Beach that need access to these services but can't get to us or haven't heard about us. That demonstrates the urgent need for more of these services."

Contact the writer: jchandler@ocregister.com and @jennakchandler on Twitter

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Damoth, Debbie@DCA

From: NABP <news@pmta173.dedicated.bmsend.com> on behalf of NABP <news@awarerx.pharmacy>
Sent: Thursday, May 05, 2016 3:29 PM
To: Damoth, Debbie@DCA
Subject: AWARxE: Consumers Advised to Not Use Weight Loss Product Propell Platinum Due to Hidden Ingredients

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AWARxE GET INFORMED.™ Prescription Drug Safety News

Consumers Advised to Not Use Weight Loss Product Propell Platinum Due to Hidden Ingredients

Food and Drug Administration (FDA) is advising consumers not to purchase or use Propell Platinum, a product promoted for weight loss, because FDA laboratory analysis confirmed it contains sibutramine and phenolphthalein. Propell Platinum is sold on the Internet and possibly in some retail stores. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons, indicates the FDA public notification. The product poses a threat because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. This product may also interact in life-threatening ways with other medications a consumer may be taking. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer-causing risk. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Issues Public Notification Advising Consumers to Not Buy

The AWARxE® Prescription Drug Safety Program is brought to you by the National Association of Boards of Pharmacy Foundation®.

In This Issue

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FDA Issues Public Notification Advising Consumers to Not Buy or Use ENVY BP

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Prescription Opioid Abuse Common in Workplace, New Report Offers Alternatives to Help Prevent Misuse and Abuse

or Use ENVY BP

FDA is advising consumers not to purchase or use ENVY BP, a product promoted for weight loss, because FDA laboratory analysis confirmed that ENVY BP contains sibutramine. ENVY BP is sold on various websites and possibly in some retail stores. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons, indicates the FDA public notification. The product poses a threat because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. This product may also interact in life-threatening ways with other medications a consumer may be taking. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Seattle City Council Resolution Urges Prescription Drug Disposal Sites Be Installed at Pharmacies and Police Precincts

The Seattle City Council passed a resolution that requests pharmacies and the Seattle Police Department install drug disposal drop boxes across the city to reduce the risk of nonmedical use of unused prescription drugs. The countywide safe prescription drug disposal program will accept prescription medicines, including controlled substances, and nonprescription (over-the-counter) medicines for safe disposal, according to Resolution 31654. The resolution does not require pharmacies and police precincts to install a drop box, notes *KUOW.org*.

Prescription Opioid Abuse Common in Workplace, New Report Offers Alternatives to Help Prevent Misuse and Abuse

Almost a third of opioid painkiller prescriptions funded by employer plans are being abused, indicates a recent report. The authors of the report suggest that companies should provide employees with a thorough explanation of their benefit programs to help prevent misuse and abuse. For example, using physical therapy benefits may be a good option for some patients suffering from lower back pain, rather than opioid medications. Data for the study is based on nearly 1 million employees who used a benefit platform from Castlight Health between 2011 and 2015. Companies may also want to consider offering programs that provide access to opioid abuse treatment, notes *Partnership for Drug-Free Kids*.

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DEA Prescription Drug Take-Back Day Collection Site Locator Now Available

The Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day collection site locator is now available, allowing consumers to search for nearby locations to dispose of unneeded, unwanted, or expired medications on Saturday, April 30, 2016. On this day from 10 AM to 2 PM, thousands of DEA-coordinated collection sites will be available across the United States. Consumers are encouraged to use this unique opportunity to safely and legally dispose of any unneeded medications, including prescription painkillers and other controlled substance medicines.

The take-back service is free and anonymous with no questions asked, DEA reminds consumers. Participating sites will accept tablets, capsules, and all other solid dosage forms of unwanted medication. Personal information should be blacked out on prescription bottles, or medications may be emptied from the bottles into bins provided at the locations. Check the DEA collection site locator often, as new locations will be added until April 30, 2016.

Consumers have disposed of at least 5.5 million pounds of unwanted medication during previous DEA Take-Back Days. The 10th national DEA take-back event was held on September 26, 2015, and more than 5,000 locations provided take-back services. More information and a link to the DEA Take-Back Day collection site locator are available on the AWARxE®

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website.

Super Herbs Weight Loss Dietary Supplement Recalled Due to Presence of Undeclared Ingredients

Super Herbs is recalling all bottles of Super Herbs to the consumer level because Food and Drug Administration (FDA) laboratory testing determined that the weight loss dietary supplement contains sibutramine, desmethylsibutramine, and/or phenolphthalein. These undeclared ingredients make this product an unapproved new drug for which safety and efficacy have not been established.

Sibutramine is an appetite suppressant that was withdrawn from the US market in October 2010, as indicated in the press release posted on the FDA website. Desmethylsibutramine is an active metabolite of sibutramine. Sibutramine and its active metabolites substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke, states FDA. Phenolphthalein was previously used in over-the-counter laxatives, but because of concerns of carcinogenicity, it is no longer marketed in the US.

Super Herbs was distributed nationwide to consumers via the Internet. It is packaged in a clear bottle with light green and dark green capsules. Consumers who have the recalled product should stop using it. Consumers should contact their health care provider if they have experienced any problems that may be related to using this drug product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Recalled Dietary Supplement LGD-Xtreme Contains Investigational Drug Not Approved for Use

Invisiblu International, LLC, is recalling one lot of Continuum Labs LGD-Xtreme, 3 mg, to the retail and consumer levels because the product has been found to contain LGD-4033 (Ligandrol), an investigational drug not approved for use. LGD-Xtreme is marketed as a dietary supplement to promote gains of lean muscle mass. The recalled product was sold to consumers in the US via the Internet and was exported to wholesalers in Brazil, indicates the press release posted to FDA's website.

The affected lot number is 21511166 with the expiration date of November 2018. LGD-Xtreme is packaged in a dark amber plastic bottle with 90

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capsules and can be identified by its black label with gold trim and the Continuum Labs logo. Consumers who have this product in their possession should stop using it and discard any unused capsules. Consumers are advised to contact their health care provider if they have experienced any problems that may be related to using this drug product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Consumers Are Unable to Identify Common NSAIDs, Unaware of Associated Risks

Consumers who use pain medications, such as non-steroidal anti-inflammatory drugs (NSAIDs), are unaware about the related risks, according to a new survey. Almost half of the respondents (47%) said they do not know what NSAIDs are. Examples of the most commonly used NSAIDs include over-the-counter medications ibuprofen (brand names Advil® and Motrin®) and naproxen (Aleve®) as well as prescription medications diclofenac and celecoxib. Of those who said they are aware of NSAIDs, 42% do not realize that ibuprofen is part of the NSAID class of medicine.

About 58% of those surveyed recognize that there are risks associated with taking NSAIDs, but only 27% of people surveyed are aware of FDA's recommendation to use the lowest effective NSAID dose for the shortest duration possible. The survey also found that 62% of those people experienced at least one NSAID side effect.

More than 1,000 adults in the US participated in the "Understanding America's Pain: Identifying How Americans Experience and Manage Pain" survey. Consumers should consult with their health care provider to become more informed about how to safely take pain medications, note the preparers of the survey.

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DEA to Hold Next National Prescription Drug Take-Back Day in April

Drug Enforcement Administration (DEA) has announced another opportunity for consumers to dispose of unneeded and expired prescription drugs during the 11th DEA National Prescription Drug Take-Back Day, which will be held April 30, 2016. On this day, from 10 AM to 2 PM, thousands of collection sites will be available across the country to accept unneeded prescription drugs, including controlled substances, for safe and legal disposal. To date, DEA's Take-Back Day initiative has collected a combined total of more than 5.5 million pounds (over 2,750 tons) of unneeded medications, helping to prevent diversion, misuse, and abuse of the drugs. More information about safely disposing of medications at home and finding a permanent local drug disposal program is available in the Dispose Safely section of the AWARxE Prescription Drug Safety website.

FDA Warns Consumers About Fraudulent Drug and Supplement Products Sold at Nontraditional Venues

Food and Drug Administration (FDA) warns consumers about fraudulent dietary supplements and nonprescription drug products imported and sold at

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ethnic or international stores, flea markets, swap meets, or online. People who prefer to shop at nontraditional places are targeted by health scammers, indicates Cariny Nunez, MPH, a public health advisor in the Office of Minority Health at FDA. Advertisers use the word "natural" to attract certain groups of people, but that word does not indicate a product is safe or that it is free of hidden drug ingredients, indicates the FDA Consumer Update. Many products may be contaminated or contain potentially harmful chemicals or drug ingredients not listed on the label, according to FDA.

Under the law, companies that make dietary supplements are not required to obtain FDA approval before marketing their products. FDA's national health fraud coordinator, Gary Coody, RPh, indicates dietary supplements are "not substitutes for the drugs your health care professional prescribes." Coody suggests keeping your health care provider informed about what supplements you are taking, because they may interact in harmful ways with prescribed medicines or prevent a prescribed drug from working. Before buying an unproven product that has questionable claims, verify it is safe with your health care provider first. Consumers can visit FDA's website to see if action has already been taken against a company. Consumers can also inform FDA about bad reactions to a product so that they can be investigated and, if a product is deemed harmful, FDA can take appropriate action. To report a bad reaction or product defect, call the Consumer Complaint Coordinator in your state or report online to FDA's MedWatch program.

Over 200 Health Centers Awarded Funding to Treat Opioid Abuse in Underserved Communities

United States Department of Health & Human Services (HHS) has announced that 271 health centers in 45 states, the District of Columbia, and Puerto Rico have been granted $94 million in Affordable Care Act funding to improve and expand substance abuse services, with a specific focus on treatment of opioid use disorders in underserved populations. The funding, administered by the HHS Health Resources and Services Administration (HRSA), will support efforts to screen more patients for substance use disorders, connect more patients to treatment, and expand patient access to medication-assisted treatment for opioid use and other substance use disorder treatment, notes the HHS news release. The funding will also offer health professionals training and educational resources to make informed prescribing decisions.

Visit the HRSA website for a list of each state's grantees and award amounts.

National Poison Prevention Week Promotes Safe Medication

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Storage

The Poison Prevention Week Council aims to educate both children and adults about the prevention of unintentional poisonings and accidental exposures around the home. This year's National Poison Prevention Week, which runs through March 26, 2016, focuses on preventing accidental medicine ingestions by young children. The *Up and Away and Out of Sight* campaign reminds adults that storing medicines safely is an important part of preventing poisonings in the home.

The AWAR$_X$E website has advice on properly storing medications to prevent accidental ingestion by young children in the Secure Storage section. The AWAR$_X$E website also has a Drug Disposal Locator Tool that provides locations of permanent drug disposal sites in the US. Safely disposing of unwanted medications can help prevent exposing young children to accidental ingestion.

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Opioid painkillers to carry new boxed label warning

It's part of an effort to stem rising deaths from abuse and overdose

03/23/2016 | ConsumerAffairs | Health (https://www.consumeraffairs.com/news_index/health.html)

By Mark Huffman

Mark Huffman has been a consumer news reporter for ConsumerAffairs since 2004. He covers real estate, gas prices and the economy and has reported extensively on negative-option sales. He was previously an Associated Press reporter and editor in Washington, D.C., a correspondent for Westwoood One Radio Networks and Marketwatch. Read Full Bio→ (https://www.consumeraffairs.com/about/staff/mark-huffman/)

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The Food and Drug Administration (FDA) has moved to stem the tide of opioid painkiller misuse, announcing

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(http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm) class-wide safety label changes for immediate-release opioid drugs.

The new regulations call for a boxed warning that outlines the potential dangers – misuse, abuse, addiction, and overdose, which can be fatal.

The agency said the move is an attempt to thread the needle – dealing with the mounting misuse of these powerful drugs while leaving physicians enough leeway to provide patients with needed relief from pain.

The action comes on the heels of new guidelines (https://www.consumeraffairs.com/news/cdc-releases-guidelines-in-hopes-of-curbing-opioid-prescriptions-031616.html) from the Centers for Disease Control and Prevention (CDC) that ask doctors to limit the prescribing of opioid painkillers. Dr. Tom Frieden, director of the CDC, said it is hoped that the recommendations for doctors will bring about “a culture shift for patients and doctors.”

The FDA's new plan requires a number of additional safety labeling changes, to include information about the risks the medications pose.

Epidemic levels

“Opioid addiction and overdose have reached epidemic levels over the past decade, and the FDA remains steadfast in our commitment to do our part to help reverse the devastating impact of the misuse and abuse of prescription opioids,” FDA Commissioner Robert Califf said in a statement. “Today’s actions are one of the largest undertakings for informing prescribers of risks across opioid products, and one of many steps the FDA intends to take this year as part of our comprehensive action plan to reverse this epidemic.”

Opioid drugs include many widely-prescribed painkillers, including oxycodone, hydrocodone, and morphine. They are generally divided into two categories – immediate-release products that are effective over a shorter time frame, and extended-release products, intended to be taken once or twice a day.

Warning for pregnant women

The new boxed warning on immediate release opioid analgesics will include a precaution that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), a potentially life-threatening condition in newborns.

Some illegal drugs, such as heroin and fentanyl, are also classified as opioid drugs. Some rural states, such as Maine and Indiana, where drug abuse has not been a problem in the past, have recently grappled with the misuse of these drugs, both legal and illegal. Overdoes deaths (https://www.consumeraffairs.com/news/more-than-47000-drug-overdose-deaths-last-year-122115.html) from these drugs spiked 14% in 2014.

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Centers for Disease Control and Prevention
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CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Recommendations and Reports / March 18, 2016 / 65(1);1–49

On March 15, 2016, this report was posted as an MMWR *Early Release on the* MMWR *website (http://www.cdc.gov/mmwr* (http://www.cdc.gov/mmwr)*).*

Please note: *An erratum has been published for this report. To view the erratum, please click here.*

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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 (http://stacks.cdc.gov/view/cdc/38025)) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html (http://www.cdc.gov/drugoverdose/prescribing/resources.html)) with additional tools to guide clinicians in implementing the recommendations.

Introduction

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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 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

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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 (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 (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 (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 (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 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 (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 (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

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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 (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 (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 (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

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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 (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 (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 (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 (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

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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.

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 (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 (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 (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 non-pregnant 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 (http://buprenorphine.samhsa.gov/bwns_locator)); SAMHSA's Opioid Treatment Program Directory (http://dpt2.samhsa.gov/treatment/directory.aspx (http://dpt2.samhsa.gov/treatment/directory.aspx)); SAMHSA's Provider Clinical Support System for Opioid Therapies (http://pcss-o.org (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 (http://pcssmat.org)), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

Conclusions and Future Directions

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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 (http://stacks.cdc.gov/view/cdc/38025)), additional resources such as fact sheets (http://www.cdc.gov/drugoverdose/prescribing/resources.html (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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* 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.

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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

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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).

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
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.
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 ≥8,000 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 dosages ≥20 MME/day were associated with increased odds of road trauma among drivers.

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
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							

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
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).
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.

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
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.
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

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Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4

Opioid	Conversion factor*
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.

BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

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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

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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.

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Obama Will Ask For More Than $1 Billion To Combat Opioid Epidemic

The administration's proposal focuses on expanding treatment for abuse and providing access to the so-called overdose antidote naloxone.

The New York Times: Obama Seeks More Than $1 Billion To Fight Opioid Abuse

The Obama administration said on Tuesday that it would ask Congress to spend an additional $1.1 billion next year to combat a growing epidemic of prescription painkiller and heroin abuse. Almost half of the new money would be used to expand treatment facilities, which are in short supply in much of the nation. (Harris, 2/2)

The Washington Post: White House Seeks Nearly $1.2 Billion For Drug Prevention, Treatment, Overdose Response

The centerpiece of the proposal is $1 billion in mandatory funding over two years to expand access to treatment for prescription drug abuse and heroin use, $920 million of which would go to the states. Another $500 million, some of which is a continuation of existing funds, would support work by the departments of Health and Human Services and Justice to expand not just treatment but access to the overdose-reversal drug naloxone, and support targeted enforcement activities. (Eilperin, 2/2)

USA Today: White House Proposes New Funding For Heroin, Prescription Opioid Abuse

President Obama will seek an extra $1.1 billion to pay for drug treatment for people addicted to opioid medications and heroin, which the White House says kills more people than automobile crashes, officials said Tuesday. This funding includes $920 million to support cooperative agreements with states to expand access to medication-assisted treatment for opioid use disorders [and] $50 million in National Health Service Corps funding to expand access to about 700 substance use treatment providers. (O'Donnell, 2/2)

NPR: White House Proposes $1 Billion Fund To Combat Opioid Abuse

The White House is proposing more than $1 billion in new funding to fight heroin and opioid drug abuse. (Horsley, 2/2)

Meanwhile, lobbying is already ramping up for the president's other funding request from this week —

STAT: No Guarantees In Congress For Cancer Moonshot Funding, But Lobbying Is Underway

Congressional Republicans said on Tuesday that they're open to boosting federal funding for cancer research, as the Obama administration proposed the day before. But they aren't willing to simply rubberstamp the $755 million that the White House is asking for in the next fiscal year. (Scott, 2/2)

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The New York Times | http://nyti.ms/206SIGP

POLITICS

Obama Seeks More Than $1 Billion to Fight Opioid Abuse

By GARDINER HARRIS FEB. 2, 2016

WASHINGTON — The Obama administration said on Tuesday that it would ask Congress to spend an additional $1.1 billion next year to combat a growing epidemic of prescription painkiller and heroin abuse.

Almost half of the new money would be used to expand treatment facilities, which are in short supply in much of the nation.

“Opioid abuse and overdoses have hurt families from across this nation,” Sylvia Mathews Burwell, the secretary of health and human services, said in a news conference. “My home state of West Virginia has felt the cost almost more than any other.”

The other half of the money would go to programs intended to prevent prescription drug overdoses, crack down on illegal sales, and improve access to naloxone, a drug that can rescue those who have overdosed.

The announcement reflected the administration’s growing concerns about one of the few public health epidemics to substantially worsen during President Obama’s tenure. Opioids, which include prescription painkillers and heroin, were involved in 28,648 deaths in the United States in 2014, according to the Centers for Disease Control and Prevention. The drugs were a bigger killer than motor vehicle crashes.

The administration's efforts to combat the toll have been modest and largely ineffective. The epidemic has leveled off somewhat, but it shows no signs of abating, leading addiction experts to complain about Mr. Obama's response.

In Tuesday's news conference, Michael P. Botticelli, the director of the White House Office of National Drug Control Policy, defended the administration's actions.

"We have made some progress, but we need to do more, particularly as it relates to people accessing treatment," Mr. Botticelli said.

The administration hopes Congress will allocate $460 million next year for states to fund medication-assisted treatment for opioid abuse. While such programs are opposed by some officials and advocates, who say that the medications merely lead to another form of addiction, studies show that they are effective. States would receive funding based on the severity of the epidemic and the strength of their strategy to combat it.

In October, Mr. Obama issued a presidential memorandum requiring federal doctors to receive more training in prescribing opioids. In December, he signed a budget agreement that provided $400 million to fight the opioid epidemic, an increase of $100 million over the previous year.

Efforts to combat the opioid epidemic try to strike a balance between preventing addicts from getting inappropriate prescriptions and ensuring that cancer and surgical patients and others with severe pain can quickly receive the treatment they need.

Mr. Obama traveled to Charleston, W.Va., in October to hear from addicts, their parents and police officers about the epidemic's effect on communities, and he spoke in personal terms about how he could have been similarly affected himself.

"I did stuff, and I've been very honest about it," he said, referring to his admissions of illegal drug use in his youth. "So when I think about it, there but for the grace of God."

In his final State of the Union address last month, Mr. Obama mentioned "helping people who are battling prescription drug abuse and heroin abuse" as one of the few areas of common ground between Democrats and Republicans.

Senator Rob Portman, Republican of Ohio, who has sponsored legislation to combat the opioid epidemic, said in a statement Tuesday that "if the White House is serious about fighting the heroin epidemic," Mr. Obama would support his bill.

In response, Mr. Botticelli said that the administration would continue to work with lawmakers. "We agree with the intent of the legislation in that we really need a comprehensive response," he said.

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A version of this article appears in print on February 3, 2016, on page A13 of the New York edition with the headline: Obama Seeks $1.1 Billion to Help Fight Opioid Abuse.

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ENTERTAINMENT / MOVIES

For 'Prescription Thugs' filmmaker, drug abuse hit close to home

"You get addicted so quick," said Chris Bell, 43, who 10 years ago became addicted to painkillers after hip replacement surgery. (Mel Melcon / Los Angeles Times)

By **Jeffrey Fleishman · Contact Reporter**

JANUARY 22, 2016, 3:30 AM

While making a documentary on pharmaceutical companies and prescription drug abuse, Chris Bell was drinking heavily and trolling urgent-care clinics for Xanax in an unraveling of addiction and delusion similar to the slide that had killed his brother years earlier.

Bell's life was a lie and an irony: a filmmaker crusading against Big Pharma, he was an addict who exposed in others the scourge he kept hidden. His documentary, "Prescription Thugs," which opens

Friday, is a man's dark venture into an epidemic that highlights the nation's low tolerance for pain, a powerful drug lobby, lax government oversight and an American culture that craves quick fixes and escapism.

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The movie is less a revelation than a perceptive primer on a prescription drug market that has reached into schools, nursing homes, inner cities, suburbia and Midwestern hamlets where abuse of OxyContin and other prescribed opioids have led to increased heroin use in what Bell calls the United States of addiction. The film's list of victims include Whitney Houston, Michael Jackson, football players, professional wrestlers and a Minnesota mother hooked on her daughter's Adderall.

"When you think of a drug addict," Bell notes in the film, "you don't think of a housewife with four kids."

"No," says the mother sitting in her kitchen, "but we're everywhere."

There are about "100 million people in this world who are on psyche [anxiety] meds," Bell said in a recent interview. "They're showing up at work, and who knows where their head is at. And these drugs aren't even proven to be effective. You have 2 million people in the U.S. alone checked out on pain medicine, walking around, driving the same streets as your kids. No one's making a stink about it. Where are the people going, 'I am outraged'"?

