



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Victor Law, Licensee Member, Chairperson
Deborah Veale, Licensee Member, Vice-Chairperson
Ryan Brooks, Public Member

Report of the Communication and Public Education Committee Meeting held September 8, 2016. A copy of the minutes from the meeting is provided in **Attachment 10**.

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

Background

At the October 2015 Board Meeting, President Gutierrez asked the committee to develop a survey for licensees about patient consultation. At the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office's ability to develop the patient consultation survey for the board's licensees.

Committee Discussion and Recommendation

At the September 2016 Communication and Public Education Committee, the committee discussed the advantages of the board funding an additional survey. Board staff provided the committee with rough estimates from the DCA of approximately \$15,000-\$20,000 plus an additional \$1/per pharmacist surveyed. The DCA recommended surveying 10,000-20,000 pharmacists.

The committee discussed the importance of ensuring patient consultation is provided to patients; however, they expressed hesitation in a survey being the most effective instrument used to increasing patient consultation. The committee discussed various means to ensure patient consultation including licensing and enforcement measures.

Committee Member Ryan Brooks expressed concern that the earlier board survey on why pharmacists do not provide consultations provided answers that the board already knew and asked what jurisdiction the board has other than enforcement. He noted that the board cannot force pharmacies to pay more money or change their structure to increase consultations.

Chairperson Law said that the board could enforce patient consultation requirements by disciplining both the pharmacist and the pharmacy license if the board found that they were not doing consultations.

Committee Member Debbie Veale noted that the board is doing some enforcement but that members also want to consider legislation. Ms. Veale expressed the board is not looking at consultation itself but how to make the pharmacist more available for patients. She said that the board's study showed that pharmacists feel that they are not available because board regulations are keeping them away from the consultation and forcing them to do tasks that are non-discretionary and the purpose of this survey was to look at the regulations. Ms. Veale stated perhaps the issue should be handled by the Licensing Committee. She added that at the last board meeting, members seemed to come to the conclusion that maybe another study is not needed. She said that all the studies seem to reach the same conclusion, so maybe the issue should simply be handed to Licensing.

Chairperson Law said that there is nothing in the board's regulations to impose a severe punishment on violators and asked if the board needs a statutory change. Ms. Herold noted that the board currently has the ability to revoke a license if the board wanted to take formal discipline against a pharmacist for failing to consult or if there were evidence that an error would not have happened if the pharmacist had taken time to consult.

Mr. Brooks asked what barriers are placed on pharmacists that the board could remove or change to make pharmacists more efficient. He said that is the important question and that a questionnaire about patient consultations probably could not provide the answers. Ms. Veale said that there are some tasks that could be offloaded to others. She said that was the reason the board was going through the process of looking for studies to back up the board's efforts.

Ms. Veale noted the committee should recommend to the board that the issue be passed to the Licensing Committee to look at the regulations. Chairperson Law said that he agreed and that there is no point in getting more surveys. Mr. Brooks agreed to Ms. Veale's proposed recommendation.

The committee recommended the board discontinue pursuing a survey on patient consultation. Further, the committee recommended a review of pharmacists' duties required by board regulation through the Licensing Committee as a more effective way to increase the availability of pharmacists thereby increasing consultations to consumers.

Committee Recommendation (Motion): Recommend that the board re-direct the subject of patient consultation to the Licensing Committee; recommend that the Licensing Committee focus on regulations that could be streamlined to increase pharmacist availability for consultations; and recommend that no survey be conducted.

Additionally, the committee recommended canceling the pharmacist survey by the DCA.

Committee Recommendation (Motion): Recommend canceling the pharmacist survey by the Department of Consumer Affairs.

b. Update and Discussion on Development of FAQs Received from ask.inspector@dca.ca.gov

Attachment 1

Licensees continue to be able to call and ask general questions of pharmacy inspectors. Inspectors answer calls on Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email inquiry to an inspector at ask.inspector@dca.ca.gov. Board staff in concert with legal counsel developed a series FAQs including the most frequent questions and issues posed to the inspector during this time. A copy of the FAQs posted on the board's website can be found at **Attachment 1**.

The FAQs 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.

c. Discussion and Consideration of Naloxone Related Matters

Attachment 2

1. Communication to the California Healing Art Boards Regarding Naloxone

Background

At previous committee meetings, committee members have expressed interest in reaching out to California healing arts boards regarding naloxone access, and the regulation and protocol.

Recent Update

Board staff recently developed an article about pharmacists and naloxone to be shared with the other California healing arts boards including the Medical Board of California, Board of Registered Nursing, Dental Board of California, Dental Hygiene Committee of California, California State Board of Optometry, Osteopathic Medical Board of California, Physician Assistant Board, California Board of Podiatric Medicine, Veterinary Medical Board, and Board of Vocational Nursing and Psychiatric Technicians. A copy of the article and transmittal letter is included in **Attachment 2**.

2. Naloxone FAQs

Background and Recent Update

At previous committee meetings, committee members have expressed the need for a naloxone FAQ. Board staff drafted naloxone FAQs in concert with legal counsel. The naloxone FAQs are posted on the board's website. A copy of the

FAQs is included in **Attachment 2**.

3. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

Committee Discussion and Recommendation

The committee discussed SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016) that requires the California Department of Public Health to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide naloxone to first responders and to at-risk opioid users through programs that serve at-risk drug users, including syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers. There is approximately \$3 million available from this law. The board is not eligible to apply for the funding.

Pharmacies that want to provide naloxone should contact to the Department of Public Health for this funding. Ms. Herold indicated the board would disseminate information via subscriber alerts when the information is available on how to apply for the funding.

Ms. Veale told the committee that many pharmacies are not dispensing naloxone. She suggested that subscriber alerts also be sent out every so often to remind pharmacists that they now can provide naloxone and direct them to the protocol on the board's website.

Ms. Herold said board staff could develop an article that could be sent out as a subscriber alert to pharmacies about this. She said the article could remind pharmacists that with an hour of CE, they can dispense naloxone on their own autonomy. She said staff could develop a statement about naloxone that could be sent out as a subscriber alert and perhaps do the same for the immunization and hormonal contraceptive protocols.

The Summer 2016 edition of *The Script* included an article about the regulations authorizing pharmacists to furnish naloxone. She expressed support for Ms. Veale's suggestion about sending subscriber alerts to remind pharmacists that taking an hour of CE in furnishing naloxone would enable them to provide for the health care needs of patients who receive opioids.

Recent Update

Board staff contacted Holly Sisneros of Prescription Drug Overdose Prevention at California Department of Public Health (CDPH), which is authorized by SB 833 to award the grant money. Ms. Sisneros indicated SB 833 is aimed at funding local non-profits

and community groups to support programs that provide Naloxone to first responders and at-risk opioid users. Ms. Sisneros stated CDPH is starting implementation of SB 833 and anticipates awarding funds in 2017. CDPH plans on updating the public and state agencies as the process is developed. Board staff will continue to check on the status with CDPH and report to the board and committee.

The board released a subscriber alert on October 5, 2016, specifically addressing pharmacists and reminding them of the naloxone protocol requirements in an effort to increase their awareness of the new protocol. A copy of the subscriber alert is included in **Attachment 2**.

Additionally, board staff will draft and send a reminder periodically to pharmacists of what training and continuing education is required for the naloxone protocol as well as protocols related to SB 493.

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

On July 22, 2016, President Obama signed into law US S. 524 – known as the Comprehensive Addiction and Recovery Act (CARA) of 2016 – in an effort to combat the national epidemic of prescription opioid abuse and heroin use. A copy of the enacted law was included in **Attachment 2**.

i. Lali's Law

Committee Discussion and Recommendation

Lali's Law was passed by the House by a vote of 415-4 on May 12, 2016, and the bill was signed into law as part of the Comprehensive Addiction and Recovery Act of 2016 on July 22, 2016. Lali's Law increases access to naloxone throughout the United States. The bill is named in memory of Alex Laliberte, an Illinois resident who passed away seven years ago from a drug overdose.

The committee discussed how Lali's Law creates a competitive grant program that will help states increase access to naloxone. The primary purpose of the grant is to fund state programs that allow pharmacists to distribute naloxone without a prescription. Many states use these programs to allow local law enforcement officers to carry and use naloxone.

Ms. Herold reported to the committee that awarding grants is a competitive process and that state agencies such as the Department of Justice and the Department of Public Health both pursue grants for such purposes. Ms. Freedman commented that she also would also want to review the board's authority should the board decide to apply for grants.