The United States has 5% of the world's population but consumes 75% of its prescription drugs. Every day, at least 44 people in America die of painkiller overdoses, and an additional 7,000 end up in emergency rooms. In the last decade, according to the film, 11 of the largest drug corporations made $711 billion; in 2013 drug companies spent nearly $226 million and marshaled more than 1,400 lobbyists to influence Congress.

"It's the worst epidemic we face in America today," said Richard Taite, CEO of Cliffside Malibu, a drug rehabilitation center that caters to celebrities. "Every 19 minutes someone dies in this country of an accidental overdose."

“

When you think of a drug addict you don't think of a housewife with four kids.

— Chris Bell, director of "Prescription Thugs"

Bell's is a troubling personal story echoing inside a larger American drama where big business intersects with healthcare. This is a country, after all, where one can go to a medicine cabinet and fill a hand with a kaleidoscope of colors for pain, anxiety, sexual dysfunction, stress and other problems. There's even a version of Prozac for dogs.

Raised in Poughkeepsie, N.Y., Bell, a husky man with a shaved head and the fading lines of a bodybuilder, was an athlete who once squat-lifted 675 pounds. His brother Michael went into professional wrestling, taking the name Mad Dog and soothing his injuries with an addiction to pain medication.

Bell and his father intervened, but Michael, the subject of his brother's 2008 film about steroid abuse, "Bigger, Stronger, Faster," had unhealthy potassium levels and died of unknown causes in a rehab center.

Michael is the film's lost soul, a man who, when measured against boyhood dreams of fame, failed in the battered rings of second-rate arenas. His predicament and drift into drug abuse allows "Prescription Thugs" to transcend polemics in favor of discerning the dangers that arise when human frailties collide with potent painkillers such as OxyContin, Vicodin and Percocet.

"You get addicted so quick," said Chris Bell, who 10 years ago, when he was 33, became addicted to painkillers after hip replacement surgery. He later shifted to alcohol and Xanax. "You don't even see it happening. One day you take two pills every four hours, and the next day you have to take it. Over the course of a month, you become addicted. It just snowballs."

Bell's style is reminiscent of Michael Moore and Morgan Spurlock ("Super Size Me"), everyman filmmakers ferreting through suspicions in a ride-along exploration to fix out-of-whack systems. But Bell is more earnest than self-righteous; he's perplexed by the prescription drug culture and hunts for legitimate answers. His film would have benefited, though, by comments from drug companies (they refused to cooperate) and a more incisive look at how doctors, often unaware of the effects of opiates, became complicit with Big Pharma, most notably in the "pill mills" Florida has clamped down on in recent years.

"I started realizing that I wasn't getting the full picture," Gwen Olsen, a former pharmaceutical representative, says in the film. "The information was being presented to me through rose-colored glasses so that I would present it to physicians through rose-colored glasses. I was being encouraged to misinform people, and if I was misinforming doctors, that meant doctors were misinforming patients."

In 2007, Purdue Pharma, which makes OxyContin, agreed to pay $600 million in fines and damages stemming from criminal and civil charges that executives misled patients, regulators and doctors about the drug's addictive qualities. The Food and Drug Administration has recommended restrictions on how doctors prescribe painkillers, but Congress has been criticized by drug-abuse prevention groups for not backing stricter oversight on the potency of painkillers and on how pharmaceuticals are priced and marketed.

During the making of his documentary, Bell, who on a regime of heavy drinking and diluting his hangovers with Xanax, interviewed Cliffside Malibu's Taite, a former addict who founded the facility. The interview lasted three hours, and Bell said he feared that a life of running to emergency-care clinics for a fix would ruin him.

"The whole time during the interview I was thinking I wish I could come here," Bell said. "I was probably drunk when I interviewed him. But I was also kind of trapped in this situation. The movie was rolling, it was going on. So it wasn't like, 'Hey, everybody, time out. Let me fix this drug problem.'"

After the interview, the two drove to Taite's rehab center to discuss the film.

"Some people just walk into your life and just flip it around," said Bell. "He [Taite] wanted me to come in his car with him. He's got this nice Mercedes. We're speeding down the hill in Malibu from his nice house. I'm like, this guy's out of his mind, at first. He's like, errrrrr, and he pulls over the car ... and he goes, 'Listen, your brother dying is what made you a drug addict. We can fix this. We can fix anything."

Bell said he wasn't ready to be fixed that day but he did eventually get clean.

"I was lost," he said. "We all get lost."

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A version of this article appeared in print on January 31, 2016, in the Arts + Entertainment section of the Los Angeles Times with the headline "Filmmaker's life too close to subject - Bell was an addict while he made `Prescription Thugs' documentary" — Today's paper | Subscribe

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For Teenagers, Adult-Sized Opioid Addiction Treatment Doesn't Fit

By Heidi Benson | NPR (http://www.npr.org/)
Friday, January 15, 2016

Trina Dalziel / Illustration Works/Getty Images

Addicted to prescription painkillers after a high-school sports injury, Cameron Burke moved on to heroin, which was cheaper and more easily accessible. His parents tried everything, more than once sending him out of state for treatment.

"It was never enough," Jennifer Weiss-Burke of Albuquerque, N.M., told a local TV reporter last year. "Thirty days here, 30 days there, maybe detox for five days. It was never long-term, and that's what he needed. Recovery from heroin addiction requires long-term treatment."

During the course of two years, Cameron would seem to recover, only to relapse. In 2011, Weiss-Burke found him dead in his room.

Weiss-Burke turned her grief into action, lobbying for state legislation that would require all medical practitioners to complete a course in addiction and pain management when their licenses are renewed, and pushing for the creation of Serenity Mesa, a long-term treatment center for youths in Albuquerque that opened its doors last year.

Although drug addiction was described as a disease as long ago as the 1700s, addiction medicine has been neglected by the medical system, according to a 2012 study (http://www.casacolumbia.org/newsroom/press-releases/addiction-medicine-report-1) by the National Center on Addiction and Substance Abuse (http://www.casacolumbia.org/) at Columbia University.

"While a wide range of evidence-based screening, intervention, treatment and disease management tools and practices exist, they are rarely employed," the report found.

Lack of effective treatment in the teen years can blight an entire life. "When substance use disorders occur in adolescence, they affect key developmental and social transitions, and they can interfere with normal brain maturation," the National Institute on Drug Abuse reported in 2014 (http://www.drugabuse.gov/publications/principles-adolescent-substance-use-disorder-treatment-research-based-guide/acknowledgements). "These potentially lifelong consequences make addressing adolescent drug use an urgent matter."

The first line of defense is primary health care, according to Dr. David E. Smith, an addiction medical specialist who founded the Haight Ashbury Free Clinics in San Francisco. To increase the number of physicians trained to diagnose and treat addiction and to recognize early signs of adolescent substance use disorder, Smith would like to see addiction medicine mandatory in medical school.

"Engaging people earlier in their addiction improves their chances of recovery and overall better health," Smith said. "Meanwhile, costs for the health care system are dramatically reduced."

A youth-centered approach

Deaths from heroin overdose in all age groups doubled from 2010 to 2012, according to a 2014 study (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6339a1.htm) from the Centers for Disease Control and Prevention (http://www.cdc.gov/).

In response, communities are seeking new strategies to treat addiction and speed access to care. That includes trying to meet the unique needs of youth after years of addiction treatments geared to adults. Serenity Mesa is one of those youth-centered efforts.

Such programs offer evidence-based treatment, types of therapy that have shown scientifically validated results. They include: Screening, Brief Intervention and Referral to Treatment (SBIRT (http://www.samhsa.gov/sbirt)), a preventative protocol for early detection;

Motivational Interviewing (http://www.motivationalinterviewing.org/), a counseling approach that guides individuals to set goals; and Functional Family Therapy (FFT (http://www.fftllc.com/)), which treats teens in a family setting.

While public policy and social attitudes have begun to catch up with science, treatment for teens lags far behind. The 2012 National Survey on Drug Use and Health (http://archive.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/Index.aspx) found that 90 percent of drug-addicted youth ages 12 to 17 get no treatment at all.

"Twenty years ago, we were just beginning to focus on evidence-based treatment for drug-involved youth," says Dr. Holly Waldron, a senior scientist at the Oregon Research Institute who studies adolescent behavior. "Historically, interventions for addictive behaviors have included confrontational approaches, but we've learned that confrontation does not produce effective change in substance-abuse behavior."

Instead, Waldron and her colleagues favor evidence-based interventions including functional family therapy and cognitive behavioral treatments for adolescent substance abuse.

"We're actively involved in taking these treatments to community settings," she said. "If we can connect kids to treatment, we know they'll improve."

Most health insurers now require proof that addiction programs use evidence-based treatment, a sign of efficacy. And since the 2010 Affordable Care Act expanded the Mental Health Parity and Addiction Equity Act (http://www.dol.gov/ebsa/mentalhealthparity/), more adolescents have better access to insurance coverage.

Yet, teenagers rarely enter rehab voluntarily. "Clinicians are dependent on systems like juvenile justice and the schools to get teens connected to treatment," Waldron said.

Making family therapy work

Some treatments for teens with substance use disorder engage the whole family. Functional Family Therapy uses a dozen or more one-hour sessions to defuse negativity, then teach skills training in family communication, parenting, problem solving and conflict management. Later sessions strengthen a family's capacity to navigate community resources, which can prevent relapse.

Waldron is also testing the effectiveness of delivering therapy to New Mexico's scattered rural population via videoconference. Privacy is one benefit of videoconferencing, Waldron noted. "If you live in a small town and your car is parked in the lot at the mental health clinic, everybody knows that's your car," she says. "In Native American communities, if you go to a tribal counselor, it's more likely people will know your business." So talking at home over the Internet offers greater confidentiality. "That's important to families."

Videoconference dynamics can be complicated, however. "It's harder to discern over a video stream how people are responding," Waldron said. "If they're quiet, if they're becoming emotional, we might not see cues."

To compensate, "the therapist has to do verbal check-ins with each member of the family," Waldron explained. She posed an example, meant to invite participants to describe their feelings: "I hear you being quiet. Does this topic hit close to home for you all?"

The study ran through November, and Waldron said preliminary data shows the online treatment is as effective as treatment delivered face-to-face at home. If, as Waldron expects, the final data shows measurably improved outcomes such as a decline in drug use and better family dynamics, she hopes that the results can be reproduced elsewhere.

"It will mean that it's possible to get the best treatment to kids who would never have access otherwise," she said.

Treating addiction with medication

At HealthRIGHT 360, a nonprofit in San Francisco created in 2011 when the Haight-Ashbury Clinic merged with the local residential center Walden House, treatment can include individual or group therapy, family therapy and mindfulness meditation. All can be used in combination with medications (http://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat) such as methadone.

While methadone can be effective in addiction recovery for adults, it is not well-suited for teens, according to Dr. Ako Jacintho, HealthRIGHT 360's medical director.

Methadone is highly regulated and can only be administered at methadone clinics. The drug must be taken daily, so trips to and from the clinic, often far from home and work, can be especially difficult for teens. And, Jacintho noted, teens may encounter other addicts at the clinic, as well as opportunities to buy drugs.

The maintenance drug often prescribed for teens is Suboxone (http://www.suboxone.com/), a combination of buprenorphine (http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine), an opiate substitute that eliminates craving, and naloxone (http://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone), which blocks euphoric effects. Suboxone doesn't cause drowsiness, and, the equilibrium it provides can make it easier to identify and treat co-occurring disorders like depression or anxiety. The dosage is eventually tapered.

A 2014 Yale School of Medicine study (http://archinte.jamanetwork.com/article.aspx?articleid=1916910) showed that ongoing maintenance treatment with Suboxone is more effective than detoxification and abstinence alone.

"There is strong data on Suboxone," Jacintho said. When combined with behavioral therapy, he says, Suboxone can reduce relapses and promote recovery. And, it can be prescribed and given by a trained and certified primary care physician — in a doctor's office, rather than a clinic, Jacintho noted. "We get better outcomes when we change from methadone clinics to primary care."

As education and training around addiction improve, Smith hopes more attention will be paid to the people he calls "role models of recovery."

Vitka Eisen, CEO of HealthRIGHT 360, is one of them. She was a heroin addict from age 19 to 25, until the Haight Ashbury Free Clinic and Walden House put her back on her feet. Three college degrees later, including a doctorate in education from Harvard University, she's proud to call herself "a 1987 Walden House graduate."

Having been homeless during periods of her addiction, Eisen knows the difficulties teenage addicts may face.

"It's hard for these kids to get off heroin, because they lead such challenging lives. If a kid's using heroin, there's a high likelihood of trauma exposure" from school, work or family life, she said. "Drugs may seem like the best thing in their life, the thing that helped them deal with how they experience the circumstances of their lives."

The most effective treatments for teens, she says, build on the individual's strengths while empowering them to better handle stressful circumstances.

And these treatments can gain in effectiveness when used in combination with medications such as Suboxone.

Jacintho also says there soon will be greater acceptance of integrated treatment for teens. "The data is going to show positive health outcomes," he predicted.

Smith is cautiously optimistic, too. "Every interface with a health care professional should give a consistent message," he said. "We care."

This story was produced by Youth Today (http://www.youthtoday.org/), the national news source for youth-service professionals, including child welfare and juvenile justice, youth development and out-of-school-time programming.

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REVIEW ARTICLE

Dan L. Longo, M.D., *Editor*

Relationship between Nonmedical Prescription-Opioid Use and Heroin Use

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THE NONMEDICAL USE OF PRESCRIPTION OPIOIDS IS A MAJOR PUBLIC health issue in the United States, both because of the overall high prevalence and because of marked increases in associated morbidity and mortality.[1] In 2014, a total of 10.3 million persons reported using prescription opioids nonmedically (i.e., using medications that were not prescribed for them or were taken only for the experience or feeling that they caused).[2] Emergency department visits involving misuse or abuse of prescription opioids increased 153% between 2004 and 2011, and admissions to substance-abuse treatment programs linked to prescription opioids more than quadrupled between 2002 and 2012.[3,4] Most troubling, between 2000 and 2014 the rates of death from prescription-opioid overdose nearly quadrupled (from 1.5 to 5.9 deaths per 100,000 persons) (Fig. 1).

The pattern of nonmedical use of prescription opioids varies, from infrequent use once or twice per year to daily or compulsive heavy use and addiction. A key underlying characteristic of the epidemic is the association between the increasing rate of opioid prescribing and increasing opioid-related morbidity and mortality.[6-9] Pain has also been identified as a poorly addressed clinical and public health problem for which treatment with prescription opioids may play an important role.[10] Taken together, these trends suggest the need for balanced prevention responses that aim to reduce the rates of nonmedical use and overdose while maintaining access to prescription opioids when indicated.

In response to these interrelated public health problems, federal, state, and other vested interests are implementing a variety of policies and programs aimed at curbing inappropriate prescribing.[1,6,11-16] These efforts include educating health professionals and the public about appropriate use, implementing prescription-drug monitoring programs, taking enforcement and regulatory actions to address egregious prescribing (e.g., eliminating "pill mills"), and developing prescription opioids that incorporate abuse-deterrent technologies.

Although more rigorous evaluation is needed, there are some indications that these initiatives are beginning to show some success. A recent study showed that the rate of opioid prescribing in the United States stabilized between 2010 and 2012, with some medical specialties showing declines in the rate of opioid prescribing after consistent increases for a number of years.[17] States and localities that took the most decisive action are seeing a decrease in the availability of prescription opioids coupled with a decline in the rate of deaths from overdose.[13-15] Using national data, the Centers for Disease Control and Prevention reported that there were 16,007 and 16,235 overdose-related deaths in 2012 and 2013, respectively, involving opioid analgesic agents, down from a peak of 16,917 deaths in 2011; however, the 18,893 deaths reported in 2014 suggest continued concerns.[5] An-

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other study showed that abuse of prescription opioids increased between 2002 and 2010 and then plateaued between 2011 and 2013.[18]

Coinciding with these efforts to reduce nonmedical prescription-opioid use and overdose are reports of increases in the rates of heroin use (including both injection and noninjection routes of administration) and deaths from heroin overdose. According to national surveillance data, 914,000 people reported heroin use in 2014, a 145% increase since 2007,[2] and mortality due to heroin overdose more than quintupled, from 1842 deaths in 2000 to 10,574 deaths in 2014.[5] Some researchers suggest that the very policies and practices that have been designed to address inappropriate prescribing are now fueling the increases in rates of heroin use and death.[16,18] This is the key question addressed in this review.

Some persons certainly use heroin when they are unable to obtain their preferred prescription opioid; however, whether the increases in heroin trends in the overall population are driven by changes in policies and practices regarding prescription opioids is much less clear. As an alternative explanation, we explore the complexity and reciprocal nature of this relationship and review the pharmacologic basis for heroin use among people who use prescription opioids nonmedically, the patterns of heroin use among people who use prescription opioids nonmedically, the current trends in heroin use and their correlates, and the effects on heroin use of policies aimed at curbing inappropriate prescribing of opioids. A clearer understanding of these relationships will help to guide clinical practice and public health interventions and avoid the error of simply shifting the problem from one drug to another.

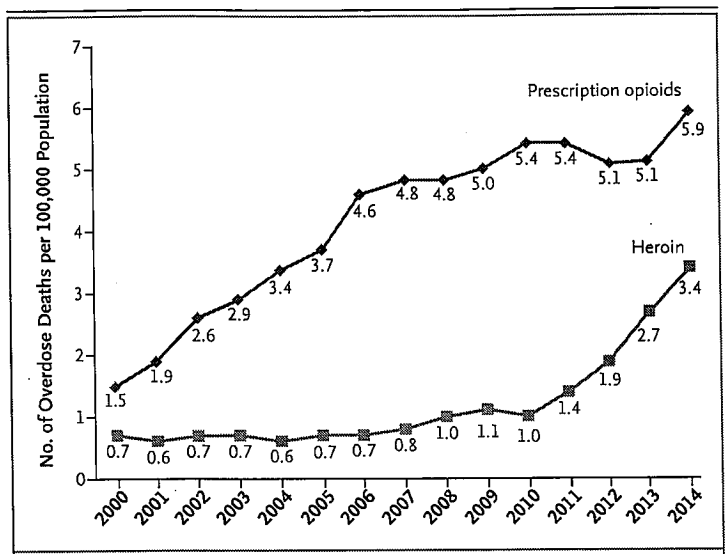

Figure 1. Age-Adjusted Rates of Death Related to Prescription Opioids and Heroin Drug Poisoning in the United States, 2000–2014.
Data are from the Centers for Disease Control and Prevention.[5]

PHARMACOLOGIC SIMILARITIES OF HEROIN AND PRESCRIPTION OPIOIDS

Heroin is pharmacologically similar to prescription opioids. All these drugs produce their action through endogenous opioid systems that regulate a wide range of functions through three major types of G-protein–coupled receptors: mu, delta, and kappa, with particularly potent agonist activity at the mu receptor and weak activity at the delta and kappa receptors.[19,20] Mu-receptor activation by an agonist such as heroin or a prescription opioid triggers a complex cascade of intracellular signaling events, which ultimately lead to an increase in dopamine release in the shell of the nucleus accumbens.[19,20] The resulting burst of dopamine in this critical area of the reward circuitry becomes strongly coupled with the subjective "high" that is caused by drugs of abuse.[21]

The abuse liability of an opioid is determined by multiple factors, including the lipophilicity of the drug (i.e., its ability to cross the blood–brain barrier rapidly), its binding affinity for the mu receptor, and various pharmacokinetic and physicochemical characteristics (e.g., the ease with which it can be abused by means of injection and insufflation routes of administration).[22,23] Thus, although prescription opioids and heroin both have the potential to use similar pharmacologic mechanisms to induce euphoria (or analgesia), different opioid molecules have different euphorigenic properties and withdrawal-syndrome patterns.

These factors could also influence the potential for abuse of the various opioid drugs, because opioid drug–taking behavior is likely to be influenced by the balance between positive and negative subjective ratings engendered by a specific opioid. For example, a study involving heroin abusers showed that the reinforcing effects of oxycodone were similar to those produced by

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morphine or heroin, but unlike morphine or heroin, oxycodone produced no "bad" effects in the participants in the study.[23] Similar considerations may help explain why several prescription opioids — such as hydromorphone, fentanyl, morphine, and oxycodone — have a potential for abuse that is similar to, and in some cases even higher than, the potential for abuse with heroin.[22,23] Finally, these differential properties and effects are likely to interact with interindividual variability in powerful, complex, and incompletely predictable ways, so that some persons who abuse prescription opioids could find heroin less rewarding than prescription opioids, similarly rewarding, or even more rewarding.[24,25]

HEROIN USE AMONG PEOPLE WHO USE PRESCRIPTION OPIOIDS NONMEDICALLY

Studies that address the patterns of heroin use in nonmedical users of prescription opioids are mostly observational and descriptive (i.e., nonexperimental). Thus, conclusions about cause and effect are uncertain. Yet, certain consistent findings of a positive association between nonmedical use of prescription opioids and heroin use are highly suggestive and plausible, given the common pharmacologic principles described above.