Ms. Freedman suggested to the committee that the board might be better suited to facilitate or get the word out about Lali's Law. Ms. Herold said that perhaps staff could add the information to the subscriber alert and suggested contacting the lawmaker's office for information on how they expect grants to be distributed.

Recent Update

The law authorizes the CDC to award grants to states to encourage pharmacies to dispense medications that reverse opioid overdoses. Board staff contacted the Congressman Dold's legislative assistant who responded the Department of Health and Human Assistance will implement the Lali's Law grant programs, but the assistant was unaware which sub-agency or department would actually carry it out. She also indicated she would advise board staff when additional information is available. A copy of the press release from Congressman Dold's office announcing Lali's law is included in **Attachment 2**.

ii. Provisions regarding Partial Fills for Schedule II

Committee Discussion and Recommendation

The committee discussed potential conflict between Section 702 (f)(2)(A)(ii) of CARA and California law. Board staff is seeking direction of legal counsel and will provide an update at the board meeting.

The committee discussed this issue should be brought to the attention of pharmacists by the board such as an article in *The Script* for the Winter 2016/17 edition. Board staff will work on developing an article for the Winter edition of *The Script*.

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

Background

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.

Committee Discussion and Recommendation

At the September 2016 Communication and Public Education Committee, board staff reported the draft was under legal review and posted on the board's website as soon as possible. An update will be provided at the board meeting.

e. **Discussion on CE Courses Available for Naloxone, Self-Administered Hormonal Contraception and Nicotine Replacement Therapy under Protocols**

Attachment 3

Committee Discussion and Recommendation

The committee members reviewed a chart summarizing options for CE that are available specific to naloxone, self-administered hormonal contraception and nicotine replacement therapy under protocols. The committee concurred the chart should be updated to reflect the training required prior to initiation of the protocol and show any continuing education required, if applicable.

Recent Update

Board staff updated the chart. Board staff will seek legal approval and post to the board's website. As part of the update, board staff included the vaccination protocol. A copy of the updated chart is included in **Attachment 3**.

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

Attachment 4

Background

At prior meetings, the committee reviewed multiple items for posting on the board's website as resources for consumers and licensees. At the May 2016 meeting, the committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee.

Board staff consulted with other boards within DCA and state agencies and drafted the California State Board of Pharmacy's Website Guidelines. The need for the policy statement arose because the board received general requests to post items on the board's website. Committee members agreed that the draft policy is a good place for the board to start and see how it works and make changes as necessary.

Committee Discussion and Recommendation

The committee directed staff to move forward with the policy and post on the board's website. A copy of the policy has been added to the board's website and can be found in **Attachment 4**. The board will have an opportunity to discuss the proposal policy at this meeting.

g. **Discussion of a Board-Developed Billboard Message and Related Communication Materials**

Attachment 5

Committee Discussion and Recommendation

Through the efforts and actions of Board Member Ryan Brooks, the committee reviewed the concept for a roadside bulletin board message and related communication materials.

Ms. Herold unveiled photos of two draft concepts for a billboard intended to encourage parents to talk to their children about prescription drug abuse. The draft concepts were developed by staff at Mr. Brooks' firm. The first draft included drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids." The second draft featured "Kid KILLER" with capital letters superimposed on a prescription drug pill.

After discussing both concepts, committee members decided to recommend that the board proceed with the first draft concept, which committee members said was eye-catching and self-explanatory. Committee members also said the billboard should tell the public that the message is sponsored by the Board of Pharmacy and provide information on how to contact the board. A copy of both draft concepts can be found in **Attachment 5**.

Committee Recommendation (Motion): Sponsor the billboard message and move the concept with the full board's consent.

h. Communication Plan for Consumers and Licensees

Attachment 6

Committee Recommendation and Discussion

In accordance with the board's strategic plan, staff provided committee members with copies of a draft communication plan that included aspects for both consumers and licensees.

The committee reviewed the draft communication plan. Chairperson Law complimented the plan. The committee agreed the plan was a good start and said the committee would continue working with it at future committee meetings. A copy of the draft Communication Plan is included in **Attachment 6**.

i. Update and Discussion on the Forty-Fifth Annual Report of the Research Advisory Panel of California for 2015 Regarding Controlled Drugs Research

Attachment 7

Background

Pursuant to Health & Safety Code Sections §11480 & §11481, California law requires proposed research projects using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office.

The Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel Members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

During 2015 the Panel reviewed forty-five research study submissions. Forty-three were approved by the Panel. Among the approved studies, fourteen studies were Academic research studies, two studies were Substance Abuse Treatment research protocols, and twenty-seven studies were Multi-Clinical Drug Trial research studies. At the end of 2015, the Panel was monitoring one hundred and twenty-one research projects.

Committee Discussion and Recommendation

Chairperson Law reported to the committee the Research Advisory Panel of California recently submitted its annual report to the Legislature and Governor. A copy of the Forty-Fifth Annual Report of the Research Advisory Panel of California 2015 is included in **Attachment 7**.

j. Board Publications – Review and Recommendations for Changes

Attachment 8

- 1. Counterfeit Prescription Drugs: Protect Yourself, Your Family and Your Pets**
- 2. Buying Prescription Medications Online: Are the Drugs you Buy Real or Fake?**

Committee Discussion and Recommendation

Chairperson Law requested that the committee assess the two board produced publications to determine if the pamphlets should be updated or removed from publication. A copy of both documents is included in **Attachment 8**.

Chairperson Law said the pamphlets contained good information but perhaps they were not hitting the proper target audience and suggested asking retailers associations to distribute the pamphlets to customers when they fill their prescriptions. Ms. Herold added that copies also could be made available at board meetings and speaking presentations.

Chairperson Law asked that the pamphlets also be translated into the top five languages and that pharmacies should be notified that they are available so they can be distributed to customers.

Ms. Sodergren suggested updating the pamphlets to include information about the .pharmacy domain.

Lori Hensic of Kaiser Permanente asked if online pharmacies could post this type of information on their websites. Ms. Herold said that was a good idea and that staff could look into that. Ms. Hensic added that perhaps online sites that use the .pharmacy domain also could be required to disseminate this type of information, because their customers are obviously seeking out and using online pharmacy sites.

Recent Update

Board staff will work on updating these publications for future distribution.

k. Update on *The Script* Newsletter

The Summer 2016 edition of *The Script* was published early September 2016. Board staff was currently working on articles for the Winter 2016/17 edition of *The Script*. The goal is to have the newsletter published by January 1, 2017.

l. Update on Media Activity

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

- **MPA Media**, July 14, 2016: Kathryn Feather, regulation of acupuncture needle distributors.
- **Capitol Television Network News**, July 27, 2016: Jonathan Underland, drug- take back regulations.
- **KPIX**, Aug. 16, 2016: Molly McCrea, opioid compound U-47700
- **Veterinary Information Network News Service**, Aug. 29, 2016: Edie Lau, unlicensed business selling veterinary prescription drugs online.
- **Glendale News Press**, Sept. 6, 2016: Alene Tchekmedyan , disciplinary case against Kenneth Road Pharmacy in Glendale
- **The Hollywood Reporter**, Sept. 21, 2016: Peter Flax, pharmacy law re providing false information for prescriptions

m. 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:

- July 18: Supervising Inspector Christine Acosta presented HD compounding for CPhA.
- August 9: Inspector Jennifer Hall provided a review of new laws to the board's competency committee.
- August 18: Supervising Inspector Christine Acosta presented the new compounding regulations to Tenet health.
- August 24: Inspector Trang Song presented at the Vietnamese Pharmacist Association
- October 5: Supervising Inspector Christine Acosta presented the new compounding regulations to the Kaiser Permanente Operations Team.

- n. **Review and Discussion of the California Department of Public Health’s Comparison Between the Centers for Disease Control and Prevention’s *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California’s *Guidelines for Prescribing Controlled Substances for Pain*.**

Attachment 9

The committee discussed the California Department of Public Health’s Comparison Between the Centers for Disease Control and Prevention’s *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California’s *Guidelines for Prescribing Controlled Substances for Pain*. A copy the California Department of Public Health’s Comparison is included in **Attachment 9**.

Ms. Herold advised the committee that the Medical Board’s goal is to not have duplicate guidelines out in the community. The Medical Board put out its guidelines two years before the CDC acted. Ms. Herold noted the information is there for prescribers to see what both organizations believe is appropriate pain treatment with opioids, which is similar in most cases.