Using national-level data, Becker et al. found that heroin users were 3.9 times as likely to report nonmedical use of opioids in the previous year, and 2.9 times as likely to meet the criteria for abuse or dependence on opioids, as persons who did not use heroin.[26] Grau et al. found that nonmedical use of multiple opioids was associated with transitioning to heroin.[27] Similarly, Muhuri et al. found that the incidence of heroin use among people who reported prior nonmedical use of prescription opioids was 19 times as high as the incidence among persons who reported no previous nonmedical use.[28] Additional studies involving persons from various geographic, economic, and drug-using backgrounds have shown similar associations.[29-33]

A limited number of small studies examined the sequence of and trajectories from nonmedical use of prescription opioids to heroin use. In 2003, Siegal et al. were among the first to suggest the pathway from nonmedical use of opioids to heroin use.[34] They found that in Ohio, 50% of persons 18 to 33 years of age who had recently begun using heroin reported having abused opioids, primarily OxyContin, before initiating heroin use.[34] A larger study involving young urban people who used injected heroin in New York and Los Angeles in 2008 and 2009 showed that 86% had used opioids nonmedically before using heroin.[35] Similar studies conducted in San Diego, Seattle, and New York showed that 40%, 39%, and 70% of heroin users, respectively, reported that they had used prescription opioids nonmedically before initiating heroin use.[36-38]

Trajectory analysis of patterns of nonmedical use of prescription opioids suggests that persons most often start with oral nonmedical use of opioids. They move to more efficient routes of administration, such as insufflation, smoking, or injection, as tolerance to opioids develops and it becomes more costly to maintain their abuse patterns. By the time they initiate heroin use, usually through contact with drug users, sexual partners, or drug dealers, they view heroin as reliably available, more potent, easier to manipulate for nonoral routes, and more cost-effective than prescription opioids.[34-36,38-41]

In an effort to examine whether the findings from these small studies were consistent with findings in the broader population of nonmedical users, the sequence regarding initiation of use was assessed with the use of both treatment-population data and general-population data. Among heroin users entering substance-abuse treatment programs, Cicero et al. found significant shifts in the pattern of the first opioid used by those with recent onset as compared with those started using opioids 40 to 50 years ago.[41] Among persons who began their opioid use in the 1960s, more than 80% reported that their first opioid was heroin; conversely, in the 2000s, a total of 75% of users initiated opioid use with prescription opioids.[41]

Using national-level, general-population data, Jones found that in the period from 2008 through 2010, among people who used both prescription opioids for nonmedical reasons and heroin during the previous year, 77.4% reported using prescription opioids before initiating heroin use.[42] Similarly, Muhuri and colleagues found that 79.5% of persons who recently began using heroin had used prescription opioids nonmedically before initiating heroin use.[28] Both studies showed that heroin use was most common among persons who were frequent users of

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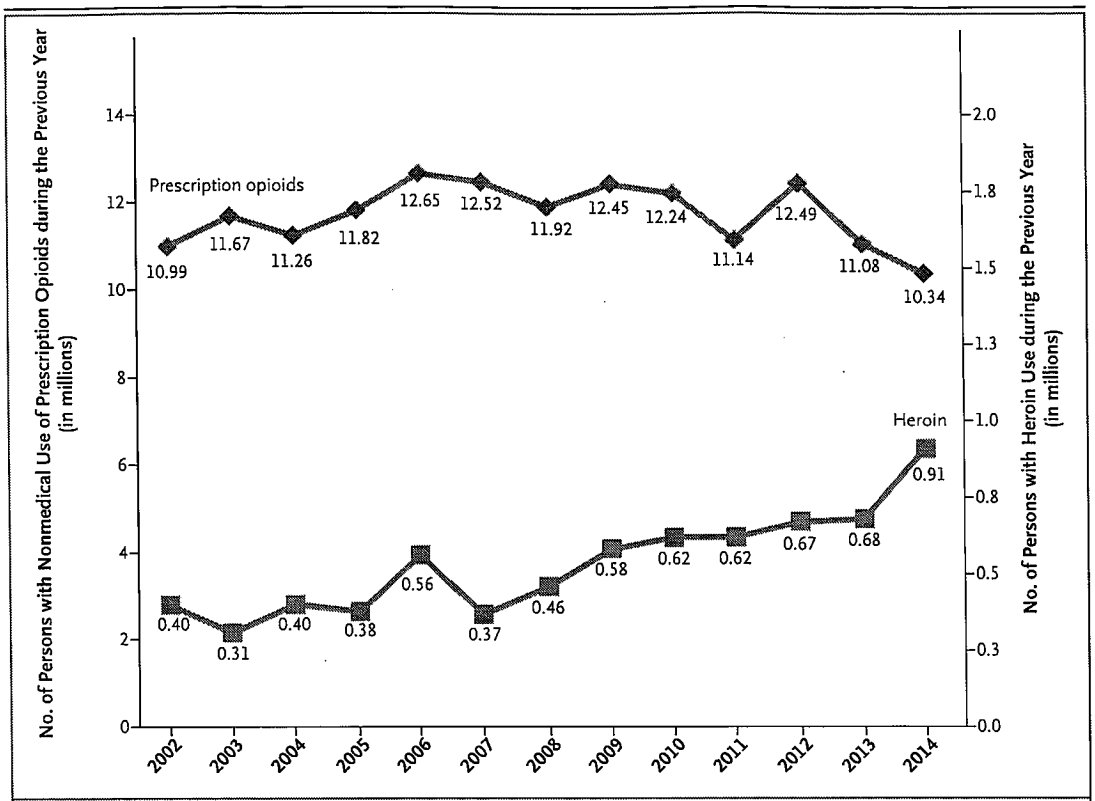

Figure 2. Nonmedical Use of Prescription Opioids and Heroin during the Previous Year among Noninstitutionalized Persons 12 Years of Age or Older, 2002–2014.

Data are from the Center for Behavioral Health Statistics and Quality.[2]

nonmedical opioids.[28,42] A recent study with data through 2013 showed that prescription-opioid abuse or dependence was associated with a likelihood of heroin abuse or dependence that was 40 times as great as the likelihood with no prescription-opioid abuse or dependence, even after accounting for sociodemographic, geographic, and other substance abuse or dependence characteristics.[43] These studies suggest a clear link between nonmedical use of prescription opioids and heroin use, especially among persons with frequent nonmedical use or those with prescription-opioid abuse or dependence.

CURRENT TRENDS IN HEROIN USE AND THEIR CORRELATES

Heroin use has been increasing in the United States for the past 10 years, especially since 2007 (Fig. 2), an increase that has occurred in the context of broad use of multiple substances.[43] As seen in Table 1, in addition to the 138.9% increase in heroin use among nonmedical users of prescription opioids between the period of 2002–2004 and the period of 2011–2013, heroin use increased 97.5% among nonmedical users of other prescription drugs (stimulants, tranquilizers, and sedatives), 87.3% among users of cocaine, 57.3% among people who binge drink, and 45.4% among marijuana users.[43] Moreover, heroin users increasingly report abuse of or dependence on other substances.[43] There have also been shifts in the demographic characteristics associated with heroin use; the rate has increased particularly steeply among persons 18 to 25 years of age, and increases have been observed in both large urban areas and other geographic regions, in both sexes but more among women than among men, and in all races and ethnic groups but more among non-Hispanic whites than among others.[43]

Table 2 shows the sociodemographic, geographic, and substance-use groups that are associated with the greatest risk of heroin abuse or dependence during the previous year in the period of 2011–2013.[43] Other studies have shown

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Table 1. Annual Average Rates of Heroin Use during the Previous Year, According to Substance-Use Characteristic and Time Period, in the United States, 2002–2013.*

Characteristic	2002–2004		2005–2007		2008–2010		2011–2013	Percent Change		P Value†
	Rate (95% CI)	P Value	Rate (95% CI)	P Value	Rate (95% CI)	P Value	Rate (95% CI)	2008–2010 to 2011–2013	2002–2004 to 2011–2013	
								percent		
Binge drinking during previous month	3.7 (3.0–4.5)	0.001	4.1 (3.3–5.1)	0.02	5.2 (4.3–6.3)	0.38	5.8 (4.4–6.4)	12.30	57.3	0.006
Marijuana use during previous year	11.6 (9.5–14.1)	0.004	13.2 (10.6–16.4)	0.07	14.4 (12.6–16.6)	0.16	16.9 (14.4–19.8)	16.70	45.4†	0.004
Cocaine use during previous year	48.9 (40.2–59.3)	<0.001	57.6 (45.9–72.2)	<0.001	68.3 (55.4–83.9)	0.02	91.5 (78.2–106.8)	34.00	87.3†	<0.001
Nonmedical use of prescription opioid during previous year	17.8 (14.3–22.0)	<0.001	25.1 (19.9–31.7)	<0.001	34.0 (28.9–39.8)	0.048	42.4 (36.6–49.1)	24.80	138.9†	<0.001
Nonmedical use of other psychotherapeutic agent during previous year‡	23.1 (18.6–28.7)	<0.001	28.5 (23.1–35.1)	<0.001	41.6 (33.8–51.0)	0.48	45.6 (38.9–53.4)	9.70	97.5†	<0.001

* Data are from Jones et al.[43] The rate is per 1000 population in each analytic group. P values are for the comparison with the rate in the period of 2011–2013.
† The P values are for trend.
‡ Other psychotherapeutic agents included tranquilizers, sedatives, and stimulants.

that recent cohorts of heroin users entering treatment have been likely to be white, middle-class, and living in nonurban areas; this result mirrors the populations that have had the largest increases in rates of nonmedical use of prescription opioids since 2002.[2,41,42,44] These findings are generally consistent with those from a number of smaller studies.[34-40]

A key factor underlying the recent increases in rates of heroin use and overdose may be the low cost and high purity of heroin.[45,46] The price in retail purchases has been lower than $600 per pure gram every year since 2001, with costs of $465 in 2012 and $552 in 2002, as compared with $1237 in 1992 and $2690 in 1982.[45] A recent study showed that each $100 decrease in the price per pure gram of heroin resulted in a 2.9% increase in the number of hospitalizations for heroin overdose.[46] In addition, regions of the United States that are not typically centers for heroin distribution or availability have seen marked increases in recent years.[47,48]

In the context of marked increases in the rates of heroin use, it is important to note that only a small percentage of nonmedical users of prescription opioids initiate heroin use. Muhuri and colleagues found that 3.6% of nonmedical users initiated heroin use within 5 years after beginning nonmedical use of prescription opioids.[28] Jones et al. found that approximately 4.2% of persons who had used prescription opioids nonmedically during the previous year in the period of 2011–2013 also reported using heroin during the previous year.[43] Of note, given the large number of nonmedical users, even a small percentage who initiate heroin use translates into several hundred thousand new heroin users. Yet, taken in total, the available data suggest that nonmedical prescription-opioid use is neither necessary nor sufficient for the initiation of heroin use and that other factors are contributing to the increase in the rate of heroin use and related mortality.

EFFECTS OF OPIOID-PRESCRIBING INTERVENTIONS ON HEROIN USE

Multiple studies that have examined why some persons who abuse prescription opioids initiate heroin use indicate that the cost and availability of heroin were primary factors in this process. These reasons were generally consistent across

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time periods from the late 1990s through 2013.[34-41] Some interviewees made reference to doctors generally being less willing to prescribe opioids as well as to increased attention to the issue by law enforcement, which may have affected the available supply of opioids locally.[38,40] It should be noted that most of these studies were conducted before 2009 — a time when few policies targeting opioid prescribing were implemented.

It appears that the shift toward heroin use among some nonmedical users of prescription opioids was occurring before the recent policy focus on prescription-opioid abuse took hold. This observation is supported by data on heroin use reported to U.S. poison control centers that show increases starting in 2006,[18] as well as national surveillance data that show a rise in heroin use starting in 2007.[2] Similarly, a study examining hospitalizations for heroin overdose between 1993 and 2009 showed that the rate of such hospitalizations increased 69% between 1993 and 2006 and then rose more sharply, by 44%, between 2005 and 2009.[49] Furthermore, this study showed that these increases occurred in the context of continued increases in the rate of hospitalization for overdose of prescription opioids.

The results of the studies by Dart et al. and Cicero et al. suggest an association between the introduction of an abuse-deterrent formulation of OxyContin and increases in rates of heroin use.[16,18] Dart et al. found evidence that rates of heroin use increased after the introduction of the abuse-deterrent formulation, but they also reported that the rate of heroin use was increasing previously.[18] Cicero et al. found that a decrease in the rate of OxyContin abuse corresponded with an increase in the rate of heroin use over the 2 years after the introduction of the abuse-deterrent formulation.[16] However, in a follow-up study, Cicero and Ellis found that over the ensuing 18 months, the rates of OxyContin abuse no longer decreased whereas the rates of heroin use continued to increase.[50] Moreover, a separate study involving patients who were being screened for substance-abuse treatment showed no significant differences between the prevalence of heroin use before the introduction of the reformulation and the prevalence after the reformulated drug was available.[51]

Five recent quantitative studies provide additional insights into the relationship between opioid-prescribing policies and practices and heroin use and overdose. First was an analysis of deaths due to overdose in North Carolina be-

Table 2. Demographic and Substance-Use Characteristics Associated with Heroin Abuse or Dependence during the Previous Year in the United States, 2011–2013.*

Characteristic	Adjusted Odds Ratio (95% CI)	P Value
Sex		
Male	2.1 (1.4–3.0)	<0.001
Female	1.0	
Age group		
12–17 yr	0.3 (0.1–0.6)	0.001
18–25 yr	1.0	
≥26 yr	0.6 (0.4–0.9)	0.008
Race or ethnic group†		
Non-Hispanic white	3.1 (1.8–5.1)	<0.001
Other	1.0	
Geographic region of residence		
CBSA with ≥1 million persons	2.4 (1.5–3.6)	<0.001
Other	1.0	
Annual household income		
<$20,000	1.0	
$20,000–$49,999	0.5 (0.3–0.7)	0.001
≥$50,000	0.6 (0.3–0.9)	0.02
Insurance coverage		
No insurance	3.1 (2.2–4.3)	<0.001
Medicaid	3.2 (1.9–5.4)	<0.001
Private or other insurance	1.0	
Substance abuse or dependence in previous year		
None	1.0	
Alcohol	1.8 (1.2–2.9)	0.009
Marijuana	2.6 (1.5–4.6)	0.002
Cocaine	14.7 (7.4–29.2)	<0.001
Prescription opioid	40.0 (24.6–65.3)	<0.001
Other psychotherapeutic agent‡	1.6 (0.8–3.2)	0.22

* Odds ratios and 95% confidence intervals were calculated with the use of multivariable logistic-regression analyses. Data are from Jones et al.[43] CBSA denotes core-based statistical area.

† Race and ethnic group were based on survey respondents' self-classification of racial and ethnic origin and identification according to the classifications developed by the U.S. Census Bureau.

‡ Other psychotherapeutic agents included tranquilizers, sedatives, and stimulants.

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tween 2007 and 2013, which documented a shift toward an increasing risk of death due to heroin use.[52] However, the shift began in 2009, before changes such as the introduction of abuse-deterrent formulations of opioids were in effect.[52] The second study showed that heroin-related emergency department visits, hospital admissions, and overdose deaths in Wisconsin started to increase in 2007.[53] Furthermore, these increases in rates of heroin overdose were superimposed on continued increases in rates of prescription-opioid overdoses through 2012.[53]

The third study examined deaths from overdose in Florida through 2012.[13,54] Florida had a well-documented prescription-opioid problem.[54] Between 2010 and 2011, Florida instituted a series of major policy changes that were designed to reduce the inappropriate supply of prescription opioids. After these policies were implemented, prescriptions were curtailed and the rate of death from prescription-opioid overdose declined 27% between 2010 and 2012.[13,54] Moreover, these significant declines in prescription-opioid mortality were accompanied by an increase of only 60 deaths related to heroin, with the overall number of total deaths from overdose declining by 535 between 2010 and 2012.[13]

The fourth study, which examined opioid overdoses in New York, showed a 29% reduction in the rate of death from prescription-opioid overdose coupled with declines in the rates of overall and high-dose opioid prescribing in Staten Island, New York, in 2013 after the implementation of targeted and general public health initiatives, including a heavy focus on prescribing behaviors.[15] Importantly, these decreases were not offset by increases in mortality from heroin-involved overdose during the same time period.[15]

Finally, in an investigation of deaths related to heroin and prescription-opioid use in 28 states between 2010 and 2012, Rudd and colleagues found no association between declines in prescription-opioid–related mortality and increases in heroin-related mortality.[55] In fact, they found that increases in the rates of death due to heroin overdose were associated with increases in the rates of death due to prescription-opioid overdose in these states.[55]

Although none of these studies can disprove a potential relationship between policies that are aimed at decreasing the availability of inappropriately prescribed opioids and the motivation for heroin use in some people, the results of these studies consistently suggest that the transition to heroin use was occurring before most of these policies were enacted, and such policies do not appear to have directly led to the overall increases in the rates of heroin use.

CONCLUSIONS

Available data indicate that the nonmedical use of prescription opioids is a strong risk factor for heroin use. Yet, although the majority of current heroin users report having used prescription opioids nonmedically before they initiated heroin use, heroin use among people who use prescription opioids for nonmedical reasons is rare, and the transition to heroin use appears to occur at a low rate.

The transition from nonmedical use of prescription opioids to heroin use appears to be part of the progression of addiction in a subgroup of nonmedical users of prescription opioids, primarily among persons with frequent nonmedical use and those with prescription opioid abuse or dependence. Although some authors suggest that there is an association between policy-driven reductions in the availability of prescription opioids and increases in the rates of heroin use,[16,18] the timing of these shifts, many of which began before policies were robustly implemented, makes a causal link unlikely.

In the majority of studies, the increase in the rates of heroin use preceded changes in prescription-opioid policies, and there is no consistent evidence of an association between the implementation of policies related to prescription opioids and increases in the rates of heroin use or deaths, although the data are relatively sparse. Alternatively, heroin market forces, including increased accessibility, reduced price, and high purity of heroin appear to be major drivers of the recent increases in rates of heroin use.[46,56] Regardless of the causes of the high rates of both nonmedical prescription-opioid use and heroin use, in order to minimize overall opioid-related morbidity and mortality, efforts are needed to help people who are already addicted, in parallel with efforts to prevent people from becoming addicted in the first place.

Addressing the combined and interrelated

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opioid epidemics requires comprehensive action, including the prevention of the initiation of nonmedical use of opioids, interventions for persons who have clinically significant complications from opioid use, and improved treatment for those with opioid-use disorders. Prevention efforts should target the major risk factors for the initiation of opioid use, including the excess availability of prescription opioids; these risk factors may be addressed with policy and practice interventions such as the enhanced use of prescription-drug monitoring programs and the development of clinical guidelines to educate clinicians.[14,57] Universal family-based drug-abuse prevention, which has been shown to reduce the rates of initiation of nonmedical use of prescription opioids, may also play an important role.[58] Whether the opioid is heroin or a prescription medication, interventions to reduce morbidity and mortality include expanded access to naloxone in contexts in which overdoses occur[59-61] and increased use of effective treatment for opioid-use disorders, particularly medication-assisted treatment administered for an adequate duration.[62-65]

Fundamentally, prescription opioids and heroin are each elements of a larger epidemic of opioid-related disorders and death. Viewing them from a unified perspective is essential to improving public health. The perniciousness of this epidemic requires a multipronged interventional approach that engages all sectors of society.[14,66]

The views expressed in this article are those of the authors and do not necessarily represent those of the National Institute on Drug Abuse, the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, or the Department of Health and Human Services.

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Prescription Drug Safety News

Doctors Are Unaware Patients Overdose on Prescription Opioids, Continue to Prescribe Opioids Afterward

Over 90% of patients who survived an overdose from prescription opioids continued to receive prescriptions for the drugs after the overdose event, indicates a new report published in the December 28, 2015 issue of the *Annals of Internal Medicine*. These incidents occur because the doctors who prescribe the drugs often do not receive a record of the overdose from emergency departments, and patients who are dependent on opioids are less likely to report to their prescribing physician that they overdosed and were in the emergency room.

The study found that patients who continued taking drugs such as OxyContin®, Vicodin®, and Percocet® following an overdose were two times more likely to experience another overdose within two years, notes MedlinePlus. Oxycodone and hydrocodone are the most frequently prescribed opioids, and according to the study, cause more overdose deaths than any other narcotic, indicates MedlinePlus. To conduct the study, researchers used an insurance claims database to gather data on nearly 3,000 people who overdosed on prescription opioids over 12 years. Dr Marc Larochelle, lead researcher of the study, suggests that improving communication between emergency departments and prescribing physicians is one step to addressing this problem.

The AWARxE® Prescription Drug Safety Program is brought to you by the National Association of Boards of Pharmacy Foundation™.

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Non-medical Use of Prescription Opioids Among Teens Increases Likelihood of Heroin Use

The more frequently a teen uses prescription opioids for non-medical reasons, the higher the risk that he or she will become dependent on opioids, indicates a new study. Specifically, over 77% of teens who reported using heroin also reported using prescription opioids, indicates MedlinePlus. Joseph Palamar, lead researcher of the study, noted that teens who become dependent on prescription opioids often begin using heroin because it is cheaper and more available than illicit prescription pain pills. Further, nearly one-quarter of teens who reported taking prescription opioids over 40 times also reported using heroin. The article, "Nonmedical Opioid Use and Heroin Use in a Nationally Representative Sample of US High School Seniors," is published in the journal *Drug and Alcohol Dependence*.

Massachusetts House Proposes Law Aimed at Addressing Opioid Abuse and Overdose Deaths

Aimed to address opioid abuse and overdose deaths, Massachusetts lawmakers have proposed a bill that would put restrictions on certain opioid prescriptions and require an evaluation of patients seen in emergency rooms for opioid overdoses. Specifically, the house bill would limit initial prescriptions for opioids to a seven-day supply, and would "require an in-depth evaluation be made by a licensed medical professional to anyone who shows up in an emergency room with an opiate-related overdose," indicates WBUR. The law would also require an individual who is admitted to the hospital and deemed to be experiencing an opiate-related overdose to receive substance abuse evaluation within 24 hours. The patient's substance use disorder must be documented in the diagnosis. Hospitals would be prohibited from releasing a patient within 24 hours without first completing the evaluation.

In addition, the bill includes legal protections for anyone administering Narcan, the overdose reversal drug naloxone, to a person during an opiate overdose. The bill also requires a doctor to check the state's Prescription Monitoring Program each time a patient is prescribed a "high-risk" opiate medication. The House and Senate versions of the bill are expected to go to a conference committee before going to Governor Charlie Baker, indicates WBUR.

Weight Loss Dietary Supplements Recalled Due to Undeclared Ingredients

BeeXtreme LLC, is recalling all lots of the weight loss

dietary supplements La'Trim Plus, Oasis, and Jenesis. Food and Drug Administration (FDA) analysis confirmed that the recalled products contain undeclared sibutramine and phenolphthalein. Sibutramine and phenolphthalein pose a significant health hazard, indicates a press release on the FDA website.

Sibutramine is an appetite suppressant that was withdrawn from the United States market in October 2010. It is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. Phenolphthalein is an ingredient previously used in over-the-counter laxatives. Because of concerns of carcinogenicity, phenolphthalein is not currently approved for marketing in the US. Health risks associated with phenolphthalein include potentially serious, gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use.

As noted in the FDA safety alert, consumers are advised to discontinue use and dispose of the recalled products. Contact information for BeeXtreme is available in the alert on FDA's website.