- o. **Future Meeting Dates**

2016

- December 1, 2016

Attachment 1

Frequently Asked Questions

from ask.inspector@dca.ca.gov

As part of its licensee education efforts, the board restored a service whereby a board inspector and board staff are available to respond to verbal and written inquiries from the board and board licensees. To ensure that all licensees receive the benefits of service, the board has developed these FAQs.

It is important to note that the questions and answers below are not intended, nor should they be construed, as legal advice. The answers provided are intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment in determining the appropriate course of action. Should you require legal advice or detailed research, you will need to contact an attorney or another source.

Question: Does a pharmacist have to perform a final verification by physically inspecting the patient's medication if it was filled by a pharmacy technician or an intern?

Answer: There are a few sections of law that address this question and the answer varies based on various factors: Relevant legal references include:

1. With respect to interns, section 1726 of title 16 of the California Code of Regulations states a pharmacist supervising an intern be responsible for all professional activities performed by the intern under his or her supervision, including the correct dispensing of a prescription.
2. With respect to pharmacy technicians, section 1793.7 of title 16 of the California Code of Regulations states any function performed by a pharmacy technician in connection with dispensing of a prescription, including repackaging from bulk, must be verified and documented in writing by a pharmacist. Except certain situations, the pharmacist must initial the prescription label as verification of the pharmacy technician's work.

Question: What is the pharmacist to intern pharmacist ratio?

Answer: Business and Professions Code Section 4114(b) provides that a pharmacist may not supervise more than two interns at one time.

Question: What is the pharmacist to pharmacy technician ratio in a community pharmacy?

Answer: Business and Professions Code section 4115(f)(1) specifies that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing pharmacy technician functions. The ratio of pharmacy technicians increases for each additional pharmacist to a ratio not to exceed 2 technicians to 1 pharmacist for pharmacy technicians performing duties specified as pharmacy technician duties.

Question: How do I identify the dates of the renewal period within which I must earn 30 units of continuing education (CE) to renew my pharmacist license?

Answer: Pharmacists must earn 30 units of continuing education each renewal cycle.

Example: A pharmacist's license expires October 31, 2017. The current renewal period runs November 1, 2015 through October 31, 2017, within which the pharmacist must have earned 30 units of CE to renew the license in an active status. The next renewal period will be November 1, 2017 through October 31, 2019. Please note that California law requires pharmacists to keep CE certificates for four years.

Question: Is it possible to purchase pen needles over the counter in California?

Answer: Business and Professions Code Section 4145.5(a) provides the authority for a pharmacist or physician to furnish hypodermic needles and syringes for human use, without a prescription or permit, with the following restrictions:

The person is known to the furnisher and the furnisher has previously been provided with a prescription or other proof of legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

Question: Can a Schedule II controlled substance be refilled?

Answer: Health & Safety Code Section 11200 (c) prohibits the refilling of a Schedule II controlled substance.

Question: How long is a controlled substance prescription valid?

Answer: Health & Safety Code Section 11200 (a) specifies that no person shall dispense or refill a controlled substance more than six months (180 days) after the date written.

Question: How many times can a Schedule III or IV controlled substance be filled?

Answer: Health & Safety Code Section 11200 (b) specifies that no prescription for a Schedule III or Schedule IV controlled substance may be refilled more than five times. Further, this section also creates a limit of a 120 day total supply of refills for a Schedule III or Schedule IV controlled substance prescription.

Example: A prescription is written for temazepam 15mg QHS, quantity #30 with 5 refills. The prescription is dispensed on 7/1/2016 for a quantity of 30. The pharmacy refills the prescription on 8/1/2016, 9/1/2016, 10/1/2016, and 11/1/2016, a 30 day supply for each refill and a total of a 120 day supply between the four refills. Although the prescriber wrote for 5 refills, the pharmacy cannot dispense the remaining refill because the 120 day limit was reached after dispensing the refill on 11/1/2016. A new prescription is required for any additional dispenses.

Question: Where is the law that establishes the requirement for a pharmacist to exercise corresponding responsibility?

Answer: A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Health & Safety Code Section 11153 (a) provides that the responsibility for the proper prescribing and dispensing of controlled substances is upon both the prescribing practitioner AND a corresponding responsibility rests with the pharmacist who fills the prescription.

NOTE: Additional information about corresponding responsibility can be found using the following link http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf and http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf for the DEA Pharmacist Manual. Information on the board's precedential decision can be found at <http://www.pharmacy.ca.gov/enforcement/precedential.shtml> and http://www.pharmacy.ca.gov/enforcement/fy1516/sternberg_lexis.pdf.

Question: Am I required to apply for registration to California's prescription drug monitoring program, CURES?

Answer: Health & Safety Code Section 11165.1 (a)(1)(A)(ii) required a pharmacist, on or before July 1, 2016, or upon licensure, to submit an application to the Department of Justice to obtain approval to access the CURES system. The CA Department of Justice website to register for CURES is <https://oag.ca.gov/cures>

Question: How often does a pharmacy need to report controlled substances dispensing information to CURES?

Answer: Health & Safety Code Section 11165 (d) specifies that a dispensing pharmacy must report information to the Department of Justice as soon as reasonably possible, but not longer than seven days after the controlled substance is dispensed.

Question: How do I get on the Board's email distribution list?

Answer: You may sign up for the Board's email distribution list by visiting the following website and signing up: <https://www.dca.ca.gov/webapps/pharmacy/subscribe.php>

Question: Where can I find prescription drug take back locations?

Answer: The US Department of Justice, Drug Enforcement Administration, Office of Diversion Control maintains a list of locations with a search function that can be found at: <https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>

Attachment 2

**Communication
to the CA Healing
Arts Boards
Regarding
Naloxone**



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Oct. 7, 2016

Kimberly Kirchmeyer
Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

Dear Ms. Kirchmeyer:

California pharmacists are proud to work with all health care professionals in an ongoing effort to prevent deaths from opioid abuse. Toward that goal, the California State Board of Pharmacy is reaching out to the healing arts professions with an attached article describing the pharmacists' role in furnishing the prescription drug naloxone hydrochloride, an opioid-overdose antidote, to consumers without a prescription.

Legislative authority for pharmacists to furnish naloxone was established by AB 1535 (Bloom) in 2014. The law authorized the furnishing of naloxone (also known as Narcan) pursuant to a protocol developed by the Board of Pharmacy and approved by the Medical Board of California. The protocol, published in California Code of Regulations Title 16, section 1746.3, lays out specific requirements for pharmacists to screen potential recipients and to provide them with training in preventing, recognizing and responding to an opioid overdose and administering naloxone. The medication may be furnished to a recipient who uses opioids or who "is in contact" with anyone using illicit or prescription opioids.

Pharmacists are taking these active measures to prevent deaths from opioid overdoses in cooperation with other members of health care teams. Pharmacists may provide naloxone to patients who are also filling prescriptions for opioids.

The protocol also calls for a pharmacist, with a patient's consent, to notify the patient's primary care provider of any naloxone drug product or device furnished, or to enter this information in a patient record system that is shared with the primary care provider. If the patient does not consent to notification or does not have a primary care provider, the pharmacist must provide a written record of the furnished naloxone drug product or device and advise the patient to consult an appropriate primary care provider.

The full text of CCR section 1746.3 is available on the Board of Pharmacy website at http://www.pharmacy.ca.gov/publications/naloxone_protocol.pdf. We invite you to share this information with your members by reprinting the enclosed article in your newsletter. Thank you.

Sincerely,

Virginia Herold
Executive Officer



Visit our website at www.pharmacy.ca.gov

Protocol Enables Pharmacists to Expand Public Access to Antidote for Opioid Overdose

California pharmacists are taking a more active role in efforts to prevent deaths from opioid overdoses by increasing access to naloxone hydrochloride, a medication that reverses opioid overdose.

Authority for pharmacists to furnish naloxone was established by AB 1535 (Bloom), which was passed in 2014. The law authorized the furnishing of naloxone pursuant to a protocol developed by the Board of Pharmacy and approved by the Medical Board of California. The medication may be administered by intramuscular injection, intranasal spray or auto-injector.