AWARxE Prescription Drug Safety News is a publication prepared by the NABP Foundation™.

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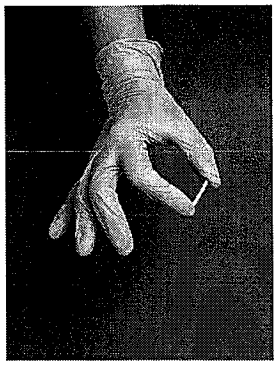
Panel recommends FDA approve implant to treat opiate addiction

Liz Szabo, USA TODAY *3:30 p.m. PST January 12, 2016*



(Photo: Braeburn Pharmaceuticals)

An advisory committee recommended Tuesday that the Food and Drug Administration (FDA) approve an implant designed to reduce addicts' cravings for heroin or prescription painkillers.

The implant, probuphine, provides a steady dose of buprenorphine, which has been shown to ease withdrawal symptoms, decrease cravings and cut the risk of relapse. Buprenorphine is currently available only as a pill or dissolvable film that's placed under the tongue. Although it can be life-saving, it carries major risks: some addicts sell their supplies to get money for other drugs.

Probuphine's manufacturer, New Jersey-based Braeburn Pharmaceuticals, says the implant eliminates that risk. The FDA typically follows committees' advice.

Probuphine's development comes at a time when addiction to opiates — which include illegal drugs such as heroin, as well as prescription painkillers such as morphine and OxyContin — has been called an epidemic.

The death rate from drug overdoses more than doubled from 1999 to 2013, according to the Centers for Disease Control and Prevention. Drug overdoses now kill 44,000 Americans a year – more than car accidents.

At the advisory panel's meeting Tuesday, several witnesses described how opiate addiction has harmed them or their families. Two fathers described how their sons died from drug overdoses, and both asked the committee to recommend approving probuphine.

Medications to treat addiction are strictly regulated.

Methadone is available only at specialized clinics, where patients typically must go every day to receive a dose. Buprenorphine is considered safer than methadone because it's less likely to cause an overdose. Patients can receive buprenorphine at a doctor's office, but physicians prescribing the drug must be certified to dispense it and are only allowed to treat 100 patients at a time.

Like all pills, buprenorphine can be accidentally swallowed by children. About 1 million people took buprenorphine in 2012, according to the FDA.

The White House has recommended expanding the use of medications that treat opiate addiction. Addicts who are given such "medication-assisted treatment" cut their risk of death in half, according to the Substance Abuse and Mental Health Services Administration. The medications also halve a person's risk of becoming infected with HIV, the virus that causes AIDS.

USA TODAY

Advocates push to expand use of medications to treat addiction

(http://www.usatoday.com/story/news/2015/07/08/addiction-treatment-debate/29819285/)

Probuphine works like a contraceptive implant, such as Norplant. Four implanted rods, each smaller than a match stick, provide a steady amount of medication for up to 6 months. The FDA is considering approving it for a specific population: "stable" patients who are already taking the dissolvable buprenorphine film at a low dose. The committee voted 12-5 in favor of probuphine.

"I think this will save some folks' lives," said advisory committee member David Pickar, an adjunct professor of psychiatry at Johns Hopkins Medical School in Baltimore.

Doctors who want to prescribe probuphine would have to refer patients to providers trained to implant medical devices, or undergo training to learn how to safely implant and remove it, said Behshad Sheldon, president and CEO of Braeburn Pharmaceuticals, who spoke at Tuesday's advisory committee hearing.

Implanting probuphine takes 10 to 15 minutes and removing it takes about 20 minutes, said Steven Chavoustie, a physician involved in a clinical trial of the device.

Pharmacist Tracy Rupp urged the committee to reject probuphine, noting that its manufacturer presented only one clinical study showing the drug was effective.

In the study, doctors compared the use of probuphine implants and buprenorphine film, Sheldon said. Patients in the study were considered "stable" because they had been safely using the films. After 6 months, 85% of those given probuphine tested negative for illegal drugs, compared to 72% of those given the film.

The study had multiple flaws, said Rupp, director of public health policy initiatives at the National Center for Health Research, a nonpartisan group that analyzes health data.

Some missing urine tests were counted as negative, as if the patient had no drugs in their system. But Rupp noted that people addicted to opiates "often skip tests to avoid a positive test." That could skew the results, Rupp said.

"It is disappointing that the advisory committee set such a low bar for safety and effectiveness," Rupp said after the vote. "Is probuphine effective? We still don't know because the study was poorly designed and missing data."

Judith Kramer, the committee's acting chairwoman, said she voted against recommending probuphine's approval because doctors don't yet know if it's effective for more than 6 months. Many people who are addicted to opiates need to take medication for years, she added.

"We all desperately want something to be available" to treat opiate addiction, said Kramer, a professor emerita at Duke University in Durham, N.C. Yet she added: "I'm very concerned about the precedent this sets."

USA TODAY

Addiction treatment hard to find, even as overdose deaths soar (http://www.usatoday.com/story/news/2015/05/24/addiction-treatment-shortage/27181773/)

Some addiction specialists say they're concerned about probuphine's safety.

Doctors don't yet know how to safely transition patients from buprenorphine films to the implant, said pharmacist Tracy Rupp, director of public health policy initiatives at the National Center for Health Research, a nonpartisan group that analyzes health data.

Rupp, who recommended the committee reject probuphine, said it takes up to four weeks for the implant to provide the same level of medication provided by the film strips. That suggests patients will need to continue taking buprenorphine by mouth for the first few weeks after receiving the implant, Rupp said.

Rupp said she's worried patients could relapse during that transition. "This is an unacceptable risk for stable patients," Rupp said.

Rupp also said the study didn't match the demographics of addicts in real life, noting 84% of the patients in the study were white. Jennifer Higgins, the committee's acting consumer representative, said she would like the FDA to require studies in more diverse populations.

"This is not the real world of opioid addiction," Rupp said. "Many of these patients will require treatment for years. We need long-term safety data from diverse populations. Patients will require a new incision every 6 months, creating an ongoing risk of harm due to bleeding and infectious complications."

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: January 7, 2016

RE: Live Student and Healthcare Professional Continuing Education Webinar Hosted by FDA's Division of Drug Information

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The National Association of Boards of Pharmacy (NABP) is pleased to announce that the Food and Drug Administration (FDA) Center for Drug Evaluation and Research, Division of Drug Information is presenting a series of continuing educational webinars targeted toward students and health care professionals who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff.

The first webinar of 2016:

Introduction to FDA's MedWatch Adverse Event Reporting Program

Date: Tuesday, January 26, 2016
Time: 1 PM EST | 10 AM PST
Duration: 60 minutes

This webinar will give an overview of the FDA MedWatch Adverse Event reporting program, how and why to report adverse events to MedWatch, and where to find clinically relevant information from MedWatch. This is part one of a two-part series of webinars with information on safety reporting. Part two will be held on February 9, 2016.

The FDA Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-16-001-L04-P). This program meets the criteria for (0.1 CEU -1 contact hour) of pharmacy education.

NABP encourages you to forward this information to your staff and to health care professionals in your state.

For more information and to learn about future webinars, please visit *www.fda.gov/DDIWebinars*.

cc: NABP Executive Committee

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

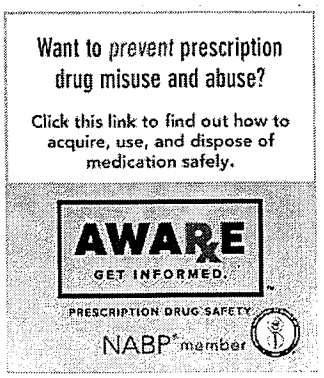
DATE: January 7, 2016

RE: New AWARxE URL and Web Ad Available

As communicated in a National Association of Boards of Pharmacy® news release on Friday, November 6, 2015, the Association launched a redesigned website for the AWARxE® Prescription Drug Safety Program that day. In addition, the URL of the site changed to *www.AWARErx.pharmacy*, helping consumers identify the site as a safe and legitimate source for pharmacy-related information.

If your board of pharmacy website has a link to AWARxE, please ask your website administrator to update the link to *www.AWARErx.pharmacy* (the former URL was *www.AWARErx.org*); this will help keep our site prominent in search results. If you do not currently link to AWARxE, please consider adding this helpful consumer website as a resource to your board of pharmacy's website.

In addition, some boards of pharmacy may have posted the AWARxE web ad that was distributed in October 2012. If so, a redesigned web ad and the program's new logo are available to update your board's website. When your website administrator adds either image to your website, he or she can add a link that users can click to visit the AWARxE website. The images shown are attached to this memo as .png files, if you would like to add them to your board's website.



If you have any questions, please feel free to contact Executive Office staff at 847/391-4400 or via email at exec-office@nabp.net; if you have any questions about AWARxE, please contact Larissa Doucette, communications and marketing senior manager, at 847/391-4468 or via email at ldoucette@nabp.net.

Drug overdose deaths hit record numbers in 2014

Over 47,000 deaths last year, mostly due to opioid pain relievers and heroin

Press Release

Embargoed Until: Friday, December 18, 2015, 2:00 p.m. ET
Contact: Media Relations (http://www.cdc.gov/media)
(404) 639-3286

From 2000 to 2014 nearly half a million Americans died from drug overdoses. Opioid overdose deaths, including both opioid pain relievers and heroin, hit record levels in 2014, with an alarming 14 percent increase in just one year, according to new data published today in CDC's *Morbidity and Mortality Weekly Report (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm64e1218a1.htm?s_cid=mm64e1218a1_w)*.

The most commonly prescribed opioid pain relievers, those classified as natural or semi-synthetic opioids such as oxycodone and hydrocodone, continue to be involved in more overdose deaths than any other opioid type. These deaths increased by 9 percent (813 more deaths in 2014 than 2013).

Increases in prescription opioid pain reliever and heroin deaths are the biggest driver of the drug overdose epidemic. Deaths from heroin increased in 2014, continuing a sharp rise that has seen heroin overdoses triple since 2010. Deaths involving illicitly made fentanyl, a potent opioid often added to or sold as heroin, also are on the upswing.

"The increasing number of deaths from opioid overdose is alarming," said CDC Director Tom Frieden, M.D., M.P.H. "The opioid epidemic is devastating American families and communities. To curb these trends and save lives, we must help prevent addiction and provide support and treatment to those who suffer from opioid use disorders. This report also shows how important it is that law enforcement intensify efforts to reduce the availability of heroin, illegal fentanyl, and other illegal opioids."

Drug overdose deaths are up in both men and women, in non-Hispanic whites and blacks, and in adults of nearly all ages. Rates of drug overdose deaths were highest among five states: West Virginia, New Mexico, New Hampshire, Kentucky, and Ohio. A map of drug overdose deaths by state (2013 and 2014) is available at http://www.cdc.gov/drugoverdose/data/statedeaths.html (http://www.cdc.gov/drugoverdose/data/statedeaths.html).

Intertwined trends drive overdose deaths

The findings show that two distinct but intertwined trends are driving America's overdose epidemic: a 15-year increase in deaths from prescription opioid pain reliever overdoses as a result of misuse and abuse, and a recent surge in illicit drug overdoses driven mainly by heroin. Both of these trends worsened in 2014.

More than six out of 10 drug overdose deaths in 2014 involved opioids, including opioid pain relievers and heroin. The largest increase in opioid overdose deaths involved synthetic opioids (not including methadone), which were involved in 5,500 deaths in 2014, nearly twice as many as the year before. Many of these overdoses are believed to involve illicitly-made fentanyl, a short-acting opioid.

In addition, heroin-related death rates increased 26 percent from 2013–2014, totaling 10,574 deaths in 2014. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use—especially among people who became dependent upon or abused prescription opioids in the past year. The increased availability of heroin, its relatively low price (compared to prescription opioids), and high purity appear to be major drivers of the upward trend in heroin use, overdoses, and deaths.

How to stop the epidemic

The new findings point to four ways to prevent overdose deaths:

- Limit initiation into opioid misuse and addiction. Opioid pain reliever prescribing has quadrupled since 1999. Providing health care professionals with additional tools and information—including safer guidelines for prescribing these drugs—can help them make more informed prescribing decisions.
- Expand access to evidence-based substance use disorder treatment—including Medication-Assisted Treatment—for people who suffer from opioid use disorder.
- Protect people with opioid use disorder by expanding access and use of naloxone—a critical drug that can reverse the symptoms of an opioid overdose and save lives.
- State and local public health agencies, medical examiners and coroners, and law enforcement agencies must work together to improve detection of and response to illicit opioid overdose outbreaks to address this emerging threat to public health and safety.

CDC works with states, communities, and prescribers to prevent opioid misuse and overdose by tracking and monitoring the epidemic and helping states scale up effective programs. CDC also improves patient safety by equipping health care providers with data, tools, and guidance so they can make informed treatment decisions. Learn more at www.cdc.gov/drugoverdose (http://www.cdc.gov/drugoverdose).

Secretary Burwell has made addressing opioid abuse, dependence, and overdose a priority and work is underway within HHS on this important issue. The evidence-based initiative (http://www.hhs.gov/news/press/2015pres/03/20150326a.html) focuses on three promising areas: informing opioid prescribing practices, increasing the use of naloxone, and using Medication-Assisted Treatment to move people out of opioid addiction.

These efforts build on work that began in 2010, when the President released his first National Drug Control Strategy, which emphasized the need for action to address opioid use disorders and overdose, while ensuring that individuals with pain receive safe, effective treatment. The next year, the White House released its national Prescription Drug Abuse Prevention Plan (https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf) to outline goals for addressing prescription drug misuse and overdose. Since then, the Administration has supported and expanded community-based efforts to prevent drug use, pursue "smart on crime" approaches to drug enforcement, improve prescribing practices for pain medication, increase access to treatment, work to reduce overdose deaths, and support the millions of Americans in recovery.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (http://www.hhs.gov/)

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(http://www.cdc.gov/Other/plugins/#pdf)

Page last reviewed: December 18, 2015

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Content source: Centers for Disease Control and Prevention (/)

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™
Morbidity and Mortality Weekly Report (*MMWR*)

Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014

Weekly
January 1, 2016 / 64(50);1378-82

Rose A. Rudd, MSPH1; Noah Aleshire, JD1; Jon E. Zibbell, PhD1; R. Matthew Gladden, PhD1

On December 18, this report was posted as an MMWR *Early Release on the* MMWR *website* (http://www.cdc.gov/mmwr).

The United States is experiencing an epidemic of drug overdose (poisoning) deaths. Since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin). CDC analyzed recent multiple cause-of-death mortality data to examine current trends and characteristics of drug overdose deaths, including the types of opioids associated with drug overdose deaths. During 2014, a total of 47,055 drug overdose deaths occurred in the United States, representing a 1-year increase of 6.5%, from 13.8 per 100,000 persons in 2013 to 14.7 per 100,000 persons in 2014. The rate of drug overdose deaths increased significantly for both sexes, persons aged 25–44 years and ≥55 years, non-Hispanic whites and non-Hispanic blacks, and in the Northeastern, Midwestern, and Southern regions of the United States. Rates of opioid overdose deaths also increased significantly, from 7.9 per 100,000 in 2013 to 9.0 per 100,000 in 2014, a 14% increase. Historically, CDC has programmatically characterized all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids) as "prescription" opioid overdoses (1). Between 2013 and 2014, the age-adjusted rate of death involving methadone remained unchanged; however, the age-adjusted rate of death involving natural and semisynthetic opioid pain relievers, heroin, and synthetic opioids, other than methadone (e.g., fentanyl) increased 9%, 26%, and 80%, respectively. The sharp increase in deaths involving synthetic opioids, other than methadone, in 2014 coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid; however, illicitly manufactured fentanyl cannot be distinguished from prescription fentanyl in death certificate data. These findings indicate that the opioid overdose epidemic is worsening. There is a need for continued action to prevent opioid abuse, dependence, and death, improve treatment capacity for opioid use disorders, and reduce the supply of illicit opioids, particularly heroin and illicit fentanyl.

The National Vital Statistics System multiple cause-of-death mortality files were used to identify drug overdose deaths.* Drug overdose deaths were classified using the *International Classification of Disease, Tenth Revision* (ICD-10), based on the ICD-10 underlying cause-of-death codes X40–44 (unintentional), X60–64 (suicide), X85 (homicide), or Y10–Y14 (undetermined intent) (2). Among the deaths with drug overdose as the underlying cause, the type of opioid involved is indicated by the following ICD-10 multiple cause-of-death codes: opioids (T40.0, T40.1, T40.2, T40.3, T40.4, or T40.6); natural and semisynthetic opioids (T40.2); methadone (T40.3); synthetic opioids, other than methadone (T40.4); and heroin

(T40.1). Some deaths involve more than one type of opioid; these deaths were included in the rates for each category (e.g., a death involving both a synthetic opioid and heroin would be included in the rates for synthetic opioid deaths and in the rates for heroin deaths). Age-adjusted death rates were calculated by applying age-specific death rates to the 2000 U.S standard population age distribution (*3*). Significance testing was based on the z-test at a significance level of 0.05.

During 2014, 47,055 drug overdose deaths occurred in the United States. Since 2000, the age-adjusted drug overdose death rate has more than doubled, from 6.2 per 100,000 persons in 2000 to 14.7 per 100,000 in 2014 (Figure 1). The overall number and rate of drug overdose deaths increased significantly from 2013 to 2014, with an additional 3,073 deaths occurring in 2014 (Table), resulting in a 6.5% increase in the age-adjusted rate. From 2013 to 2014, statistically significant increases in drug overdose death rates were seen for both males and females, persons aged 25–34 years, 35–44 years, 55–64 years, and ≥65 years; non-Hispanic whites and non-Hispanic blacks; and residents in the Northeast, Midwest and South Census Regions (Table). In 2014, the five states with the highest rates of drug overdose deaths were West Virginia (35.5 deaths per 100,000), New Mexico (27.3), New Hampshire (26.2), Kentucky (24.7) and Ohio (24.6).† States with statistically significant increases in the rate of drug overdose deaths from 2013 to 2014 included Alabama, Georgia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Mexico, North Dakota, Ohio, Pennsylvania, and Virginia.

In 2014, 61% (28,647, data not shown) of drug overdose deaths involved some type of opioid, including heroin. The age-adjusted rate of drug overdose deaths involving opioids increased significantly from 2000 to 2014, increasing 14% from 2013 (7.9 per 100,000) to 2014 (9.0) (Figure 1). From 2013 to 2014, the largest increase in the rate of drug overdose deaths involved synthetic opioids, other than methadone (e.g., fentanyl and tramadol), which nearly doubled from 1.0 per 100,000 to 1.8 per 100,000 (Figure 2). Heroin overdose death rates increased by 26% from 2013 to 2014 and have more than tripled since 2010, from 1.0 per 100,000 in 2010 to 3.4 per 100,000 in 2014 (Figure 2). In 2014, the rate of drug overdose deaths involving natural and semisynthetic opioids (e.g., morphine, oxycodone, and hydrocodone), 3.8 per 100,000, was the highest among opioid overdose deaths, and increased 9% from 3.5 per 100,000 in 2013. The rate of drug overdose deaths involving methadone, a synthetic opioid classified separately from other synthetic opioids, was similar in 2013 and 2014.

Discussion

More persons died from drug overdoses in the United States in 2014 than during any previous year on record. From 2000 to 2014 nearly half a million persons in the United States have died from drug overdoses. In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes (*4*). Opioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths. In 2014, opioids were involved in 28,647 deaths, or 61% of all drug overdose deaths; the rate of opioid overdoses has tripled since 2000. The 2014 data demonstrate that the United States' opioid overdose epidemic includes two distinct but interrelated trends: a 15-year increase in overdose deaths involving prescription opioid pain relievers and a recent surge in illicit opioid overdose deaths, driven largely by heroin.

Natural and semisynthetic opioids, which include the most commonly prescribed opioid pain relievers, oxycodone and hydrocodone, continue to be involved in more overdose deaths than any other opioid type. Although this category of opioid drug overdose death had declined in 2012 compared with 2011, and had held steady in 2013, there was a 9% increase in 2014.

Drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country (*5*) and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse (*5*). The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose (*6*).

The rate of drug overdose deaths involving synthetic opioids nearly doubled between 2013 and 2014. This category includes both prescription synthetic opioids (e.g., fentanyl and tramadol) and non-pharmaceutical fentanyl manufactured in illegal laboratories (illicit fentanyl). Toxicology tests used by coroners and medical examiners are unable to distinguish between prescription and illicit fentanyl. Based on reports from states and drug seizure data, however, a substantial portion of the increase in synthetic opioid deaths appears to be related to increased availability of illicit fentanyl (*7*), although this cannot be confirmed with mortality data. For example, five jurisdictions (Florida, Maryland, Maine, Ohio, and Philadelphia, Pennsylvania) that reported sharp increases in illicit fentanyl seizures, and screened persons who died from a suspected drug overdose for fentanyl, detected similarly sharp increases in fentanyl-related deaths (*7*).§ Finally, illicit fentanyl is often combined with heroin or sold as heroin. Illicit fentanyl might be contributing to recent increases in drug overdose deaths involving heroin. Therefore, increases in illicit fentanyl-associated deaths might represent an emerging and troubling feature of the rise in illicit opioid overdoses that has been driven by heroin.

The findings in this report are subject to at least three limitations. First, several factors related to death investigation might affect estimates of death rates involving specific drugs. At autopsy, toxicological laboratory tests might be performed to determine the type of drugs present; however, the substances tested for and circumstances under which the tests are performed vary by jurisdiction. Second, in 2013 and 2014, 22% and 19% of drug overdose deaths, respectively, did not include information on the death certificate about the specific types of drugs involved. The percent of overdose deaths with specific drugs identified on the death certificate varies widely by state. Some of these deaths might have involved opioids. This increase in the reporting of specific drugs in 2014 might have contributed to some of the observed increases in drug overdose death rates involving different types of opioids from 2013 to 2014. Finally, some heroin deaths might be misclassified as morphine because morphine and heroin are metabolized similarly (*8*), which might result in an underreporting of heroin overdose deaths.

To reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity, efforts to improve safer prescribing of prescription opioids must be intensified. Opioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with overdoses involving the most commonly used opioid pain relievers (*1*). CDC has developed a draft guideline for the prescribing of opioids for chronic pain to address this need.¶

In addition, efforts are needed to protect persons already dependent on opioids from overdose and other harms. This includes expanding access to and use of naloxone (a safe and effective antidote for all opioid-related overdoses)** and increasing access to medication-assisted treatment, in combination with behavioral therapies (*9*). Efforts to ensure access to integrated prevention services, including access to syringe service programs when available, is also an important consideration to prevent the spread of hepatitis C virus and human immunodeficiency virus infections from injection drug use.

Public health agencies, medical examiners and coroners, and law enforcement agencies can work collaboratively to improve detection of outbreaks of drug overdose deaths involving illicit opioids (including heroin and illicit fentanyl) through improved investigation and testing as well as reporting and monitoring of specific drugs, and facilitate a rapid and effective response that can address this emerging threat to public health and safety (7). Efforts are needed to distinguish the drugs contributing to overdoses to better understand this trend.

1Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC.

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* Additional information available at http://www.cdc.gov/nchs/nvss/mortality_public_use_data.htm.

† Additional information available at http://www.cdc.gov/drugoverdose/data/statedeaths.html.

§ Additional information available at http://pub.lucidpress.com/NDEWSFentanyl /.

¶ Additional information available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

** Additional information available at https://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf .

Summary

What is already known on this topic?

The rate for drug overdose deaths has increased approximately 140% since 2000, driven largely by opioid overdose deaths. After increasing since the 1990s, deaths involving the most commonly prescribed opioid pain relievers (i.e., natural and semisynthetic opioids) declined slightly in 2012 and remained steady in 2013, showing some signs of progress. Heroin overdose deaths have been sharply increasing since 2010.

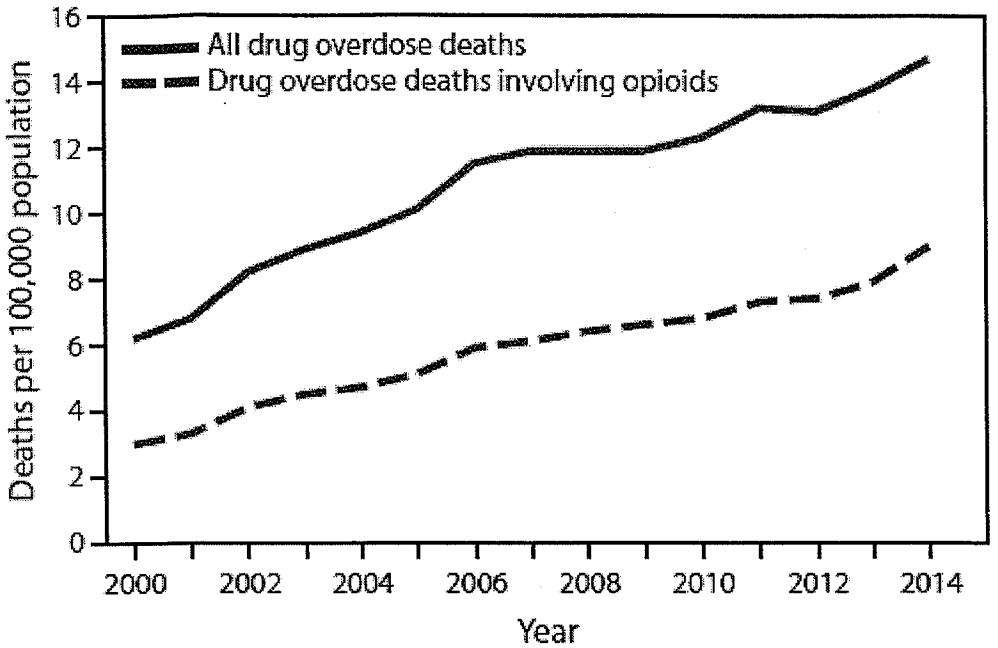
What is added by this report?

Drug overdose deaths increased significantly from 2013 to 2014. Increases in opioid overdose deaths were the main factor in the increase in drug overdose deaths. The death rate from the most commonly prescribed opioid pain relievers (natural and semisynthetic opioids) increased 9%, the death rate from heroin increased 26%, and the death rate from synthetic opioids, a category that includes illicitly manufactured fentanyl and synthetic opioid pain relievers other than methadone, increased 80%. Nearly every aspect of the opioid overdose death epidemic worsened in 2014.

What are the implications for public health practice?

Efforts to encourage safer prescribing of opioid pain relievers should be strengthened. Other key prevention strategies include expanding availability and access to naloxone (an antidote for all opioid-related overdoses), increasing access to medication-assisted treatment in combination with behavioral therapies, and increasing access to syringe service programs to prevent the spread of hepatitis C virus infection and human immunodeficiency virus infections. Public health agencies, medical examiners and coroners, and law enforcement agencies can work collaboratively to improve detection of and response to outbreaks associated with drug overdoses related to illicit opioids.

FIGURE 1. Age-adjusted rate* of drug overdose deaths† and drug overdose deaths involving opioids§,¶ — United States, 2000–2014



Source: National Vital Statistics System, Mortality file.

* Age-adjusted death rates were calculated by applying age-specific death rates to the 2000 U.S. standard population age distribution.

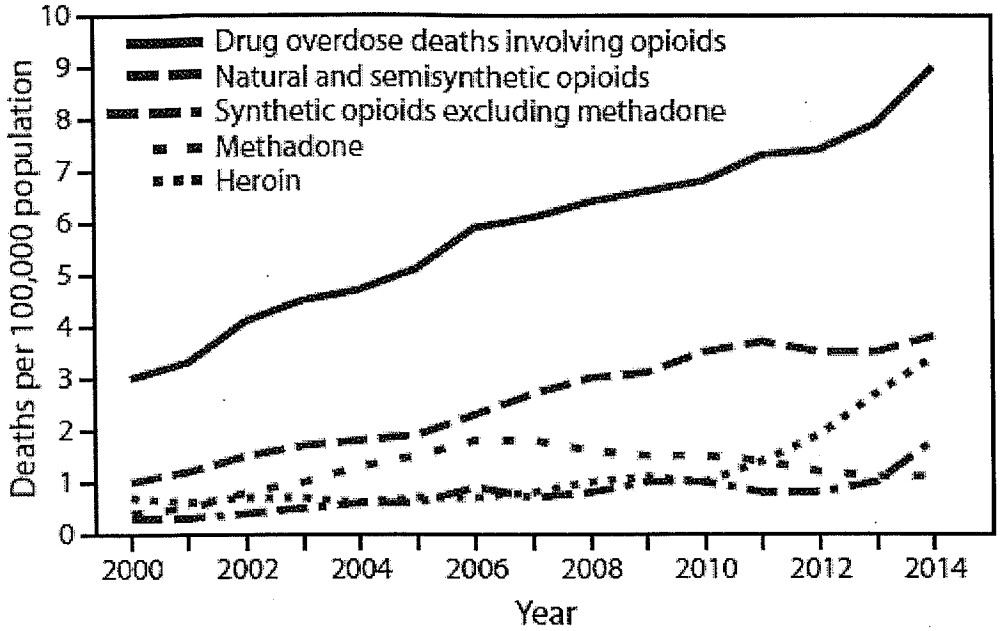
† Drug overdose deaths are identified using *International Classification of Diseases, Tenth Revision* underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14.

§ Drug overdose deaths involving opioids are drug overdose deaths with a multiple cause-of-death code of T40.0, T40.1, T40.2, T40.3, T40.4, or T40.6. Approximately one fifth of drug overdose deaths lack information on the specific drugs involved. Some of these deaths might involve opioids.

¶ Opioids include drugs such as morphine, oxycodone, hydrocodone, heroin, methadone, fentanyl, and tramadol.

Alternate Text: The figure above is a line chart showing the age-adjusted rates of drug overdose deaths and drug overdose deaths involving opioids in the United States during 2000-2014.

FIGURE 2. Drug overdose deaths* involving opioids,†,§ by type of opioid¶ — United States, 2000–2014



Source: National Vital Statistics System, Mortality file.

* Age-adjusted death rates were calculated by applying age-specific death rates to the 2000 U.S. standard population age distribution.

† Drug overdose deaths involving opioids are identified using *International Classification of Diseases, Tenth Revision* underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14 with a multiple cause code of T40.0, T40.1, T40.2, T40.3, T40.4, or T40.6.

§ Opioids include drugs such as morphine, oxycodone, hydrocodone, heroin, methadone, fentanyl, and tramadol.

¶ For each type of opioid, the multiple cause-of-death code was T40.1 for heroin, T40.2 for natural and semisynthetic opioids (e.g., oxycodone and hydrocodone), T40.3 for methadone, and T40.4 for synthetic opioids excluding methadone (e.g., fentanyl and tramadol). Deaths might involve more than one drug thus categories are not exclusive.

Alternate Text: The figure above is a line chart showing drug overdose deaths involving opioids, by type of opioid, in the United States during 2000-2014.

TABLE. Number and age-adjusted rates of drug overdose deaths,* by sex, age, race and Hispanic origin,† Census region, and state —United States, 2013 and 2014

Decedent characteristic	2013		2014		% change from 2013 to 2014
	No.	Age-adjusted rate	No.	Age-adjusted rate	
All	**43,982**	**13.8**	**47,055**	**14.7**	**6.5§**
Sex					
Male	26,799	17.0	28,812	18.3	7.6§

Female	17,183	10.6	18,243	11.1	4.7§
Age group (yrs)					
0–14	105	0.2	109	0.2	0.0
15–24	3,664	8.3	3,798	8.6	3.6
25–34	8,947	20.9	10,055	23.1	10.5§
35–44	9,320	23.0	10,134	25.0	8.7§
45–54	12,045	27.5	12,263	28.2	2.5
55–64	7,551	19.2	8,122	20.3	5.7§
≥65	2,344	5.2	2,568	5.6	7.7§
Race and Hispanic origin†					
White, non-Hispanic	35,581	17.6	37,945	19.0	8.0§
Black, non-Hispanic	3,928	9.7	4,323	10.5	8.2§
Hispanic	3,345	6.7	3,504	6.7	0.0
Census region of residence					
Northeast	8,403	14.8	9,077	16.1	8.8§
Midwest	9,745	14.6	10,647	16.0	9.6§
South	15,519	13.1	16,777	14.0	6.9§
West	10,315	13.6	10,554	13.7	0.7
State of residence					
Alabama	598	12.7	723	15.2	19.7§
Alaska	105	14.4	124	16.8	16.7
Arizona	1,222	18.7	1,211	18.2	-2.7
Arkansas	319	11.1	356	12.6	13.5
California	4,452	11.1	4,521	11.1	0.0
Colorado	846	15.5	899	16.3	5.2
Connecticut	582	16.0	623	17.6	10.0
Delaware	166	18.7	189	20.9	11.8

District of Columbia	102	15.0	96	14.2	-5.3
Florida	2,474	12.6	2,634	13.2	4.8
Georgia	1,098	10.8	1,206	11.9	10.2§
Hawaii	158	11.0	157	10.9	-0.9
Idaho	207	13.4	212	13.7	2.2
Illinois	1,579	12.1	1,705	13.1	8.3§
Indiana	1,064	16.6	1,172	18.2	9.6§
Iowa	275	9.3	264	8.8	-5.4
Kansas	331	12.0	332	11.7	-2.5
Kentucky	1,019	23.7	1,077	24.7	4.2
Louisiana	809	17.8	777	16.9	-5.1
Maine	174	13.2	216	16.8	27.3§
Maryland	892	14.6	1,070	17.4	19.2§
Massachusetts	1,081	16.0	1,289	19.0	18.8§
Michigan	1,553	15.9	1,762	18.0	13.2§
Minnesota	523	9.6	517	9.6	0.0
Mississippi	316	10.8	336	11.6	7.4
Missouri	1,025	17.5	1,067	18.2	4.0
Montana	137	14.5	125	12.4	-14.5
Nebraska	117	6.5	125	7.2	10.8
Nevada	614	21.1	545	18.4	-12.8
New Hampshire	203	15.1	334	26.2	73.5§
New Jersey	1,294	14.5	1,253	14.0	-3.4
New Mexico	458	22.6	547	27.3	20.8§
New York	2,309	11.3	2,300	11.3	0.0
North Carolina	1,259	12.9	1,358	13.8	7.0
North Dakota	20	2.8	43	6.3	125.0§

Ohio	2,347	20.8	2,744	24.6	18.3§
Oklahoma	790	20.6	777	20.3	-1.5
Oregon	455	11.3	522	12.8	13.3

TABLE. (*Continued*) Number and age-adjusted rates of drug overdose deaths,* by sex, age, race and Hispanic origin,† Census region, and state — United States, 2013 and 2014

Decedent characteristic	2013		2014		% change from 2013 to 2014
	No.	Age-adjusted rate	No.	Age-adjusted rate	
Pennsylvania	2,426	19.4	2,732	21.9	12.9§
Rhode Island	241	22.4	247	23.4	4.5
South Carolina	620	13.0	701	14.4	10.8
South Dakota	55	6.9	63	7.8	13.0
Tennessee	1,187	18.1	1,269	19.5	7.7
Texas	2,446	9.3	2,601	9.7	4.3
Utah	594	22.1	603	22.4	1.4
Vermont	93	15.1	83	13.9	-7.9
Virginia	854	10.2	980	11.7	14.7§
Washington	969	13.4	979	13.3	-0.7
West Virginia	570	32.2	627	35.5	10.2
Wisconsin	856	15.0	853	15.1	0.7
Wyoming	98	17.2	109	19.4	12.8

Source: National Vital Statistics System, Mortality file.

* Deaths are classified using the *International Classification of Diseases, Tenth Revision* (ICD –10). Drug overdose deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Age-adjusted death rates were calculated by applying age-specific death rates to the 2000 U.S standard population age distribution.

† Data for Hispanic origin should be interpreted with caution; studies comparing Hispanic origin on death certificates and on census surveys have shown inconsistent reporting on Hispanic ethnicity.

§ Statistically significant change from 2013 to 2014.

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Temple study finds opioid prescribing guideline significantly decreases prescription rates

TEMPLE UNIVERSITY HEALTH SYSTEM

(Philadelphia, PA) - Emergency medicine physicians at Temple University Hospital have found that an opioid prescribing guideline had an immediate and sustained impact on opioid prescribing rates for minor conditions and chronic noncancer pain in an acute care setting. The results of the study are published in the January 2016 *Journal of Emergency Medicine*.

The United States is in the midst of a crisis regarding the abuse of prescription drug opioids. According to the Centers for Disease Control and Prevention, the U.S. death rate from prescription opioid overdose now exceeds the combined death rates from heroin and cocaine.

Acute care settings are a major source of opioid prescriptions, often for minor conditions and chronic noncancer pain. Emergency physicians have identified themselves as targets for patients who seek opioids for nonmedical purposes. Given the difficulty in striking a balance that provides appropriate analgesia for patients without creating or exacerbating drug dependence, the U.S. Department of Health and Human Services recommends the synthesis of pain management guidelines and the creation of clinical decision support tools.

Temple University Hospital (TUH) and Temple University Hospital-Episcopal Campus (TUH-Episcopal) were among those that created a guideline for prescribing opioids in order to maximize safety and avoid misuse.

"The impact of this type of guideline had never been studied in an acute care setting," says Daniel del Portal, MD, FAAEM, Assistant Professor of Clinical Emergency Medicine at the Lewis Katz School of Medicine at Temple University, Assistant Director of Clinical Operations at TUH and Jeanes Hospital, and principal investigator of the study. "We hypothesized that the rate at which opioids were prescribed in the emergency department for dental, neck/back and chronic pain would decrease after adoption of the guideline. We also hypothesized that physicians would support the use of the guideline."

The retrospective observational study compared the rate of opioid prescriptions for dental, neck/back and chronic noncancer pain before and after adoption of the guideline in January 2013. The research team used data from 13,187 patients aged 18 years or older who met the diagnosis criteria and were discharged from the emergency departments at TUH and TUH-Episcopal.

The team also administered a survey to the faculty emergency medicine physicians who were practicing in the two emergency departments.

Results showed the prescribing guideline had an immediate and sustained impact in reducing opioid prescribing rates for all age groups and for each of the three categories of complaints with a high degree of statistical significance. Also, 100% of physicians surveyed supported implementation of the voluntary guideline. Most (97%) felt the guideline had facilitated discussions with patients when opioids were being withheld, and nearly three-quarters of respondents reported encountering less hostility from patients since adoption of the guideline.

"Emergency physicians and other acute care providers can use various tools to promote the rational prescribing of dangerous opioid medications," adds Dr. del Portal. "In contrast to electronic prescription drug monitoring programs, which show promise but require significant infrastructure and regulation (and are as yet unavailable to prescribers in Pennsylvania), an easily implemented guideline empowers physicians and protects patients from the well documented dangers of opioid misuse."

###

Other physicians contributing to the study include Dr. Robert M. McNamara, Dr. Megan E. Healy and Dr. Wayne A. Satz from the Department of Emergency Medicine at the Lewis Katz School of Medicine.

About Temple Health

Temple University Health System (TUHS) is a $1.6 billion academic health system dedicated to providing access to quality patient care and supporting excellence in medical education and research. The Health System consists of Temple University Hospital (TUH), ranked among the 'Best Hospitals' in the region by *U.S. News & World Report*; TUH-Episcopal Campus; TUH-Northeastern Campus; Fox Chase Cancer Center, an NCI-designated comprehensive cancer center; Jeanes Hospital, a community-based hospital offering medical, surgical and emergency services; Temple Transport Team, a ground and air-ambulance company; and Temple Physicians, Inc., a network of community-based specialty and primary-care physician practices. TUHS is affiliated with the Lewis Katz School of Medicine at Temple University.

The Lewis Katz School of Medicine (LKSOM), established in 1901, is one of the nation's leading medical schools. Each year, the School of Medicine educates approximately 840 medical students and 140 graduate students. Based on its level of funding from the National Institutes of Health, the Katz School of Medicine is the second-highest ranked medical school in Philadelphia and the third-highest in the Commonwealth of Pennsylvania. According to *U.S. News & World Report*, LKSOM is among the top 10 most applied-to medical schools in the nation.

Temple Health refers to the health, education and research activities carried out by the affiliates of Temple University Health System (TUHS) and by the Katz School of Medicine. TUHS neither provides nor controls the provision of health care. All health care is provided by its member organizations or independent health care providers affiliated with TUHS member organizations. Each TUHS member organization is owned and operated pursuant to its governing documents.

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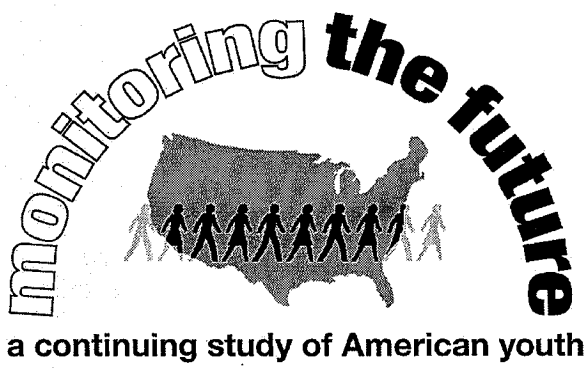
NEWS RELEASES

Wednesday, December 16, 2015

Drug use trends remain stable or decline among teens

NIH's 2015 Monitoring the Future survey shows long term decline in illicit drug use, prescription opioid abuse, cigarette and alcohol use among the nation's youth.

The 2015 Monitoring the Future survey (MTF) shows decreasing use of a number of substances, including cigarettes, alcohol, prescription opioid pain relievers, and synthetic cannabinoids ("synthetic marijuana"). Other drug use remains stable, including marijuana, with continued high rates of daily use reported among 12th graders, and ongoing declines in perception of its harms.



The MTF survey measures drug use and attitudes among eighth, 10th, and 12th graders, and is funded by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health. The survey has been conducted by researchers at the University of Michigan at Ann Arbor since 1975.

For the first time, daily marijuana use exceeds daily tobacco cigarette use among 12th graders.

Daily marijuana use for this group remained relatively stable at 6 percent, compared to 5.5 percent reporting daily cigarette smoking (down from 6.7 percent in 2014).

"We are heartened to see that most illicit drug use is not increasing, non-medical use of prescription opioids is decreasing, and there is improvement in alcohol and cigarette use rates," said Nora D. Volkow, M.D., director of NIDA. "However, continued areas of concern are the high rate of daily marijuana smoking seen among high school students, because of marijuana's potential deleterious effects on the developing brains of teenagers, and the high rates of overall tobacco products and nicotine containing e-cigarettes usage."

"This year's Monitoring the Future data continue the promising trends from last year with declining rates of adolescent substance use, and support the value of evidence-based prevention, treatment, and recovery," said National Drug Control Policy Director Michael Botticelli. "Efforts to prevent drug use from ever starting are particularly important as we work to reduce the rising number of drug overdoses across the country. I encourage parents, teachers, coaches, and mentors to have a conversation with the young people in their lives about making the healthy decisions that will keep them on a path toward a successful future."

"We are very encouraged by the continued decline in underage drinking illustrated in these data," said George F. Koob, Ph.D., director of the National Institute on Alcohol Abuse and Alcoholism. "However, the percent of underage individuals

drinking still remains unacceptably high. For example, approximately 40 percent of 12th graders have reported being drunk in the past year and binge drinking remains a significant problem."

Other highlights from the 2015 survey:

Drugs

- Use of many illicit drugs has trended down. Among high school seniors, 23.6 percent report using an illicit drug in the past month, with 7.6 percent reporting they used an illicit drug other than marijuana.
- Perception of marijuana use as risky continues to decline, with 31.9 percent of seniors saying regular use could be harmful, compared to 36.1 percent last year.
- Past year use of synthetic cannabinoids ("synthetic marijuana") is at 5.2 percent for 12th graders, down significantly from 11.4 in 2011, the first year it was measured in the survey.
- Past year use of heroin, typically very low among teens, is at an all-time low at 0.3 percent for eighth graders, and 0.5 for 10th and 12th graders.
- Use of MDMA (also known as Ecstasy or Molly), inhalants, and LSD are generally stable or down. In 2015, 3.6 percent of seniors reported past year use of MDMA, compared to 5 percent in 2014.
- Non-medical use of the prescription amphetamine Adderall, typically given for ADHD, remains high at 7.5 percent among 12th graders.
- Use of prescription opioids continues its downward trend, with 4.4 percent of high school seniors reporting non-medical use of Vicodin (hydrocodone and acetaminophen), down from a peak of 10.5 percent in 2003.
- Most teens abusing prescription opioids report getting them from friends or family members. However, one-third report getting them from their own prescriptions, underscoring the need to monitor teens taking opioids and evaluate prescribing practices.

Tobacco

- Cigarette smoking rates have greatly declined among teens in recent years. For example, among 10th graders, there has been a 54.9 percent drop in daily smoking in just five years, reported at just 3 percent this year compared to 6.6 percent five years ago.
- However, rates of use of other tobacco products, while not significantly changed from 2014, remain high with 12th graders, reporting rates of past year use of hookah and small cigars of 19.8 percent and 15.9 percent, respectively.
- More than 75 percent of high school seniors view smoking a pack or more a day as harmful, compared to 51.3 percent in 1975, first year of the survey.
- As e-cigarettes are currently unregulated, there is limited data on what chemicals teens are actually smoking. However, when asked what they inhaled the last time they used an e-cigarette, only about 20 percent said they were using nicotine. Most say they inhaled flavoring alone and many admitted they were unsure what they inhaled. In fact, about 13 percent of eighth graders who use e-cigarettes said they did not know what was in the device they used. Furthermore, some products labeled nicotine-free may actually contain nicotine.
- Roughly twice as many boys as girls report using e-cigarettes (21.5 percent to 10.9 percent).

Alcohol

- Alcohol use continues its gradual downward trend among teens, with significant changes seen in the past five years in nearly all measures.
- Binge drinking (described as having five or more drinks in a row within the past two weeks) is 17.2 percent among seniors, down from 19.4 percent last year and down from peak rates in 1998 at 31.5 percent.
- 37.7 percent of 12th graders say they have been drunk in the past year, compared to 41.4 percent in 2014 and 53.2 percent in 2001, when rates were highest for that group.
- High school seniors see a distinction in potential harmfulness between one or two drinks nearly every day (21.5 percent) versus four to five drinks nearly every day (59.1 percent).

Overall, 44,892 students from 382 public and private schools participated in this year's MTF survey. Since 1975, the survey has measured drug, alcohol, and cigarette use and related attitudes in 12th graders nationwide. Eighth and 10th graders were added to the survey in 1991. Survey participants generally report their drug use behaviors across three time periods: lifetime, past year, and past month. Questions are also asked about daily cigarette and marijuana use. NIDA has provided funding for the survey since its inception by a team of investigators at the University of Michigan at Ann Arbor, led by Drs. Lloyd Johnston and Richard Miech. MTF is funded under grant number DA001411. Additional information on the MTF Survey, as well as comments from Dr. Volkow, can be found at www.drugabuse.gov/drugpages/MTF.html. The University of Michigan press release can be found at http://monitoringthefuture.org.

MTF is one of three major surveys sponsored by the U.S. Department of Health and Human Services that provide data on substance use among youth. The others are the National Survey on Drug Use and Health and the Youth Risk Behavior Survey. The MTF website is: www.monitoringthefuture.org. Follow Monitoring the Future 2015 news on Twitter at @NIDANews, or join the conversation by using: #MTF2015. Additional survey results can be found at www.hhs.gov/news or www.whitehouse.gov/ondcp. Information on all of the surveyed drugs can be found on NIDA's Web site: www.drugabuse.gov.

The National Survey on Drug Use and Health, sponsored by the Substance Abuse and Mental Health Services Administration, is the primary source of statistical information on substance use in the U.S. population 12 years of age and older. More information is available at: http://www.samhsa.gov/data/population-data-nsduh.

The Youth Risk Behavior Survey, part of HHS's Centers for Disease Control and Prevention's (CDC) Youth Risk Behavior Surveillance System, is a school–based survey that collects data from students in grades nine–12. The survey includes questions on a wide variety of health–related risk behaviors, including substance abuse. More information is available at www.cdc.gov/HealthyYouth/yrbs/index.htm. Additionally, the National Youth Tobacco Survey, a school-based survey of U.S. students in grades six-12 conducted by the CDC in collaboration with the Food and Drug Administration, collects data on the use of multiple tobacco products, including e-cigarettes. More information is available at www.cdc.gov/tobacco/data_statistics/surveys/NYTS/.

The National Institute on Drug Abuse (NIDA) is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world's research on the health aspects of drug abuse and addiction. The Institute carries out a large variety of programs to inform policy and improve practice. Fact sheets on the health effects of drugs of abuse and information on NIDA research and other activities can be found at http://www.drugabuse.gov, which is now compatible with your smartphone, iPad or tablet. To order publications in English or Spanish, call NIDA's DrugPubs research dissemination center at 1-877-NIDA-NIH or 240-645-0228 (TDD) or email requests to drugpubs@nida.nih.gov. Online ordering is available at http://drugpubs.drugabuse.gov. NIDA's media guide can be found at http://drugabuse.gov/mediaguide, and its easy-to-read website can be found at http://www.easyread.drugabuse.gov

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If you suspect Fido's owner is diverting prescription pain meds meant for the pet, checking your state's drug monitoring database may not help

by Ann M. Philbrick, PharmD, BCPS

The Centers for Disease Control and Prevention has declared prescription drug abuse an epidemic in the United States. Results from the National Survey on Drug Use and Health estimated that 4.5 million Americans age 12 and over were current nonmedical users of pain relievers in 2013. In 2012, more than 16,000 deaths in the United States were attributed to opioid analgesic overdose. Prescription drug abuse has even started to overflow into other disease states. A May 2015 outbreak of human immunodeficiency virus (HIV) infection in southern Indiana has been linked to injection of the prescription drug oxymorphone.

Prescription drug monitoring programs (PDMPs) have been enacted to help combat prescription drug abuse. Forty-nine states, plus the District of Columbia and Guam, have PDMPs. (Missouri does not have a PDMP.) PDMPs are designed to be a central database of all controlled substances dispensed for a patient. In turn, prescribers, and sometimes pharmacists, are allowed to access this information and use it to aid in decision making regarding prescription authorization and dispensing. Despite their usefulness, there are some shortfalls of PDMPs. The first is the varied time in which states require pharmacies to upload data to the PDMP. This can range from daily to monthly. Another limitation is that a patient's name and date of birth must be entered exactly the same, from writing the prescription, to filling in the pharmacy, to querying the database. Errors and inconsistencies at any of these steps can create an inadequate picture of exactly what controlled substances a patient is receiving. Additionally, there is variation in what controlled substances each state tracks. The majority

of states track and monitor schedule II – V controlled substances. However 15 states only track schedule II – IV controlled substances (see chart), and one state only tracks schedule II (Pennsylvania). A final limitation is a lack of communication between state PDMPs. Currently, 30 states (www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect) participate in interstate data sharing (see chart). While this increases sharing of information within PDMPs, there are many states that do not share this information, which can be a detriment, especially in those towns that lie on state lines.

With these limitations of state PDMPs comes an additional list of limitations regarding controlled substances dispensed to animals. While more pet owners are choosing to fill medications at "human" pharmacies, the primary dispensing location for animal prescriptions remains within the veterinarian's office. Only 14 states require veterinarians to report controlled substance dispensing within their practice setting (see chart), leaving a majority of them unreported. Interestingly, in South Carolina, veterinarians are only required to submit a report to the PDMP if the day supply is greater than five days. Additionally, phenobarbital prescriptions up to a 31-day supply do not need to be reported.

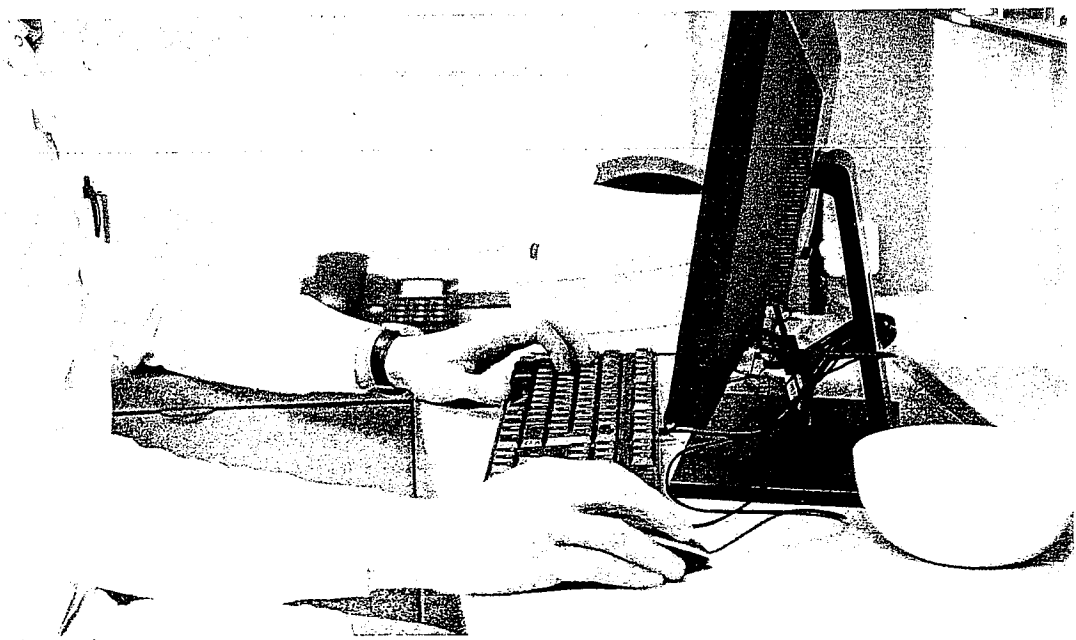
The purpose of this article is to shed light on how states handle animal prescriptions within their PDMPs and offer suggestions for improvement.

Another shortcoming of PDMPs with regard to animal prescriptions is the entry of animals into the database itself. It is common for owners to not know the exact date of birth of their pet, leading to the potential for several birthdates being used in the database. Fido Smith, with a date of birth of 1/1/2015, could have a separate entry than Fido Smith with a birthdate of 1/2/2015. Furthermore, it is also common for two owners with different last names to own the same animal. If John Smith and Jane Doe both shared the ownership of their cat, Fluffy, it could result in a variety of permutations within the PDMP, including Fluffy Smith, Fluffy Doe, Fluffy Smith-Doe, and Fluffy Doe-Smith. Additionally, it is unclear if the owner is in any way linked to the pet's profile, which would be helpful if a prescriber or pharmacist suspects diversion.

The purpose of this article is to shed light on how states handle animal prescriptions within their PDMPs and offer suggestions for improvement.

METHODS

The PDMPs for 49 states and Guam were contacted via email. Missouri was not contacted because they do not have a PDMP, and the District of Columbia was not contacted as its program has been approved but has not been enacted yet. Up to three email attempts were made. The email had open-ended questions regarding the handling of pet prescriptions with



Alabama
Arizona
Arkansas
Colorado
Connecticut
Delaware
Illinois
Indiana
Kansas
Kentucky
Louisiana
Maine
Michigan
Minnesota
Mississippi
North Dakota
New Jersey
New Mexico
Nevada
Ohio
Oklahoma
Rhode Island
South Carolina
South Dakota
Tennessee
Utah
Virginia
Wisconsin
West Virginia (allows for the sharing of prescription data across state lines)

Alabama
Alaska
Arizona
California
Connecticut
Delaware
Hawaii
Illinois
Indiana
Michigan
New York
Oklahoma
South Carolina
Washington

Arizona
California
Florida
Iowa
Kansas
Maine
Nevada
New Hampshire
Oregon
Rhode Island
South Carolina
Vermont
Virginia
West Virginia
Wyoming

Note: Pennsylvania only tracks schedule II

regard to the PDMP, and whether a pharmacist would be allowed to query the PDMP on the owner if they suspected diversion. Qualitative feedback was then analyzed to detect common themes. Of the 50 entities that were contacted, seven states either did not respond, or declined to respond because of the research nature of the question (Illinois, Indiana, Mississippi, New York, Tennessee, Texas, and Wisconsin). Of the remaining 43 states that responded, four states were excluded as their PDMP specifically does not collect data regarding animal controlled substance prescriptions (Kentucky, Montana, Nebraska, and Oregon). This left 39 states that were included in the analysis. This study was exempt from review by the University of Minnesota Investigational Review Board.

RESULTS

When asked whether the animal's records are separate from the owner's records, 28 (71.8 percent) respondents replied yes, five (12.8 percent) responded no (New Hampshire, Oklahoma, Rhode Island, Utah, and West Virginia), three (7.7 percent) respondents did not answer (Arizona, Kansas, and Pennsylvania), and three (7.7 percent) respondents replied that it depended on how the animal was entered as a patient in the pharmacy's computer system (Ohio, Virginia, and Vermont). Respondents in these states replied that there is no consistency in which pharmacies enter animals into their prescription software, so depending on how the animal was entered, it could result in merging of owner and pet profiles. One state (New Hampshire) specifically reported that it uses the owner's date of birth for the animal, which is how the two profiles are linked together. Six states stated that they use a species code to identify non-human patients (Alabama, Arizona, California, Connecticut, Massachusetts, and Washington), although one state (Washington) stated that this was not required to report.

Two states (Oklahoma and West Virginia) responded that they also required that pharmacies provide information regarding who picked up the controlled substance. Guam reported that it will eventually require this information.

PDMPs were also asked whether a pharmacist was allowed to query the database if they suspected an owner of diversion. Of these, 10 (25.6 percent) respondents replied yes (Arizona, Guam, Hawaii, New Hampshire, North Carolina, North Dakota, Oklahoma, Rhode Island, West Virginia, and Wyoming), 12 (30.8 percent) responded no (Alaska, Arkansas, California, Idaho, Maryland, Minnesota, New Mexico, Ohio, Pennsylvania, South Carolina, Utah, and Washington), and six (15.4 percent) responded yes, but only if the owner was also a patient of the pharmacy (Georgia, Iowa, Louisiana, Maine, Nevada, and New Jersey). The remaining 11 states (28.2 percent) did not provide an answer. One respondent (North Carolina) replied that while a pharmacist is allowed to access this information, a formal complaint would need to go through the department of health and human services, but could use results as grounds to refuse to fill a prescription.

DISCUSSION

The results of this study show that a majority of states do not link an animal's prescription record to the owner's prescription record within the state's PDMP. Furthermore, among approximately a third of respondents, if a pharmacist suspects an owner of diversion, they are unable to query the PDMP to investigate those suspicions. This disturbing situation, along with the knowledge that many veterinarians dispensing controlled substances within their office do not need to report dispensing, allows for the potential for unchecked diversion of controlled substances intended to be used for a companion animal.

Based on the results of this study, there are a few suggestions on how to increase the efficiency of each state or territory's PDMP to decrease diversion of animal prescriptions. First, states should mandate the reporting of controlled substances dispensed at the veterinarian's office. Second, a consistent method creating an animal's profile should be adopted within each state or territory, and preferably among all states involved in data sharing. A suggested method would be to adopt generic birthdate (such as Jan. 1 of the likely birth year year), use the first name of the pet with the last name of the owner(s), list last names of multiple owners in alphabetical order, and use a species code. Finally, animal PDMP profiles need to be linked to all adult owners' PDMP profiles, and pharmacists need to have authority to query the database if diversion is suspected.

CONCLUSION

Prescription drug abuse is a serious problem in the United States. PDMPs have been enacted to combat this problem, but there are a number of shortcomings of these programs, especially when it comes to animal prescriptions. The results of this study show that there is indeed a wide variety among how states and Guam handle animal prescriptions. However, these shortcomings can be overcome with some standardization with how PDMPs approach how animals are entered into their databases.

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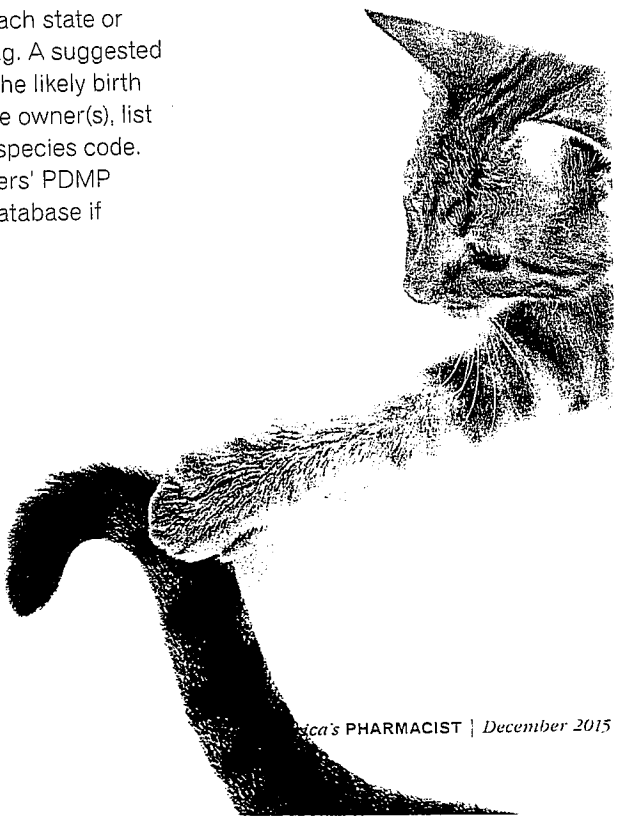
For the list of references used in this article, please contact America's Pharmacist Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.



STAT

At Walgreens and CVS, a push to collect customer health data by dangling discounts

Money At Walgreens and CVS, a push to collect customer health data by dangling discounts

By Rebecca Robbins

November 23, 2015

Alissa Ambrose/STAT

Want $50 off your next purchase at Walgreens? You'll have to run 2,000 miles. Or step on a scale 2,000 times. Or take 2,000 readings of your blood glucose level.

And you'll have to let the global pharmacy chain track all that data — and give them permission to mine it to target you with ads.

Walgreens this month launched a new smartphone app that customers can sync up wirelessly with their blood glucose and blood pressure monitors so they can feed their personal health information directly into the chain's data system in exchange for discounts. The app is novel. But the practice is increasingly familiar.

Pharmacies across the US are dangling perks to coax their customers to relinquish all sorts of personal information, ranging from daily fluctuations in their weight to their progress in quitting smoking to their real-time location every minute of the day.

At CVS, you can get $5 back for every 10 prescription refills — if you waive your right to health care privacy protected under the federal health law known as HIPAA. And Rite Aid is experimenting with a service that other retailers are using to collect tons of data: special lockers that you can use to charge your cell phone for free, if you'll give up your phone number, insurance costs, and shopping preferences.

Drugstores say they're collecting your data to encourage you to be healthy and save you money. But the growing practice is also a boon for their bottom line because it helps them target their marketing efforts more precisely.

How precisely? If you allow your drugstore to track your location, you might get a text offering a coupon for a specific cough syrup or recommending that you try a neti pot for sinus relief — while you're standing in the aisle that sells cold and flu medication.

The trend alarms consumer and privacy advocates.

"It's extremely concerning," said Paul Stephens, director of policy and advocacy at the nonprofit Privacy Rights Clearinghouse.

In exchange for modest discounts, he said, patients are giving up "very, very valuable" information and leaving themselves open to a barrage of advertising about potentially sensitive health conditions. They may also be at risk of having their data shared more widely than they want — or even stolen.

"There is no free lunch," Stephens said.

Consumers are giving up "very, very valuable" information, including extensive data on their health.

Paul Stephens, Privacy Rights Clearinghouse.

Michelle De Mooy, a consumer privacy advocate at the Center for Democracy & Technology, worries that these programs have the potential to be discriminatory in their impact. Low-income customers may not be able to afford to say no to a discount, even at the cost of personal data they would otherwise keep private, she said.

Retailers of all stripes have long mined purchase data obtained through their loyalty rewards programs for clues about their customers. What's new is that drugstores are increasingly taking advantage of the proliferation of "connection points" available to them, according to Alan Lipson, a retail industry marketing manager for the analytics firm SAS.

"Now it's coming on your smartphone, and they're texting you, and they're being more invasive," Lipson said.

And while a grocery store may know how many boxes of Cheerios you buy in a week or what brand of pasta sauce you prefer, Walgreens can collect far more sensitive data about your health, down to how many milligrams of sugar per deciliter of blood you have in your veins. And you have to share an awful lot of those data points to earn the discount.

You don't have to earn your reward points by giving the chain just one kind of data, of course. You can report all sorts of "healthy behaviors," like using a nicotine patch or setting a weight loss goal or biking for 10 miles, earning points for each bit of information you feed the app. (You can also earn rewards for refilling prescriptions or spending money at Walgreens, but you're capped at a certain number of points per day and month.)

Walgreens vice president Adam Pellegrini wouldn't disclose how many customers had downloaded the new app, called "Walgreens Connect," which makes it easier and quicker for customers to transmit their blood pressure and blood glucose readings in exchange for rewards. (They used to have to go to a website to log all their health data.)

But Pellegrini said the company had doled out 2 billion rewards points — the equivalent of 50,000 discounts of $50 — since it started rewarding customers for logging their health data last year.

The new Walgreens app lets you wirelessly send your blood pressure and blood glucose data directly to the pharmacy chain.

When asked how Walgreens was using all that health data, company spokeswoman Mailee Garcia said the company "does not sell personally identifiable information to third parties," but may sell de-identified information.

Garcia said Walgreens is not currently using health data to market to the customers who provide it. But the app's privacy policy explicitly states that Walgreens may use customer data to personalize advertising. The store can also combine data entered into the health app with personal information collected by other companies to create a more robust profile of individual customers.

The policy also gives Walgreens the right to change its privacy terms at any time and says customer data will be sold as an asset if Walgreens is acquired by another company.

All that concerns De Mooy, the consumer privacy advocate.

"It's becoming less and less possible to truly de-identify data, especially when it's at such a detailed personal level," she said. "When you're talking about really specific biometric information like your blood pressure or other metrics like that, the bar needs to be raised very high" in terms of data privacy, security, and transparency, she said.

Rite Aid, which recently agreed to be acquired by Walgreens, is testing out another way of trading perks for customer data. The drugstore is among a number of retailers — including Bloomingdale's, Whole Foods, and Nordstrom — that have installed stations where customers can securely store and charge their cell phones at no cost while they're shopping.