The protocol, in California Code of Regulations Title 16, section 1746.3, lays out specific requirements for pharmacists to screen potential recipients and to provide training in preventing, recognizing and responding to opioid overdose and in administering naloxone. In addition, the protocol requires pharmacists to complete at least one hour of approved continuing education training on all forms of naloxone hydrochloride before furnishing the medication.

The protocol requires pharmacists to determine whether the potential recipient (A) uses illicit or prescription opioids or (B) “is in contact” with anyone who uses illicit or prescription opioids. The pharmacist also must determine whether the person to whom the drug would be administered has a known sensitivity to naloxone; if so, the pharmacist may not provide the drug.



Translated screening questions for potential recipients of naloxone whose primary language is traditional Chinese, Korean, Russian, Spanish, Tagalog or Vietnamese are available on the Board of Pharmacy website at http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml.

The protocol also requires pharmacists to counsel and provide recipients with information about the medication, including “dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety.” The recipient is not permitted to waive the required consultation. The pharmacist also must provide any available information or referrals to appropriate resources to any recipient who “indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.”

As members of a health care team, pharmacists may recommend that patients filling prescriptions for opioids ask

their doctors to also prescribe naloxone. Alternatively, pharmacists may on their own suggest that patients filling prescriptions for opioid medications also obtain naloxone.

If the recipient is also the person to whom the naloxone would be administered, the recipient is considered a patient for purposes of the protocol. If the patient consents, section 1746.3(c) 7) requires the pharmacist to “notify the patient’s primary care provider of any drug(s) and/or device(s) furnished, or to enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and the primary care provider.”

If the patient does not have a primary care provider or does not consent to notification, section 1746.3(c)(7) requires the pharmacist to “provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient’s choice.”

The full text of California Code of Regulations section 1746.3 is available at http://www.pharmacy.ca.gov/publications/naloxone_protocol.pdf.

A fact sheet about naloxone is available on the Board of Pharmacy website at http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf.

The Board of Pharmacy Prescription Drug Abuse Prevention page, including public service announcement videos, is available at http://www.pharmacy.ca.gov/consumers/rx_abuse_prevention.shtml.

Naloxone

FAQs

FAQ for Naloxone Protocol

Q: Where are the provisions that authorize a pharmacist to furnish naloxone without a prescription?

A: Title 16 California Code of Regulations section 1746.3 establishes the protocol.

Q: What training or continuing education (CE) is required prior to furnishing naloxone?

A: Pharmacists using the protocol have two options to meet the required training/CE prior to administering naloxone:

1. The pharmacist must have successfully completed a minimum of a one hour approved CE program specific to all routes of naloxone administration as identified in 16 CCR 1746.3 (c)(4); or,
2. The pharmacist must have successfully completed an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

Q: Is the pharmacist required to screen the recipient prior to furnishing naloxone in accordance with the protocol?

A: Yes. The pharmacist must screen the recipient using the following questions:

1. Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question 2.);
2. Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue);
3. Whether the person to whom the naloxone would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

Q: Who is the recipient?

A: A recipient is the person to whom the naloxone is furnished.

Q: Who is the patient?

A: The patient is the person to whom the naloxone would be administered. (Note: The recipient may or may not also be the patient.)

Q: Are these screening questions available in different languages? Where can I get the translated versions?

A: Yes, the screening questions are available in Spanish, Traditional Chinese, Korean, Russian, Tagalog, and Vietnamese. The translated screening questions may be downloaded from the board's website: http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml

Q: Is the pharmacist required to provide the recipient with training? If so, what type of training is required?

A: Yes, the pharmacist is required to provide the recipient with training. Training must include the following topics: opioid overdose prevention, recognition, response and administration of the antidote naloxone.

Q: What is required to be provided to the recipient when naloxone is furnished?

A: When a pharmacist provides naloxone to a recipient, the following must be provided to the recipient:

1. Appropriate counseling and information on the furnished naloxone including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
2. Any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at the time of furnishing naloxone.
3. Responses to any questions the recipient may have about naloxone.

Q: When the pharmacist initiates patient consultation to the recipient of the naloxone, is the recipient allowed to waive the patient consultation?

A: No, the recipient is not allowed to waive the patient consultation for naloxone.

Q: What forms of naloxone may the pharmacist provide to the recipient?

A: The pharmacist may supply naloxone in the following forms:

1. Intramuscular injection;
2. Intranasal spray;
3. Auto-injector; or
4. FDA-approved product form.

Q. Does the board have sample naloxone labels available?

A: Yes. The board's sample naloxone labels can be found at:

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

Q: Is the pharmacist required to provide the naloxone fact sheet upon furnishing naloxone?

A: Yes, the pharmacist shall provide a copy of the board-approved naloxone fact sheet. It can be found at: http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf. The fact sheet is also available in other languages including Spanish, Traditional Chinese, Korean, Russian, Tagalog, and Vietnamese.

The translated fact sheets can be found at:

http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml

Q: Is the pharmacist authorized to notify a physician about the dispensing of naloxone?

A: If consent is given by the patient, the consent can be either verbal or written. The pharmacist is required to notify a patient's primary care provider (PCP) of any drug(s) and/or device(s) furnished or enter information in a patient record system shared with the PCP.

Q: If the patient does not have a PCP or chooses not to give notification consent, what must the pharmacist do?

A: The pharmacist is required to provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult a health care provider of the patient's choice.

Q: How long must records of furnishing naloxone be kept?

A: Documentation shall be maintained for at least three years from date of furnishing.

Q: Do privacy laws apply to furnishing naloxone?

A: The same laws apply to naloxone as to other dangerous drugs.

**Naloxone
Subscriber
Alert Text**

Damoth, Debbie@DCA

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV>
on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, October 05, 2016 1:06 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Pharmacists Urged to Expand Patients' Access to Naloxone

The California State Board of Pharmacy encourages pharmacists to take an active role in efforts to prevent deaths from opioid overdoses by increasing patients' access to naloxone hydrochloride.

Authority for pharmacists to furnish naloxone was established by AB 1535 (Bloom), which was passed in 2014. The law authorized the furnishing of naloxone pursuant to a protocol developed by the Board of Pharmacy and approved by the Medical Board of California. The medication may be administered by intramuscular injection, intranasal spray or auto-injector.

The protocol, in California Code of Regulations Title 16, section 1746.3, lays out specific requirements for pharmacists to screen potential recipients and to provide training in preventing, recognizing and responding to opioid overdose and in administering naloxone. In addition, the protocol requires pharmacists to complete at least one hour of approved continuing education training on all forms of naloxone hydrochloride before furnishing the medication.

The protocol requires pharmacists to determine whether the potential recipient (A) uses illicit or prescription opioids or (B) "is in contact" with anyone who uses illicit or prescription opioids. The pharmacist also must determine whether the person to whom the drug would be administered has a known sensitivity to naloxone; if so, the pharmacist may not provide the drug.

Translated screening questions for potential recipients of naloxone whose primary language is traditional Chinese, Korean, Russian, Spanish, Tagalog or Vietnamese are available on the Board of Pharmacy website at http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml.

The protocol also requires pharmacists to counsel and provide recipients with information about the medication, including "dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety." The recipient is not permitted to waive the required consultation. The pharmacist also must provide any available information or referrals to appropriate resources to any recipient who "indicates interest in addiction treatment, recovery services, or medication disposal resources at this time."

As members of a health care team, pharmacists may recommend that patients filling prescriptions for opioids ask their doctors to also prescribe naloxone. Alternatively, pharmacists may on their own suggest that patients filling prescriptions for opioid medications also obtain naloxone.

If the recipient is also the person to whom the naloxone would be administered, the recipient is considered a patient for purposes of the protocol. If the patient consents, section 1746.3(c)(7) requires the pharmacist to "notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or to enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and the primary care provider."

If the patient does not have a primary care provider or does not consent to notification, section 1746.3(c)(7) requires the pharmacist to "provide a written record of the drug(s) and/or devices(s) furnished and advise the

patient to consult an appropriate health care provider of the patient's choice.”

The full text of California Code of Regulations section 1746.3 is available at http://www.pharmacy.ca.gov/publications/naloxone_protocol.pdf.

A fact sheet about naloxone is available on the Board of Pharmacy web site at http://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf.

The Board of Pharmacy Prescription Drug Abuse Prevention page, including public service announcement videos, is available at http://www.pharmacy.ca.gov/consumers/rx_abuse_prevention.shtml.

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

**Comprehensive
Addiction and
Recovery Act
(CARA) 2016**

One Hundred Fourteenth Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday,
the fourth day of January, two thousand and sixteen*

An Act

To authorize the Attorney General and Secretary of Health and Human Services to award grants to address the prescription opioid abuse and heroin use crisis, and for other purposes.

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.

TITLE I—PREVENTION AND EDUCATION

- Sec. 101. Task force on pain management.
- Sec. 102. Awareness campaigns.
- Sec. 103. Community-based coalition enhancement grants to address local drug crises.
- Sec. 104. Information materials and resources to prevent addiction related to youth sports injuries.
- Sec. 105. Assisting veterans with military emergency medical training to meet requirement for becoming civilian health care professionals.
- Sec. 106. FDA opioid action plan.
- Sec. 107. Improving access to overdose treatment.
- Sec. 108. NIH opioid research.
- Sec. 109. National All Schedules Prescription Electronic Reporting Reauthorization.
- Sec. 110. Opioid overdose reversal medication access and education grant programs.

TITLE II—LAW ENFORCEMENT AND TREATMENT

- Sec. 201. Comprehensive Opioid Abuse Grant Program.
- Sec. 202. First responder training.
- Sec. 203. Prescription drug take back expansion.

TITLE III—TREATMENT AND RECOVERY

- Sec. 301. Evidence-based prescription opioid and heroin treatment and interventions demonstration.
- Sec. 302. Building communities of recovery.
- Sec. 303. Medication-assisted treatment for recovery from addiction.

TITLE IV—ADDRESSING COLLATERAL CONSEQUENCES

- Sec. 401. GAO report 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. Veterans treatment courts.
- Sec. 503. Infant plan of safe care.
- Sec. 504. GAO report on neonatal abstinence syndrome (NAS).

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

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

TITLE VII—MISCELLANEOUS

- Sec. 701. Grant accountability and evaluations.
Sec. 702. Partial fills of schedule II controlled substances.
Sec. 703. Good samaritan assessment.
Sec. 704. Programs to prevent prescription drug abuse under Medicare parts C and D.
Sec. 705. Excluding abuse-deterrent formulations of prescription drugs from the Medicaid additional rebate requirement for new formulations of prescription drugs.
Sec. 706. Limiting disclosure of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse.
Sec. 707. Medicaid Improvement Fund.
Sec. 708. Sense of the Congress regarding treatment of substance abuse epidemics.

TITLE VIII—KINGPIN DESIGNATION IMPROVEMENT

Sec. 801. Protection of classified information in Federal court challenges relating to designations under the Narcotics Kingpin Designation Act.

TITLE IX—DEPARTMENT OF VETERANS AFFAIRS

- Sec. 901. Short title.
Sec. 902. Definitions.

Subtitle A—Opioid Therapy and Pain Management

- Sec. 911. Improvement of opioid safety measures by Department of Veterans Affairs.
Sec. 912. Strengthening of joint working group on pain management of the Department of Veterans Affairs and the Department of Defense.
Sec. 913. Review, investigation, and report on use of opioids in treatment by Department of Veterans Affairs.
Sec. 914. Mandatory disclosure of certain veteran information to State controlled substance monitoring programs.
Sec. 915. Elimination of copayment requirement for veterans receiving opioid antagonists or education on use of opioid antagonists.

Subtitle B—Patient Advocacy

- Sec. 921. Community meetings on improving care furnished by Department of Veterans Affairs.
Sec. 922. Improvement of awareness of patient advocacy program and patient bill of rights of Department of Veterans Affairs.
Sec. 923. Comptroller General report on patient advocacy program of Department of Veterans Affairs.
Sec. 924. Establishment of Office of Patient Advocacy of the Department of Veterans Affairs.

Subtitle C—Complementary and Integrative Health

- Sec. 931. Expansion of research and education on and delivery of complementary and integrative health to veterans.
Sec. 932. Expansion of research and education on and delivery of complementary and integrative health to veterans.
Sec. 933. Pilot program on integration of complementary and integrative health and related issues for veterans and family members of veterans.

Subtitle D—Fitness of Health Care Providers

- Sec. 941. Additional requirements for hiring of health care providers by Department of Veterans Affairs.
Sec. 942. Provision of information on health care providers of Department of Veterans Affairs to State medical boards.
Sec. 943. Report on compliance by Department of Veterans Affairs with reviews of health care providers leaving the Department or transferring to other facilities.

Subtitle E—Other Matters

Sec. 951. Modification to limitation on awards and bonuses.

TITLE I—PREVENTION AND EDUCATION

SEC. 101. TASK FORCE ON PAIN MANAGEMENT.

(a) DEFINITIONS.—In this section:

(1) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(2) TASK FORCE.—The term “task force” means the Pain Management Best Practices Inter-Agency Task Force convened under subsection (b).

(b) INTER-AGENCY TASK FORCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, in cooperation with the Secretary of Veterans Affairs and the Secretary of Defense, shall convene a Pain Management Best Practices Inter-Agency Task Force.

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

(1) representatives of—

(A) the Department of Health and Human Services and relevant agencies within the Department of Health and Human Services;

(B) the Department of Veterans Affairs;

(C) the Department of Defense; and

(D) the Office of National Drug Control Policy;

(2) currently licensed and practicing physicians, dentists, and nonphysician prescribers;

(3) currently licensed and practicing pharmacists and pharmacies;

(4) experts in the fields of pain research and addiction research, including adolescent and young adult addiction research;

(5) representatives of—

(A) pain management professional organizations;

(B) the mental health treatment community;

(C) the addiction treatment community, including individuals in recovery from substance use disorder;

(D) pain advocacy groups, including patients;

(E) veteran service organizations;

(F) groups with expertise on overdose reversal, including first responders;

(G) State medical boards; and

(H) hospitals;

(6) experts on the health of, and prescription opioid use disorders in, members of the Armed Forces and veterans; and

(7) experts in the field of minority health.

(d) REPRESENTATION.—The Secretary shall ensure that the membership of the task force includes individuals representing rural and underserved areas.

(e) DUTIES.—The task force shall—

(1) identify, review, and, as appropriate, determine whether there are gaps in or inconsistencies between best practices for pain management (including chronic and acute pain) developed or adopted by Federal agencies;

(2) not later than 1 year after the date on which the task force is convened under subsection (b), propose updates to best practices and recommendations on addressing gaps or inconsistencies identified under paragraph (1), as appropriate, and submit to relevant Federal agencies and the general public

such proposed updates and recommendations, taking into consideration—

(A) existing pain management research and other relevant 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 differences within and between classes of opioids, the availability of opioids with abuse deterrent technology, and pharmacological, nonpharmacological, and medical device alternatives to opioids to reduce opioid monotherapy in appropriate cases;

(D) the management of high-risk populations who receive opioids in the course of medical care, other than for pain management;

(E) the 2016 Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention; and

(F) private sector, State, and local government efforts related to pain management and prescribing pain medication;

(3) provide the public with at least 90 days to submit comments on any proposed updates and recommendations under paragraph (2); and

(4) develop a strategy for disseminating information about best practices for pain management (including chronic and acute pain) to stakeholders, if appropriate.

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

(g) **SUNSET.**—The task force under this section shall sunset after 3 years.

SEC. 102. AWARENESS CAMPAIGNS.

(a) **IN GENERAL.**—The Secretary of Health and Human Services, in coordination with the heads of other departments and agencies, shall, as appropriate, through existing programs and activities, advance the education and awareness of the public (including providers, patients, and consumers) and other appropriate entities regarding the risk of abuse of prescription opioids if such drugs are not taken as prescribed.

(b) **TOPICS.**—The education and awareness campaigns under subsection (a) shall address—

(1) the dangers of opioid abuse;

(2) the prevention of opioid abuse, including through safe disposal of prescription medications and other safety precautions; and

(3) the detection of early warning signs of addiction.

(c) **OTHER REQUIREMENTS.**—The education and awareness campaigns under subsection (a) shall, as appropriate—

(1) take into account any association between prescription opioid abuse and heroin use;

(2) emphasize—

(A) the similarities between heroin and prescription opioids; and

- (B) the effects of heroin and prescription opioids on the human body; and
- (3) 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.

(a) **DEFINITIONS.**—In this section:

(1) **ADMINISTRATOR.**—The term “Administrator” means the Administrator of the Substance Abuse and Mental Health Services Administration.

(2) **DIRECTOR.**—The term “Director” means the Director of the Office of National Drug Control Policy.