Rite Aid spokeswoman Kristin Kellum said the company has not collected or retained any customer information from the program, but that doesn't mean it can't in the future. The charging stations are designed to collect information from shoppers, including phone numbers, insurance plan benefits, and shopping preferences — with the free power source serving as enticement for volunteering the data.

"It's really important for the retailer to offer something in return for getting information," said Doug Baldasare, chief executive of the Philadelphia-based startup ChargeItSpot, which installs the phone-charging stations.

The pharmacy chain Duane Reade — a Walgreens subsidiary — is experimenting with another way to reach customers: tracking their physical locations through the GPS on their phones and then pushing out relevant promotions through an app. Duane Reade is testing the tactic in 10 of its New York City stores. Last year, Walmart said it was rolling out the technology in some of its stores, as well, but the company didn't respond to multiple requests for comment on how it's being used.

Customers don't even have to be in the stores to get targeted.

An older Walgreens app can beam smartphone users a notification offering them a discount when they're nearby a Walgreens location.

Every time Lipson goes to see his mother in Raleigh, N.C., he drives past a Walgreens and — once he's within the range of about a block — he gets a mobile notification hawking him a promotion via his Walgreens app. "Sometimes," he said, "I just want to turn it off."

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Full length article

Nonmedical opioid use and heroin use in a nationally representative sample of us high school seniors☆

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ABSTRACT

Background: Nonmedical use of opioids has become increasingly problematic in recent years with increases in overdoses, treatment admissions, and deaths. Use also appears to be contributing to heroin initiation, which has increased in recent years. Further research is needed to examine which adolescents are at highest risk for nonmedical use of opioids and heroin and to explore potential links between nonmedical opioid use and heroin use.

Methods: Data were analyzed from a nationally representative sample of American high school seniors in the Monitoring the Future study (2009–2013, Weighted $N = 67{,}822$). We examined associations between frequency and recency of nonmedical use of opioids and heroin. Sociodemographic correlates of use of each drug were also examined.

Results: 12.4% of students reported lifetime nonmedical opioid use and 1.2% reported lifetime heroin use. As frequency of lifetime nonmedical opioid use increased, so too did the odds for reporting heroin use, with over three-quarters (77.3%) of heroin users reporting lifetime nonmedical opioid use. Recent (30-day) nonmedical opioid use was a robust risk factor for heroin use and almost a quarter (23.2%) of students who reported using opioids ≥40 times reported lifetime heroin use. Black and Hispanic students were less likely to report nonmedical opioid or heroin use than white students, but they were more likely to report heroin use in absence of nonmedical opioid use.

Discussion: Recent and frequent nonmedical opioid use are risk factors for heroin use among adolescents. Prevention needs to be targeted to those at highest risk.

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1. Introduction

Nonmedical use of prescription opioids (i.e., narcotics, analgesics, pain killers) has become increasingly problematic in the US over the last decade. Although results from national surveys suggest prevalence of use has begun to decrease in recent years (Miech et al., 2015; Substance Abuse and Mental Health Services Administration (SAMHSA), 2014a), overdoses, emergency department (ED) visits, treatment admissions, and deaths related to use have increased (Centers for Disease Control and Prevention (CDC), 2012; Chen et al., 2014; SAMHSA, 2013, 2014b). However, a new concern is that a subset of opioid users may be transitioning to heroin, which is often more likely to lead to deleterious outcomes. Research is needed to help identify adolescents at risk for nonmedical opioid and/or heroin use, and to delineate which opioid users are at highest risk for heroin use.

While medical use of opioids tends to be efficacious when used as prescribed to treat pain, nonmedical use – often through overprescribing or diversion from doctors (Wang et al., 2014; Shei et al., 2015) – has become a major public health issue. From 2004 to 2011, ED visits involving prescription opioids increased by 183% (SAMHSA, 2013) and opioid-related admissions to substance abuse treatment centers increased from 2% in 2002 to 10%

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in 2012 (SAMHSA, 2014b). Results from National Vital Statistics demonstrate that the rate of opioid overdose deaths nearly quadrupled from 1999 to 2011, growing from 1.4 per 100,000 to 5.4 per 100,000 (Chen et al., 2014), and according to the CDC (2012), almost three out of every four prescription medication overdoses were associated with opioids. While the rate of increase in overdoses has slowed somewhat since 2006 (Chen et al., 2014), there is now concern that these decelerating rates of opioid-related deaths may be related to recent increases in heroin use, as individuals dependent on prescription opioids may be transitioning to heroin, which tends to be less expensive and more freely available (Cicero et al., 2014; Kanouse and Compton, 2015; Mateu-Gelabert et al., 2015). Heroin is among the most dangerous illicit drugs (Nutt et al., 2007; Gable, 2004) and use is associated with high rates of dependence, overdose, death, transmission of pathogens such as HIV and HCV, and social marginalization (Demaret et al., 2013; Hser et al., 2015; Hosztafi, 2011; Brown, 2015; Zhou et al., 2015). Heroin overdose deaths have increased since 2002, rising from 0.7 deaths per 100,000 to 2.7 deaths per 100,000 in 2013 (Jones et al., 2015). This rise was particularly dramatic from 2011 to 2013, when rates almost doubled.

Heroin user demographics appear to be shifting in the US. While rates of heroin initiation were similar between whites and nonwhites decades ago (Cicero et al., 2014), now whites are at a higher risk for nonmedical prescription opioid use, as well as heroin use (Cicero et al., 2014; Fischer et al., 2008; Peavy et al., 2012; Pollini et al., 2011). While women previously used at substantially lower rates than men (Cicero et al., 2014), their use of opioids and transition to heroin is increasing, with prescription opioids appearing to serve as a stepping stone (Cotto et al., 2010). Furthermore, use of heroin is increasing (Cicero et al., 2015), particularly among individuals living in non-urban areas, whereas it used to be a predominantly urban phenomenon (Cicero et al., 2014). A recent analysis of the National Surveys on Drug Use and Health (NSDUH), a nationally representative sample of non-institutionalized individuals in the US, compared data from 2002–2004 to 2008–2010, and found that past-year heroin use increased among many sociodemographic groups, including whites, those with higher income and those with health insurance (Jones et al., 2015). Whites, young adults (age 18–25), and those with opioid abuse/dependence were also found to be at high risk for heroin use/dependence. Alarmingly, this recent study found that between 2002 and 2013 there was a 138% increase in heroin use among nonmedical opioid users. Other studies have also found that many heroin users have moved onto heroin after nonmedical opioid use (Lankenau et al., 2012; Peavy et al., 2012; Mateu-Gelabert et al., 2015). Nonmedical opioid users have been found to transition to heroin as they considered heroin more "practical" as it is reportedly less expensive and easier to acquire (Cicero et al., 2014; Mars et al., 2014), especially as availability is reduced due to abuse-deterrent formulations and prescription monitoring programs (Cassidy et al., 2014; Worley, 2012).

Nonmedical opioid use is associated with poor health outcomes such as opioid dependency, sexual violence, overdose, and death (Jamison and Mao, 2015; Frank et al., 2015; Jessell et al., 2015); however, moving onto heroin from prescription opioids appears to be a dangerous (and understudied) emerging pattern among younger populations. While studies focusing on national data have begun to examine associations between nonmedical opioid use and heroin use and dependence, more information is needed regarding frequency and recency of nonmedical opioid use as it relates to heroin use—in both a bivariable and multivariable manner. Assessing the risk factors associated with nonmedical opioid use, and how its use may increase risk for heroin use is critical to developing appropriate prevention, intervention, and harm reduction programming geared toward adolescents at highest risk. An examination of a nationally representative sample of adolescents allows us to determine which subgroups of high school students are at highest risk for nonmedical opioid use and heroin use. This study examines the correlates of nonmedical use of opioids and heroin and examines how frequency and recency of opioid use relates to heroin use in a nationally representative sample of high school seniors.

2. Methods

2.1. Procedure

Monitoring the Future (MTF) is a nationally representative cross-sectional study of US high school students. Approximately 15,000 high school seniors (12th graders) are surveyed every year from approximately 130 public and private schools throughout 48 states. MTF uses a multi-stage random sampling procedure: geographic areas are selected, then schools within areas are selected, and then classes within schools are selected. Since the main outcome (heroin use) is rare, in order to have adequate power, this analysis focused on aggregated data collected from the five most recent cohorts with available data (2009–2013). MTF protocols were approved by the University of Michigan Institutional Review Board (IRB) and the authors' IRB deemed this secondary data analysis exempt from review.

2.2. Drug use

Students were asked about lifetime heroin use, and answer options were use on (1) 0 occasions, (2) 1–2 occasions, (3) 3–5 occasions, (4) 6–9 occasions, (5) 10–19 occasions, (6) 20–39 occasions, and (7) 40 or more occasions. Students were also asked about nonmedical use of opioids ("narcotics other than heroin"). They were first informed that, "There are a number of narcotics other than heroin, such as methadone, opium, morphine, codeine, Demerol, Vicodin, OxyContin, and Percocet. These are sometimes prescribed by doctors." They were then asked, "On how many occasions (if any) have you taken narcotics other than heroin on your own—that is, without a doctor telling you to take them...in your lifetime?" They were also asked the same question with regard to use in the last 12 months and the last 30 days, with the same ordinal response options.

In order to examine frequency of use of opioids and heroin, we created a series of dichotomous variables indicating lifetime use (ever used; ≥1 times), and use ≥6 times, ≥10 times, and ≥40 times. Ordinal cutoffs were based on previous MTF studies that focused on use of other drugs (Boyd et al., 2015; Palamar and Acosta, 2015; Palamar et al., 2014a, 2015a,b). In order to examine recency of use, for both opioids and heroin we also created categorical variables (which were also examined as indicator variables) with the following categories: (1) no use, (2) lifetime use, but not 12-month use, (3) 12-month use, but not 30-day use, and (4) 30-day use.

2.3. Sociodemographic variables

Students reported their sex, age (public data predefined by MTF as <18, ≥18 years) and race/ethnicity (i.e., black, white, Hispanic). Population density of students' residences were defined as non-, small-, or large-metropolitan statistical areas (MSAs). Small MSAs are counties or groups of counties with at least one city of ≥50,000 inhabitants and the 24 largest MSAs are defined as large MSAs. Non-MSAs are the remaining areas. Level of religiosity was assessed via two ordinal items asking about level of religious attendance and importance. We computed these items into a composite and divided it into tertiles to indicate low (1.0–2.0), moderate (2.5–3.0) and high (3.5–4.0) religiosity. To assess family composition, we examined the number of parents students resided with. Answers were coded into two parents vs. no parents or one. Students were also asked about level of educational attainment of each parent and answer options were (1) grade school, (2) some high school, (3) high school graduate, (4) some college, (5) college graduate, and (6) graduate school. A mean score for both parents (or a raw score if only one parent) was coded into tertiles to represent low (1.0–3.0), medium (3.5–4.0), and high (4.5–6.0) education. Students were asked how much money they earn during the average week from (1) a job or other work, and (2) from other sources. Responses for each of these two items were coded into $10 or less, $11–50, or $51 or more. Coding of sociodemographic variables was based on previous MTF analyses that focused largely on socioeconomic status (SES; Palamar et al., 2014b; Palamar and Ompad, 2014; Wallace et al., 2009).

2.4. Statistical analyses

Analyses focused on students with complete opioid and heroin use data (Weighted N=67,822; Unweighted N=67,896). We first examined descriptive statistics for all variables. We then examined how lifetime opioid use related to lifetime heroin use in a bivariable manner using Rao–Scott χ^2 tests (Rao and Scott, 1984). We examined potential differences between opioid frequency and recency and whether lifetime heroin use was reported (yes/no). We then repeated these computations, but to examine potential differences by heroin use ≥6 times, ≥10 times, and ≥40 times. To test if and how each level of opioid use relates to lifetime heroin use, we constructed two separate logistic regression models, controlling for all sociodemographic variables. Thus, each level of opioid use in both models

was compared to never-use. The bivariable tests were then repeated, but with the recency of heroin use variable as the outcome. Multivariable statistics were not possible with any heroin categories other than overall lifetime use as rates of more frequent or more recent use were very rare (≤0.5%).

To further investigate correlates of use of opioids and heroin, we fit all sociodemographic variables into a multivariable logistic regression model to determine conditional associations (controlling for all variables in the model) between each variable and lifetime opioid use. The same model was repeated with (1) frequent opioid use (used ≥40 times), and (2) lifetime heroin use as the outcome. We considered lifetime opioid use and heroin use non-independent outcomes; therefore, we applied a Bonferroni correction ($\alpha = 0.05/2 = 0.025$) in order to reduce potential Type I Error. These models resulted in an adjusted odds ratio (AOR) for each covariate (in each model). Finally, within the heroin-using subsample we repeated this logistic regression model to examine potential correlates of the 22.7% who did *not* report nonmedical opioid use.

We controlled for potential cohort and/or secular trends in all multivariable models by entering indicator variables for cohort (with 2009 as the comparison). In addition, missing data indicators were entered into multivariable models for covariates with missing data instead of deleting these cases. For example, for the 14.4% who were missing race, an additional indicator was included to account for missing race (Palamar and Ompad, 2014; Terry-McElrath et al., 2013). Retaining these cases allowed us to maintain power and allowed rates to match published nationally representative MTF rates (Miech et al., 2015). All analyses were design-based for survey data (Heeringa et al., 2010) and sample weights were included. We used SAS 9.3 software (SAS Institute, 2011) for all analyses.

3. Results

Sample characteristics are presented in Table 1. Nonmedical opioid and heroin use are presented in Table 2. About 12% of the sample reported using opioids at least once and using it 1–2 times was most common among users. About one out of 100 students reported lifetime use of heroin.

Table 3 presents associations between level of lifetime opioid use and heroin use. We found that 7.5% of nonmedical opioid users reported ever using heroin, and the higher the frequency of opioid use, the higher the odds of reporting lifetime heroin use (with all else being equal). A dose-response was observed, with more frequent use being highly associated with heroin use. Using opioids ≥40 times was associated with an extreme increase in odds for lifetime heroin use (AOR = 88.05). With regard to recency of opioid use, more recent use (within the last 30 days) was most highly associated with lifetime heroin use (AOR = 44.01). Although we could not model more frequent heroin use, the raw percentages (displayed in Supplemental Table 1[1]) suggest that more frequent and recent opioid use is also associated with more frequent heroin use (e.g., 3.3% of opioid users who reported using ≥40 times also reported using heroin ≥40 times). Supplemental Table 2[2] presents the same opioid variables, but by recency of heroin use. More frequent opioid use was associated with increases in all levels of recency of heroin use. More recent opioid use (specifically, 30-day use) was associated with recent (12-month or 30-day) use of heroin; 6.9% of those who used opioids in the last 30 days also reported using heroin in the last 30 days.

Table 4 presents conditional associations between covariates and opioid and heroin use. Females were at lower odds for opioid use (both infrequent and frequent use) and heroin use. While older students were not at risk for opioid use, they were in fact at increased odds for heroin use (AOR = 1.22, $p = 0.024$). Compared to white students, black and Hispanic students were less likely to report nonmedical use of opioids, especially more frequent use, yet protective effects were less robust for heroin use. With regard to population density, students residing in large MSAs were at low odds for reporting frequent nonmedical opioid use (AOR = 0.73, $p = 0.005$). Moderate and high levels of religiosity, and residing with two parents, was consistently protective against opioid use and heroin use. Parent education, however, had mixed results. Moderate education was a risk factor for ever-using opioids (AOR = 1.12, $p = 0.002$), but not for frequent use. Higher parent education, however, was a protective factor against heroin use (AOR = 0.72, $p = 0.002$). Higher weekly student income – especially from sources other than a job – was often a robust risk factor for opioid use, especially frequent use. Results were similar for heroin, but results were not as robust as they were for frequent opioid use.

Finally, focusing on the subsample of heroin users, we delineated correlates of *not* reporting lifetime nonmedical opioid use (as only 22.7% of heroin users did not report nonmedical opioid use). Controlling for all covariates, race/ethnicity was the only significant correlate of heroin use. Specifically, Blacks (AOR = 2.73, 95% CI: 1.26–5.95, $p = 0.011$) and Hispanics (AOR = 3.05, 95% CI: 1.68–5.53, $p < 0.001$) were at increased odds for reporting lifetime heroin use without ever using opioids.

Table 1
Sample characteristics (weighted $N = 67{,}822$).

Variable	Weighted *N*	(%)
Sex		
Male	32,339	46.7
Female	33,311	49.1
Missing	2172	3.2
Age (years)		
<18 Years	28,840	42.5
≥18 Years	38,675	57.0
Missing	307	0.5
Race		
White	40,215	59.3
Black	7598	11.2
Hispanic	10,228	15.1
Missing	9781	14.4
Population density		
Non-MSA	13,939	20.6
Small MSA	33,620	49.6
Large MSA	20,262	29.9
Religiosity		
Low	20,735	30.6
Moderate	14,538	21.4
High	15,992	23.6
Missing	16,557	24.4
Parent education		
Low	20,489	30.2
Moderate	18,741	27.6
High	25,644	37.8
Missing	2,947	4.3
Family composition		
0–1 Parents	22,254	32.8
2 Parents	18,195	66.1
Missing	767	1.1
Income from job		
$10 or less	30,645	45.2
$11-50	7320	10.8
$51 or more	25,837	38.1
Missing	4019	5.9
Income from other source		
$10 or less	35,222	51.9
$11-50	21,243	31.3
$51 or more	6462	9.5
Missing	4895	7.2

Note. MSA = metropolitan statistical area.

4. Discussion

For a substantial number of individuals, especially young, white males, nonmedical opioid use is an important correlate of use of a more dangerous substance—heroin (Mateu-Gelabert et al., 2015; Peavy et al., 2012; Brands et al., 2005; Lankenau et al., 2012; Mars et al., 2014; Jones, 2013). Considering this alarming trend, it is

[1] Supplementary material can be found by accessing the online version of this paper at http://dx.doi.org and by entering doi: 10.1016/j.drugalcdep.2015.11.005.

[2] Supplementary material can be found by accessing the online version of this paper at http://dx.doi.org and by entering doi: 10.1016/j.drugalcdep.2015.11.005.

Table 2
Frequency and recency of nonmedical opioid and heroin use.

	Lifetime nonmedical opioid use		Lifetime heroin use	
	Weighted *N*	(%)	Weighted *N*	(%)
Used 0 times	59,419	87.6	67,002	98.8
Used 1–2 times	3121	4.6	388	0.6
Used 3–5 times	1684	2.5	102	0.2
Used 6–9 times	1005	1.5	70	0.1
Used 10–19 times	1009	1.5	55	0.1
Used 20–39 times	593	0.9	47	0.1
Used 40+ Times	993	1.5	157	0.2
Lifetime use, but not 12-month use	2815	4.2	365	0.5
12-Month use, but not 30-Day use	3292	4.9	216	0.3
30-Day use	2296	3.4	240	0.4

essential to determine the risk factors for nonmedical use of opioids and heroin use. Although longitudinal data would most adequately allow us to delineate correlates of transition to heroin, our study is among the first to elucidate and compare correlates of use of opioids and heroin among a sample of adolescents approaching adulthood. These findings add to a growing literature describing how nonmedical opioid use relates to heroin use in a large nationally representative sample.

We found that among students who did use opioids or heroin, "experimentation" (using only 1–2 times) was most common (for both drugs). However, the subset of students that had reported any nonmedical use of opioids was at increased odds for reporting lifetime heroin use. In fact, a dose-response was observed with students who reported more frequent opioid use being at greater odds of reporting lifetime heroin use. Frequent use (e.g., ≥40 times) was associated with an increase in odds of reporting heroin use by 8700% with all else being equal. In addition those students who reported recent use (in the last 30 days) were also much more likely to report heroin use. While temporality could not be determined, this study does confirm that nonmedical use – especially more frequent and recent use – is a robust correlate for heroin use.

Females were less likely to report use of opioids or heroin than their male counterparts. This finding was not fully consistent with the literature, which provides somewhat conflicting information about gender and opioid use in young people. An analysis of data from the NSDUH found that for young individuals, age 12 to 25 years, patterns of use were different by sex, with nonmedical use of prescription-type pain medications more frequent by females than males (Cotto et al., 2010). In a sample of individuals seeking treatment, Cicero et al. (2014) found that while men were more likely to seek treatment for opioids and heroin decades ago; currently, men and women seek treatment at similar rates. However, our results were derived from a large nationally representative sample, and we examined associations using multivariable models that controlled for multiple demographic confounders.

Increased risk of heroin use was particularly distinct among white and male students, and these findings suggest that whites are at higher odds of using heroin than racial minorities. But, while black and Hispanic students are less likely to use heroin, they are more likely to use heroin without having used prescription opioids. Importantly, this seems to indicate a different pathway to heroin use by race/ethnicity. This is consistent with a study by Fischer et al. (2008) evaluating the differences between individuals who use heroin only or illicit prescription opioids only, which found that prescription opioid users were more likely to be white. Results from one study suggest it may be more difficult for black patients to obtain prescription opioids than white patients (Hausmann et al., 2013), and another study found that blacks and Hispanics are less likely to "doctor shop" compared to whites (Weiner et al., 2015). Peavy et al. (2012) also found that heroin injectors reporting opioid dependence prior to heroin were predominantly white, and national data shows that whites are more likely to receive treatment for opioids and heroin (SAMSHA, 2014b). Recent research suggests that many individuals who begin using heroin today do so after using or becoming dependent on prescription opioids (Mateu-Gelabert et al., 2015; Cicero et al., 2014; Jones, 2013; Lankenau et al., 2012; Mars et al., 2014; Peavy et al., 2012); thus, blacks and Hispanics do appear to be at lower risk for heroin initiation through the mechanism of prescription opioid dependence.

Thus, this study supports calls for efforts to prevent students from engaging in nonmedical use of prescription opioids in order

Table 3
Lifetime heroin use according to frequency and recency of lifetime nonmedical opioid use.