(3) **DRUG-FREE COMMUNITIES ACT OF 1997.**—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.).

(4) **ELIGIBLE ENTITY.**—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.

(5) **EMERGING DRUG ABUSE ISSUE.**—The term “emerging drug abuse issue” means a substance use disorder within an area involving—

(A) a sudden increase in demand for particular drug abuse treatment services relative to previous demand; and

(B) a lack of resources in the area to address the emerging problem.

(6) **LOCAL DRUG CRISIS.**—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.

(7) **OPIOID.**—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) **PROGRAM AUTHORIZED.**—The Director, in coordination with the Administrator, may make grants to eligible entities to implement comprehensive community-wide strategies that address local drug crises and emerging drug abuse issues 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 Director at such time, in such manner, and accompanied by such information as the Director may require.

(2) **CRITERIA.**—As part of an application for a grant under this section, the Director shall require an eligible entity to submit a detailed, comprehensive, multisector plan for addressing the local drug crisis or emerging drug abuse issue 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);

(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); and

(3) for programs designed to implement comprehensive community-wide strategies to address emerging drug abuse issues in the community.

(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 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 to pay for administrative expenses.

(h) **DELEGATION AUTHORITY.**—The Director may enter into an interagency agreement with the Administrator to delegate authority for the execution of grants and for such other activities as may be necessary to carry out this section.

(i) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$5,000,000 for each of fiscal years 2017 through 2021.

SEC. 104. INFORMATION MATERIALS AND RESOURCES TO PREVENT ADDICTION RELATED TO YOUTH SPORTS INJURIES.

(a) **REPORT.**—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall, not later than 24 months after the date of the enactment of this section, make publicly available on the appropriate website of the Department of Health and Human Services a report determining the extent to which informational materials and resources described

in subsection (c) are available to teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups.

(b) **DEVELOPMENT OF INFORMATIONAL MATERIALS AND RESOURCES.**—The Secretary may, for purposes of preventing substance use disorder in teenagers and adolescents who are injured playing youth sports and are subsequently prescribed an opioid, not later than 12 months after the report is made publicly available under subsection (a), and taking into consideration the findings of such report and in coordination with relevant health care provider groups, facilitate the development of informational materials and resources described in subsection (c) for teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups.

(c) **MATERIALS AND RESOURCES DESCRIBED.**—For purposes of this section, the informational materials and resources described in this subsection are informational materials and resources with respect to youth sports injuries for which opioids are potentially prescribed, including materials and resources focused on the risks associated with opioid use and misuse, treatment options for such injuries that do not involve the use of opioids, and how to seek treatment for addiction.

(d) **NO ADDITIONAL FUNDS.**—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.

SEC. 105. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENT FOR BECOMING CIVILIAN HEALTH CARE PROFESSIONALS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 314 the following:

“SEC. 315. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN HEALTH CARE PROFESSIONALS.

“(a) PROGRAM.—

“(1) IN GENERAL.—The Secretary may establish a program, in consultation with the Secretary of Labor, consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who held certain military occupational specialties related to medical care or who have completed certain medical training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to civilian health care professions (such as emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State.

“(2) CONSULTATION AND COLLABORATION.—In determining the eligible military occupational specialties or training courses and the assistance required as described in paragraph (1), the Secretary shall consult with the Secretary of Defense, the Secretary of Veterans Affairs, and the Assistant Secretary of Labor for Veterans’ Employment and Training, and shall collaborate with the initiatives carried out under section 4114

of title 38, United States Code, and sections 1142 through 1144 of title 10, United States Code.

“(b) USE OF FUNDS.—Amounts received as a demonstration grant under this section shall be used to—

“(1) prepare and implement a plan to streamline State requirements and procedures as described in subsection (a), including by—

“(A) determining the extent to which the requirements for the education, training, and skill level of civilian health care professions (such as emergency medical technicians, paramedics, licensed practical nurses, registered nurses, physical therapy assistants, or physician assistants) in the State are equivalent to requirements for the education, training, and skill level of veterans who served in medical related fields while a member of the Armed Forces of the United States; and

“(B) identifying methods, such as waivers, for veterans who served in medical related fields while a member of the Armed Forces of the United States to forgo or meet any such equivalent State requirements; and

“(2) if necessary to meet workforce shortages or address gaps in education, training, or skill level to meet certification, licensure or other requirements applicable to becoming a civilian health care professional (such as an emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State, develop or expand career pathways at institutions of higher education to support veterans in meeting such requirements.

“(c) REPORT.—Upon the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on the program.

“(d) FUNDING.—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.

“(e) SUNSET.—The demonstration program under this section shall not exceed 5 years.”.

SEC. 106. FDA OPIOID ACTION PLAN.

(a) IN GENERAL.—

(1) NEW DRUG APPLICATION.—

(A) IN GENERAL.—Subject to subparagraph (B), prior to the approval pursuant to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) of a new drug that is an opioid, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall refer the application to an advisory committee of the Food and Drug Administration to seek recommendations from such advisory committee.

(B) PUBLIC HEALTH EXEMPTION.—A referral to an advisory committee under subparagraph (A) is not required with respect to a new opioid drug or drugs if the Secretary—

(i) finds that such a referral is not in the interest of protecting and promoting public health;

(ii) finds that such a referral is not necessary based on a review of the relevant scientific information; and

(iii) submits a notice containing the rationale for such findings to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) **PEDIATRIC OPIOID LABELING.**—The Secretary shall convene the Pediatric Advisory Committee of the Food and Drug Administration to seek recommendations from such Committee regarding a framework for the inclusion of information in the labeling of drugs that are opioids relating to the use of such drugs in pediatric populations before the Secretary approves any labeling or change to labeling for any drug that is an opioid intended for use in a pediatric population.

(3) **SUNSET.**—The requirements of paragraphs (1) and (2) shall cease to be effective on October 1, 2022.

(b) **PRESCRIBER EDUCATION.**—Not later than 1 year after the date of the enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to section 505-1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1), including recommendations on—

(1) which prescribers should participate in such programs;

and

(2) how often participation in such programs is necessary.

(c) **GUIDANCE ON EVALUATING THE ABUSE DETERRENCE OF GENERIC SOLID ORAL OPIOID DRUG PRODUCTS.**—Not later than 18 months after the end of the period for public comment on the draft guidance entitled “General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products” issued by the Center for Drug Evaluation and Research of the Food and Drug Administration in March 2016, the Commissioner of Food and Drugs shall publish in the Federal Register a final version of such guidance.

SEC. 107. IMPROVING ACCESS TO OVERDOSE TREATMENT.

(a) **GRANTS FOR REDUCING OVERDOSE DEATHS.**—Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

“SEC. 544. GRANTS FOR REDUCING OVERDOSE DEATHS.

“(a) ESTABLISHMENT.—

“(1) IN GENERAL.—The Secretary shall award grants to eligible entities to expand access to drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(2) MAXIMUM GRANT AMOUNT.—A grant awarded under this section may not be for more than \$200,000 per grant year.

“(3) ELIGIBLE ENTITY.—For purposes of this section, the term ‘eligible entity’ means a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act), an opioid treatment program under part 8 of title 42, Code

of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act, or any other entity that the Secretary deems appropriate.

“(4) **PRESCRIBING.**—For purposes of this section, the term ‘prescribing’ means, with respect to a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, the practice of prescribing such drug or device—

“(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose;

“(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorder;

“(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

“(D) in other circumstances in which a provider identifies a patient is at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

“(b) **APPLICATION.**—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary, in such form and manner as specified by the Secretary, an application that describes—

“(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

“(2) the criteria that will be used to identify eligible patients to participate in such program; and

“(3) a plan for sustaining the program after Federal support for the program has ended.

“(c) **USE OF FUNDS.**—An eligible entity receiving a grant under this section may use amounts under the grant for any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (3) and (4):

“(1) To establish a program for prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(2) To train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(3) To purchase drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program described in paragraph (1).

“(4) To offset the co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(5) To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies.

“(d) **EVALUATIONS BY RECIPIENTS.**—As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary an

evaluation of activities funded by the grant which contains such information as the Secretary may reasonably require.

“(e) **REPORTS BY THE SECRETARY.**—Not later than 5 years after the date on which the first grant under this section is awarded, the Secretary shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (d) and evaluating the outcomes achieved by the programs funded by grants awarded under this section.

“(f) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated to carry out this section, \$5,000,000 for the period of fiscal years 2017 through 2021.”

(b) **IMPROVING ACCESS TO OVERDOSE TREATMENT.**—

(1) **INFORMATION ON BEST PRACTICES.**—Not later than 180 days after the date of enactment of this Act:

(A) The Secretary of Health and Human Services may provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(B) The Secretary of Defense may provide information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(C) The Secretary of Veterans Affairs may provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(2) **RULE OF CONSTRUCTION.**—Nothing in this subsection should be construed to establish or contribute to a medical standard of care.

SEC. 108. NIH OPIOID RESEARCH.

(a) **IN GENERAL.**—The Director of the National Institutes of Health (referred to in this section as the “NIH”) may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to—

- (1) the understanding of pain;
- (2) the discovery and development of therapies for chronic pain; and
- (3) the development of alternatives to opioids for effective pain treatments.

(b) **PRIORITY AND DIRECTION.**—The prioritization and direction of the Federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016–2020, the latter of which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

SEC. 109. NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION.

(a) **AMENDMENT TO PURPOSE.**—Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

“(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and”.

(b) **AMENDMENTS TO CONTROLLED SUBSTANCE MONITORING PROGRAM.**—Section 3990 of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)(1)—

(A) in the matter preceding subparagraph (A), by inserting “, in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention,” after “the Secretary”;

(B) in subparagraph (A), by striking “or”;

(C) in subparagraph (B), by striking the period at the end and inserting “; or”; and

(D) by adding at the end the following:

“(C) to maintain an existing State-controlled substance monitoring program.”;

(2) by amending subsection (b) to read as follows:

“(b) **MINIMUM REQUIREMENTS.**—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).”;

(3) in subsection (c)—

(A) in paragraph (1)(B)—

(i) in the matter preceding clause (i), by striking “(a)(1)(B)” and inserting “(a)(1)(B) or (a)(1)(C)”;

(ii) in clause (i), by striking “program to be improved” and inserting “program to be improved or maintained”;

(iii) by redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively;

(iv) by inserting after clause (ii), the following:

“(iii) a plan to apply the latest advances in health information technology, to the extent practicable, in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients’ controlled prescription drug history;”;

(v) in clause (iv) (as so redesignated), by striking “; and” and inserting the following: “and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;”;

(vi) in clause (v) (as so redesignated)—

(I) by striking “public health” and inserting “public health or safety”; and

(II) by striking the period and inserting “; and”; and

(vii) by adding at the end the following:

“(vi) information, where applicable, on how the controlled substance monitoring program jointly works with the applicant’s respective State substance abuse agency to ensure information collected and maintained by the controlled substance monitoring program is used to inform the provision of clinically appropriate substance use disorder services to individuals in need.”;

(B) in paragraph (3)—

(i) by striking “If a State that submits” and inserting the following:

“(A) IN GENERAL.—If a State that submits”;

(ii) by inserting before the period at the end “and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability”; and

(iii) by adding at the end the following:

“(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).”; and

(C) in paragraph (5)—

(i) by striking “implement or improve” and inserting “establish, improve, or maintain”; and

(ii) by adding at the end the following: “The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).”;

(4) in subsection (d)—

(A) in the matter preceding paragraph (1)—

(i) by striking “In implementing or improving” and all that follows through “(a)(1)(B)” and inserting “In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)”; and

(ii) by striking “public health” and inserting “public health or safety”; and

(B) by adding at the end the following:

“(5) The State shall report on interoperability with the controlled substance monitoring program of Federal agencies, where appropriate, interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.”;

(5) in subsections (e), (f)(1), and (g), by striking “implementing or improving” each place it appears and inserting “establishing, improving, or maintaining”;

(6) in subsection (f)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking “misuse of a schedule II, III, or IV substance” and inserting “misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act”; and

(ii) in subparagraph (D)—

(I) by inserting “a State substance abuse agency,” after “State health department,”; and

(II) by striking “such department, program, or administration” each place it appears and inserting “such department, program, agency, or administration” in each such place; and

(B) by adding at the end the following:

“(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data to enable the Secretary—

“(A) to evaluate the success of the State’s program in achieving its purposes; or

“(B) to prepare and submit the report to Congress required by subsection (k)(2).

“(4) RESEARCH BY OTHER ENTITIES.—A department, program, agency, or administration receiving nonidentifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.”;

(7) by striking subsection (k);

(8) by redesignating subsections (h) through (j) as subsections (i) through (k), respectively;

(9) in subsections (c)(1)(A)(iv) and (d)(4), by striking “subsection (h)” each place it appears and inserting “subsection (i)”;

(10) by inserting after subsection (g) the following:

“(h) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

“(1) facilitate prescriber and dispenser use of the State’s controlled substance monitoring system, to the extent practicable; and

“(2) educate prescribers and dispensers on the benefits of the system.”;

(11) in subsection (k)(2)(A), as so redesignated—

(A) in clause (ii), by striking “or affected” and inserting “, established or strengthened initiatives to ensure linkages to substance use disorder services, or affected”; and

(B) in clause (iii), by striking “including an assessment” and inserting “and between controlled substance monitoring programs and health information technology systems, including an assessment”;

(12) in subsection (l)(1), by striking “establishment, implementation, or improvement” and inserting “establishment, improvement, or maintenance”;

(13) in subsection (m)(8), by striking “and the District of Columbia” and inserting “, the District of Columbia, and any commonwealth or territory of the United States”; and

(14) by amending subsection (n) to read as follows:

“(n) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, \$10,000,000 for each of fiscal years 2017 through 2021.”

SEC. 110. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS AND EDUCATION GRANT PROGRAMS.

(a) IN GENERAL.—Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by section 107, is further amended by adding at the end the following:

“SEC. 545. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS AND EDUCATION GRANT PROGRAMS.

“(a) GRANTS TO STATES.—The Secretary shall make grants to States to—

“(1) implement strategies for pharmacists to dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, as appropriate, pursuant to a standing order;

“(2) encourage pharmacies to dispense opioid overdose reversal medication pursuant to a standing order;

“(3) develop or provide training materials that persons authorized to prescribe or dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may use to educate the public concerning—

“(A) when and how to safely administer such drug or device; and

“(B) steps to be taken after administering such drug or device; and

“(4) educate the public concerning the availability of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose without a person-specific prescription.

“(b) CERTAIN REQUIREMENT.—A grant may be made under this section only if the State involved has authorized standing orders to be issued for drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(c) PREFERENCE IN MAKING GRANTS.—In making grants under this section, the Secretary may give preference to States that have a significantly higher rate of opioid overdoses than the national average, and that—

“(1) have not implemented standing orders regarding drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

“(2) authorize standing orders to be issued that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; or

“(3) authorize standing orders to be issued that permit police, fire, or emergency medical services agencies to acquire and administer drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(d) GRANT TERMS.—

“(1) NUMBER.—A State may not receive more than one grant under this section at a time.

“(2) PERIOD.—A grant under this section shall be for a period of 3 years.

“(3) LIMITATION.—A State may use not more than 20 percent of a grant under this section for educating the public pursuant to subsection (a)(4).

“(e) APPLICATIONS.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may reasonably require, including detailed proposed expenditures of grant funds.

“(f) REPORTING.—A State that receives a grant under this section shall, at least annually for the duration of the grant, submit a report to the Secretary evaluating the progress of the activities supported through the grant. Such reports shall include information on the number of pharmacies in the State that dispense a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose under a standing order, and other information as the Secretary determines appropriate to evaluate the use of grant funds.

“(g) DEFINITIONS.—In this section the term ‘standing order’ means a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription.

“(h) AUTHORIZATION OF APPROPRIATIONS.—

“(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated \$5,000,000 for the period of fiscal years 2017 through 2019.

“(2) ADMINISTRATIVE COSTS.—Not more than 3 percent of the amounts made available to carry out this section may be used by the Secretary for administrative expenses of carrying out this section.”.

(b) TECHNICAL CLARIFICATION.—Effective as if included in the enactment of the Children’s Health Act of 2000 (Public Law 106–310), section 3405(a) of such Act (114 Stat. 1221) is amended by striking “Part E of title III” and inserting “Part E of title III of the Public Health Service Act”.

TITLE II—LAW ENFORCEMENT AND TREATMENT

SEC. 201. COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.

(a) COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.—

(1) IN GENERAL.—Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by adding at the end the following:

“PART LL—COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM

“SEC. 3021. DESCRIPTION.