	Raw percentages	Adjusted model	
Lifetime Opioid Use	Ever used heroin	AOR	95% CI
0 Times	0.3	1.00	
1–2 Times	2.7	8.71	(6.41, 11.82)
3–5 Times	4.6	14.74	(10.78, 20.17)
6–9 Times	8.5	27.03	(19.05, 38.37)
10–19 Times	8.4	27.31	(19.80, 37.67)
20–39 Times	11.8	39.34	(27.54, 56.18)
40+ Times	23.2	88.05	(67.42, 115.00)
Ever used	7.5		
Lifetime opioid use	Ever used heroin	AOR	95% CI
Never used	0.3	1.00	
Lifetime use, but not 12-month use	5.5	17.12	(13.07, 22.43)
12-Month use, but not 30-Day use	4.9	15.36	(11.80, 20.01)
30-Day use	13.8	44.01	(35.01, 55.32)

Note. AOR = adjusted odds ratio (controlling for sex, age, race, population density, religiosity, family structure, parent education, weekly income from job, and weekly income from other sources); CI = confidence interval. All AORs presented are $p < 0.0001$.

Table 4
Logistic regression models delineating sociodemographic correlates of lifetime nonmedical opioid and heroin use.

	Lifetime opioid use (used ≥ 1 times)		Frequent lifetime opioid use (used ≥ 40 times)		Lifetime heroin use (used ≥1 times)	
	AOR	95% CI	AOR	95% CI	AOR	95% CI
Sex						
Male	1.00		1.00		1.00	
Female	0.79***	(0.75, 0.84)	0.59***	(0.50, 0.69)	0.57***	(0.48, 0.68)
Age (years)						
<18	1.00		1.00		1.00	
≥18	1.02	(0.96, 1.08)	1.11	(0.94, 1.30)	1.22*	(1.03, 1.45)
Race						
White	1.00		1.00		1.00	
Black	0.36***	(0.32, 0.41)	0.26***	(0.18, 0.39)	0.52***	(0.38, 0.73)
Hispanic	0.54***	(0.49, 0.60)	0.38***	(0.28, 0.54)	0.71*	(0.54, 0.93)
Population density						
Non-MSA	1.00		1.00		1.00	
Small MSA	1.04	(0.97, 1.12)	0.85	(0.71, 1.01)	1.20	(0.97, 1.48)
Large MSA	1.01	(0.93, 1.09)	0.73**	(0.59, 0.91)	1.12	(0.88, 1.43)
Religiosity						
Low	1.00		1.00		1.00	
Moderate	0.74***	(0.69, 0.80)	0.60***	(0.49, 0.74)	0.74***	(0.56, 0.91)
High	0.43***	(0.40, 0.47)	0.33***	(0.26, 0.43)	0.45***	(0.35, 0.59)
Family structure						
0–1 Parents	1.00		1.00		1.00	
2 Parents	0.70***	(0.66, 0.74)	0.67***	(0.57, 0.79)	0.56***	(0.47, 0.66)
Parent education						
Low	1.00		1.00		1.00	
Moderate	1.12**	(1.04, 1.21)	1.11	(0.92, 1.36)	0.80	(0.64, 0.99)
High	0.94	(0.87, 1.01)	0.85	(0.69, 1.04)	0.71**	(0.59, 0.89)
Weekly income from job						
$10 or Less	1.00		1.00		1.00	
$11–50	1.16**	(1.06, 1.28)	0.78	(0.57, 1.06)	1.40*	(1.05, 1.86)
$51 or More	1.53***	(1.44, 1.63)	1.78***	(1.50, 2.12)	1.65***	(1.36, 2.01)
Weekly income from other source						
$10 or Less	1.00		1.00		1.00	
$11–50	1.48***	(1.39, 1.57)	1.80***	(1.50, 2.16)	1.27***	(1.03, 1.56)
$51 or More	1.85***	(1.69, 2.03)	3.27***	(2.64, 4.04)	2.66***	(2.10, 3.38)

Note. The models contain all covariates presented in the table. MSA = metropolitan statistical area, AOR = adjusted odds ratio, CI = confidence interval. All models included cohort indicators and missing data indicators.
* $p < 0.025$.
** $p < 0.01$.
*** $p < 0.001$.

to prevent possible future heroin use. Such efforts may not be as effective for many racial/ethnic minority students, as previous nonmedical opioid use does not appear to be a determinant of their heroin use. Thus, although black and Hispanic students are still at low risk for heroin use, prevention efforts may need to consider race/ethnicity as they appear to be taking a different pathway to heroin use than their white counterparts. Our findings also suggest that students who live in large cities had lower risk of frequent opioid use than those who live in non-MSAs. These findings are consistent with Cicero et al. (2014), who suggest that heroin users (who have largely started on prescription opioids) are now more likely to reside in less-urban areas and these individuals were also more likely to use opioids concurrently with heroin.

We also found that higher student weekly income is a risk factor for opioid and heroin use among high school seniors. This finding corroborated an analysis of the National Health and Wellness Survey, which also found that higher income was associated with opioid abuse (Vietri et al., 2014). Furthermore, other studies have found that student disposable income is a risk factor for adolescent use of alcohol, tobacco, hookah, marijuana, ecstasy (MDMA, "Molly"), synthetic marijuana, "bath salts", and cocaine (Martin et al., 2009; Scragg et al., 2002; Zhang et al., 2008; Palamar, 2015; Palamar et al., 2015a,b). This suggests that higher student income appears to be a common risk factor for various drugs, as income is often needed to pay for the drug. We have confirmed that this is no exception for opioids and heroin. However, we did find that higher student income (from sources other than a job) was more robustly associated with frequent nonmedical opioid use than heroin use. More research is needed, but this might suggest that those with higher incomes can in fact afford high-frequency opioid use, as prescription opioids tend to be more expensive than heroin. However, it should be noted that Cerdá et al. (2015) found that income was not associated with transition from opioids to heroin in a sample of youth who reported nonmedical use of opioids at a young age; however, this measure was of family income as opposed to student disposable income.

4.1. Limitations

High school dropouts were not surveyed and this could have affected the generalizability of our findings. As these data are cross-sectional, it is not possible to determine temporal order or causality so we cannot rule out that in some instances heroin use may have taken place prior to use of other opioids. Multivariable analysis could not be utilized to examine more frequent (or recent) heroin use as an outcome as frequent and recent use was too rare. We used missing data indicators to maintain the full sample while including those with incomplete data. We compared analyses with the case-complete sample and the sample containing missing data indicators yielded similar results. Although, it should be noted that 1.9% of students ($N = 1288$) from the full dataset had to be excluded from analyses due to missing opioid and/or heroin data. Black and

Hispanic students, and students with highest income from sources other than a job were more likely to have been excluded due to missing opioid and/or heroin data, and females, students residing with both parents, and those with higher parent education were less likely to have been excluded due to missing opioid and/or heroin data (all $ps < 0.01$). Thus, it is possible that this systematic missingness may have biased results. MTF's definition of opioids ("narcotics other than heroin") contained a list of common opioids such as Oxycontin and Vicodin, but the list was not exhaustive, potentially leading to underreporting. The list included opium, a nonprescription opiate, as well as methadone, which is commonly used to treat addiction, and we were unable to select such cases out as there was no specific opium or methadone question. However, we note that methadone is also often diverted and used for nonmedical purposes (Ompad et al., 2008). Finally, family income data were not available. This is important to consider with respect to our findings related to students' income.

5. Conclusions

Increases in heroin use in the last decade may be related to opioid use and transition from opioid to heroin use, particularly among young, white, non-urban males. We found a dose-response indicating that greater frequency and more recent use of nonmedical opioids result in substantially greater odds of heroin use. Future interventions should be aimed at decreasing nonmedical opioid use among adolescents and young adults before initiation of heroin use, with special attention given to individuals who use opioids more frequently. Targeting this group may prevent future heroin initiation, and decrease the troubling trend in opiate-related deaths.

Author disclosures

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Contributors

All authors are responsible for this reported research. J. Palamar conceptualized and designed the study, and conducted the statistical analyses. J. Shearston and E. Dawson drafted the initial manuscript. J. Palamar, P. Mateu-Gelabert, and D. Ompad helped draft the manuscript, interpreted results, and critically reviewed the manuscript, All authors reviewed and revised the manuscript, and all authors approved the final manuscript as submitted.

Conflict of interest statement

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.drugalcdep.2015.11.005.

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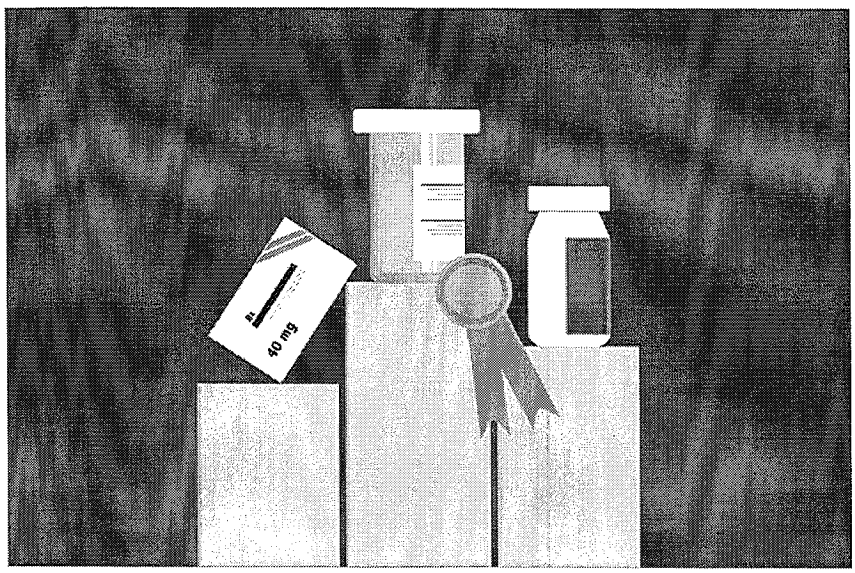
The Prescribers
Inside the Government's Drug Data

Brand-Name Drugs Increase Cost But Not Patient Satisfaction

As presidential candidates focus more on drug prices, new data from the website Iodine shows that generics scored highest among users in three popular drug categories. ProPublica has teamed up with Iodine to add user reviews to our Prescriber Checkup tool.

by Charles Ornstein
ProPublica, Nov. 19, 2015, 1:59 p.m.



(Emily Martinez/ProPublica)

This story was co-published with NPR's Shots blog.

In recent days, presidential candidates and even the American Medical Association have griped about rising drug prices, pointing to brand-name blockbusters with splashy ad campaigns.

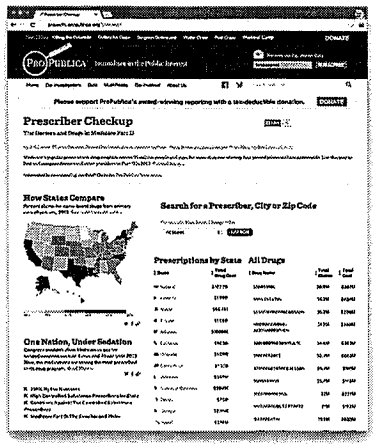
When it comes to patient satisfaction, however, there isn't much difference between brands and generics, according to data collected by the website Iodine, which is building a repository of user reviews on drugs.

ProPublica has teamed up with Iodine, which launched last year, to add data from reviews to our Prescriber Checkup tool, which allows users to see their doctors' prescribing habits in the Medicare Part D program and compare them with others in the same specialty

Prescriber Checkup

Medicare's popular prescription-drug program serves 39 million people and pays for more than one of every four prescriptions written nationwide. Use this tool to find and compare doctors and other providers in Part D in 2013.
Explore the app

and state. Our drug pages (take, for example, the antipsychotic Abilify) will now include consumers' user reviews, usage statistics by state and a listing of the top prescribers in the country.



"What is it actually like to take these medications?" asked Thomas Goetz, Iodine's co-founder and chief executive. "That is the nub of what we're trying to measure...The fact that a drug is a brand drug or a generic drug, for us, is immaterial to the patient experience."

ProPublica compared the reviews of brands and generics in three drug categories: antipsychotic medications that treat schizophrenia, antidepressants, and drugs that lower cholesterol. Iodine asks people if a drug is worth it, whether it's a hassle to take and if it works well. For each category of drug, a generic scored best on each of the three questions.

Dr. Joseph Ross, an associate professor of medicine and a health policy researcher at Yale University School of Medicine, said he wasn't surprised that patient reviews of generic and brand-name medications were similar.

"Generic medications are manufactured to be equivalent in all ways (except appearances) to brand-name medications," he said in an e-mail. "Unfortunately, many patients and physicians are convinced to spend more and use the brand-name medication by marketing initiatives, including advertisements on the television or drug coupons that promise similar out-of-pocket expenses for the higher-cost brand-name medications."

Consider antidepressants. Most drugs in the class, including Prozac, Celexa and Zoloft, are now available as generics and cost under $20 for 30 pills at Costco. By comparison, the brand-name drug Pristiq, manufactured by Pfizer, has a cash price of about $283 for 30 pills. (Those with insurance pay less, but probably still more than for a generic.) Pristiq fares worse in satisfaction than many of the cheaper alternatives.

Pfizer spokesman MacKay Jimeson said that depression manifests itself differently in different people, meaning treatment effectiveness may vary, too.

"Patients should work with their doctors to determine whether to use an antidepressant and, if so, which type of medication might be best for them," he said in an e-mail. "Any treatment of depression or anxiety disorders, whether it's medication or otherwise, must be monitored carefully by a qualified health care professional."

A similar phenomenon plays out for cholesterol-lowering drugs, known as statins. Zocor and Lipitor are now available as generics and are inexpensive. The drug Crestor, made by AstraZeneca, continues to have patent protection and costs more than $230 for 30 pills at Costco. (Again, insurance discounts would lower that price.) Crestor's user satisfaction score was about the same as the generic alternatives.

AstraZeneca spokeswoman Michele Meixell said not all statins are alike. "The efficacy and safety of Crestor has been studied in more than 120 ongoing [or] completed trials and more than 67,000 patients worldwide over the past 13 years," she said in an e-mail. "Crestor is one of the two high intensity statins available and AstraZeneca believes it's a clinically important option for many patients, who are unable to reach their cholesterol goal with diet and exercise alone."

Brand Names, Generics Have Similar Satisfaction

Based on user reviews on the website Iodine, generic drugs performed similarly, if not better than, their brand-name counterparts. Note: Some of the drugs have many more reviews than others.

Percentage of Patients Who Say Drug Is 'Worth It':

Generic cholesterol drugs

Both Pfizer and AstraZeneca noted that patients can receive discounts from the company.

Some drugs have many more Iodine reviews than others, which may affect the results. All told, Goetz said Iodine has reviews from more than 100,000 Americans covering the approximately 500 drugs in its database.

Goetz said he doesn't know why generics sometimes have higher satisfaction than brand-name drugs, but he offered one theory. "People might have outsize expectations for what a heavily marketed drug is going to do for them," he said. "They may watch the commercials and think that any given drug is going to be the answer to all their problems. And the reality of medicine and the reality of pharmacology is that every drug has some benefits for some people and some side effects for some people, and that's the whole balance."

Generics may have another advantage over newly launched drugs in the same class. By definition, a generic has been on the market a long time, so doctors know how it works, and any major problems or side effects would have already surfaced. By comparison, the studies that help brand-name drugs win approval may not have picked up safety problems or side effects that, while uncommon, can represent an issue once a medicine is taken widely.

Pravastatin (Pravachol)	54
Lovastatin (Mevacor)	43
Simvastatin (Zocor)	60
Atorvastatin (Lipitor)	64
Brand-name cholesterol drugs	
Crestor	61
Vytorin	51
Antara	24
Zetia	41
Generic antidepressant drugs	
Fluoxetine (Prozac)	59
Duloxetine (Cymbalta)	61
Bupropion (Wellbutrin)	55
Citalopram (Celexa)	58
Sertraline (Zoloft)	57
Escitalopram (Lexapro)	58
Venlafaxine (Effexor)	60
Brand-name antidepressant drugs	
Oleptro	47
Pristiq	38

Source: Iodine. Data collected on Nov. 18, 2015.

Questions about cost and quality are likely to intensify. This week, the AMA called for a ban on direct-to-consumer advertising of drugs and medical devices. AMA board chair-elect Patrice A. Harris cited "concerns among physicians about the negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices."

Ross, the Yale researcher, said eventually the costs of brand-name medications "will catch up with us, either in the form of higher out-of-pocket payments once the coupons run out or higher health insurance premium costs."

And, he added, "just because something is more expensive in health care does not mean it works better or is safer."

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Sticking With It

Written By: Heather Buschman, PhD

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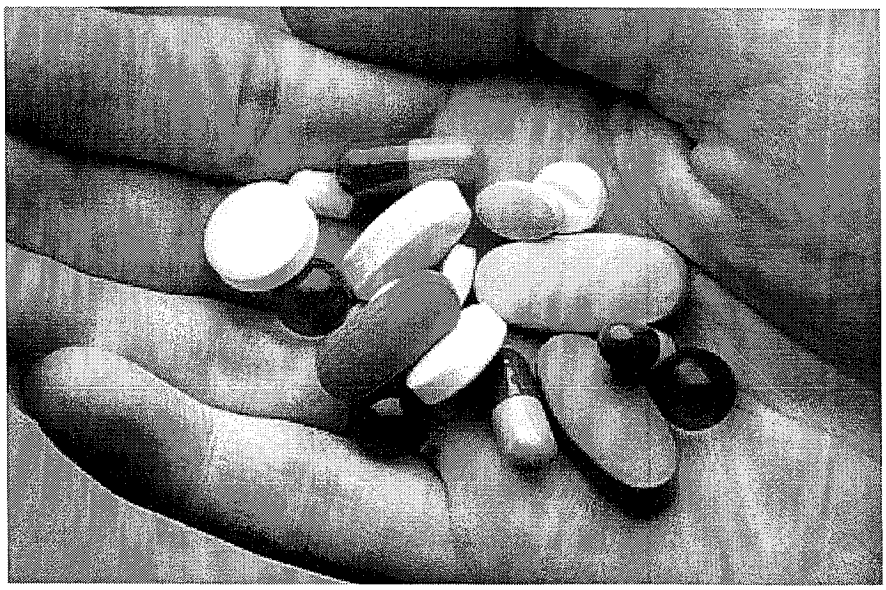
"The biggest challenge in health care today isn't lack of new drugs or their cost — it's simply getting patients to adhere to taking their current medications," says Adah Almutairi, PhD, associate professor in the Skaggs School of Pharmacy and Pharmaceutical Sciences and director of the Center for Excellence in Nanomedicine at UC San Diego.



People usually don't remember or want to take a pill every day and that's a big hurdle to researchers like Almutairi, who are developing new therapeutics for a variety of diseases. "We can have the most brilliant idea, but if a patient won't or can't do it, we have to go back to the drawing board," she says.

How big is the problem? According to the American Medical Association (AMA), approximately one-quarter of new prescriptions are never filled, and patients take their medications as prescribed roughly 50 percent of the time.

That adds up to more than $300 billion in preventable hospital costs related to failure to take medications as directed, says Jonathan Watanabe, PharmD, PhD, assistant professor of clinical pharmacy in the Skaggs School of Pharmacy.

Lack of medication adherence is a burden, says Watanabe, who studies factors that keep patients prescribed cholesterol-lowering statins from taking them, because "doctors and pharmacists often assume patients are taking

never really know how well the original drug and dose could have worked if taken properly."

Just plain forgetting

Often times a person isn't intentionally forgoing medication – we all forget sometimes. How can you make sure you take your medication on time, every time? Watanabe has a few simple tricks:

> Make it a habit – always do something else at the same time you take your medication, eating dinner, for example.
>
> Set a recurring alarm or calendar alert on your cell phone.
>
> Organize your pills in labeled pill boxes or opt for medications in blister packs — once the pills are laid out, you always know what you've already taken or need to take.
>
> If it can be done safely, keep your medications out in a place where you can't miss them — on top of your laptop, for example, where you are forced to pick up the bottle in order to open it.

Even if taking your medication on time, every time isn't always realistic, every bit counts. "There's a big difference between 80 and 90 percent adherence," Watanabe says. "Moving the needle up just a little bit can translate into big clinical improvements."

Intentional nonadherence

In a recent report, the AMA outlined eight reasons patients intentionally fail to fill their prescriptions or take their medications. These include fear of potential side effects, cost, misunderstanding (as in misunderstanding the need for medication, nature of side effects and time necessary to see results), too many medications, lack of symptoms, concerns about becoming dependent on medication, depression and mistrust of the doctor's motivations behind the prescription.

"We find that simply getting to the pharmacy to get a prescription filled is huge barrier for a lot of patients," Watanabe says. "We can greatly increase the likelihood a patient will take their medications if we can at least shorten the time interval between doctor's visit and pharmacy visit. That's why clinics that include an on-site pharmacy can be very effective. We also use free samples, vouchers and cheaper medication copayments to try to boost adherence to starting a new medication."

Education is also a key factor in helping patients stick to their drug treatments plans, Watanabe says. "It's not as simple as handing over a prescription. There needs to be a dialogue between patient and doctor or pharmacist. Patients should feel empowered to ask questions and take the time to truly understand what the medication is, what it will do and what they can expect in terms of side effects. This is especially important for the so-called 'silent syndromes' — conditions such as hypertension and high cholesterol, where the patient doesn't experience symptoms and so it can be easy to forget why it's important to take those types of medications."

The future of pharmacy

medications in an average patient visit. Pharmacists like him are now increasingly filling that gap, acting as a new type of primary health care provider. In 2014, California became the fourth state to allow pharmacists to initiate and monitor a patient's drug therapy, rather than simply fulfill a doctor's prescription.

More pharmaceutical advances are on the horizon. Watanabe says that pharmacists are trying to make drug regimens less complicated and lessen the "pill burden" with combination pills. They are also trying to reduce redundancies, so patients can take fewer medications and save money. Technological advances may help, too — "smart" pill dispensers can monitor a patient's adherence in real time, for example.

Watanabe sees a future where doctors and pharmacists treat adherence like its own syndrome — a condition that needs to be fully recognized and remedied, just like anything else.

Meanwhile, Almutairi hopes researchers will eventually be able to take the patient out of the equation entirely.

"I want to find ways to have patients see a doctor or pharmacist just once a year to get their drugs administered, then they can forget about it while an implanted device continues to releases the right doses and the right time," she says. "Taking medications should be like paying bills — it used to be time intensive, but now we set up autopay and forget about it."

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