“(a) GRANTS AUTHORIZED.—From amounts made available to carry out this part, the Attorney General may make grants to States, units of local government, and Indian tribes, for use by the State, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for any one or more of the following:

“(1) Developing, implementing, or expanding a treatment alternative to incarceration program, which may include—

“(A) prebooking or postbooking components, which may include the activities described in part DD or HH of this title;

“(B) training for criminal justice agency personnel on substance use disorders and co-occurring mental illness and substance use disorders;

“(C) a mental health court, including the activities described in part V of this title;

“(D) a drug court, including the activities described in part EE of this title;

“(E) a veterans treatment court program, including the activities described in subsection (i) of section 2991 of this title;

“(F) a focus on parents whose incarceration could result in their children entering the child welfare system; and

“(G) a community-based substance use diversion program sponsored by a law enforcement agency.

“(2) In the case of a State, facilitating or enhancing planning and collaboration between State criminal justice agencies and State substance abuse agencies in order to more efficiently and effectively carry out activities or services described in any paragraph of this subsection that address problems related to opioid abuse.

“(3) Providing training and resources for first responders on carrying and administering an opioid overdose reversal drug or device approved or cleared by the Food and Drug Administration, and purchasing such a drug or device for first responders who have received such training to so carry and administer.

“(4) Locating or investigating illicit activities related to the unlawful distribution of opioids.

“(5) Developing, implementing, or expanding a medication-assisted treatment program used or operated by a criminal justice agency, which may include training criminal justice

agency personnel on medication-assisted treatment, and carrying out the activities described in part S of this title.

“(6) In the case of a State, developing, implementing, or expanding a prescription drug monitoring program to collect and analyze data related to the prescribing of schedules II, III, and IV controlled substances through a centralized database administered by an authorized State agency, which includes tracking the dispensation of such substances, and providing for interoperability and data sharing with each other such program in each other State, and with any interstate entity that shares information between such programs.

“(7) Developing, implementing, or expanding a program to prevent and address opioid abuse by juveniles.

“(8) Developing, implementing, or expanding a program (which may include demonstration projects) to utilize technology that provides a secure container for prescription drugs that would prevent or deter individuals, particularly adolescents, from gaining access to opioid medications that are lawfully prescribed for other individuals.

“(9) Developing, implementing, or expanding a prescription drug take-back program.

“(10) Developing, implementing, or expanding an integrated and comprehensive opioid abuse response program.

“(b) **CONTRACTS AND SUBAWARDS.**—A State, unit of local government, or Indian tribe may, in using a grant under this part for purposes authorized by subsection (a), use all or a portion of that grant to contract with, or make one or more subawards to, one or more—

“(1) local or regional organizations that are private and nonprofit, including faith-based organizations;

“(2) units of local government; or

“(3) tribal organizations.

“(c) **PROGRAM ASSESSMENT COMPONENT; WAIVER.**—

“(1) **PROGRAM ASSESSMENT COMPONENT.**—Each program funded under this part shall contain a program assessment component, developed pursuant to guidelines established by the Attorney General, in coordination with the National Institute of Justice.

“(2) **WAIVER.**—The Attorney General may waive the requirement of paragraph (1) with respect to a program if, in the opinion of the Attorney General, the program is not of sufficient size to justify a full program assessment.

“(d) **ADMINISTRATIVE COSTS.**—Not more than 10 percent of a grant made under this part may be used for costs incurred to administer such grant.

“(e) **PERIOD.**—The period of a grant made under this part may not be longer than 4 years, except that renewals and extensions beyond that period may be granted at the discretion of the Attorney General.

“SEC. 3022. APPLICATIONS.

“To request a grant under this part, the chief executive officer of a State, unit of local government, or Indian tribe shall submit an application to the Attorney General at such time and in such form as the Attorney General may require. Such application shall include the following:

“(1) A certification that Federal funds made available under this part will not be used to supplant State, local, or tribal funds, but will be used to increase the amounts of such funds that would, in the absence of Federal funds, be made available for the activities described in section 3021(a).

“(2) An assurance that, for each fiscal year covered by an application, the applicant shall maintain and report such data, records, and information (programmatic and financial) as the Attorney General may reasonably require.

“(3) A certification, made in a form acceptable to the Attorney General and executed by the chief executive officer of the applicant (or by another officer of the applicant, if qualified under regulations promulgated by the Attorney General), that—

“(A) the activities or services to be funded by the grant meet all the requirements of this part;

“(B) all the information contained in the application is correct;

“(C) there has been appropriate coordination with affected agencies; and

“(D) the applicant will comply with all provisions of this part and all other applicable Federal laws.

“(4) An assurance that the applicant will work with the Drug Enforcement Administration to develop an integrated and comprehensive strategy to address opioid abuse.

“SEC. 3023. REVIEW OF APPLICATIONS.

“The Attorney General shall not finally disapprove any application (or any amendment to that application) submitted under this part without first affording the applicant reasonable notice of any deficiencies in the application and an opportunity for correction of any such deficiencies and reconsideration.

“SEC. 3024. EQUITABLE DISTRIBUTION OF FUNDS.

“In awarding grants under this part, the Attorney General shall distribute funds in a manner that—

“(1) equitably addresses the needs of underserved populations, including rural and tribal communities; and

“(2) focuses on communities that have been disproportionately impacted by opioid abuse as evidenced in part by—

“(A) high rates of primary treatment admissions for heroin and other opioids;

“(B) high rates of drug poisoning deaths from heroin and other opioids; and

“(C) a lack of accessibility to treatment providers and facilities and to emergency medical services.

“SEC. 3025. DEFINITIONS.

“In this part:

“(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 his or her professional duties, responds to fire, medical, hazardous material, or other similar emergencies.

“(2) The term ‘medication-assisted treatment’ means the use of medications approved by the Food and Drug Administration for the treatment of opioid abuse.

“(3) The term ‘opioid’ means any drug, including heroin, 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 ‘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)).

“(5) 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).

“(6) The term ‘criminal justice agency’ means a State, local, or tribal—

“(A) court;

“(B) prison;

“(C) jail;

“(D) law enforcement agency; or

“(E) other agency that performs the administration of criminal justice, including prosecution, pretrial services, and community supervision.

“(7) The term ‘tribal organization’ has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

“(8) The term ‘State substance abuse agency’ has the meaning given that term in section 508(r)(6) of the Public Health Service Act (42 U.S.C. 290bb-1).”

(2) AUTHORIZATION OF APPROPRIATIONS.—Section 1001(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3793(a)) is amended by inserting after paragraph (26) the following:

“(27) There are authorized to be appropriated to carry out part LL \$103,000,000 for each of fiscal years 2017 through 2021.”

(b) EMERGENCY FEDERAL LAW ENFORCEMENT ASSISTANCE.—Section 609Y(a) of the Justice Assistance Act of 1984 (42 U.S.C. 10513(a)) is amended by striking “September 30, 1984” and inserting “September 30, 2021”.

(c) INCLUSION OF SERVICES FOR PREGNANT WOMEN UNDER FAMILY-BASED SUBSTANCE ABUSE GRANTS.—Part DD of title I of the Omnibus Crime Control and Safe Streets Act (42 U.S.C. 3797s et seq.) is amended—

(1) in section 2921(2), by inserting before the period at the end “or pregnant women”; and

(2) in section 2927—

(A) in paragraph (1)(A), by inserting “pregnant or” before “a parent”; and

(B) in paragraph (3), by inserting “or pregnant women” after “incarcerated parents”.

(d) GAO STUDY AND REPORT ON FEDERAL AGENCY PROGRAMS AND RESEARCH RELATIVE TO SUBSTANCE USE AND SUBSTANCE USE DISORDERS AMONG ADOLESCENTS AND YOUNG ADULTS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on how Federal agencies, through grant programs, are addressing prevention of, treatment for, and

recovery from, substance use by, and substance use disorders among, adolescents and young adults. Such study shall include an analysis of each of the following:

(A) The research that has been, and is being, conducted or supported pursuant to grant programs operated by Federal agencies on prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including an assessment of—

(i) such research relative to any unique circumstances (including social and biological circumstances) of adolescents and young adults that may make adolescent-specific and young adult-specific treatment protocols necessary, including any effects that substance use and substance use disorders may have on brain development and the implications for treatment and recovery; and

(ii) areas of such research in which greater investment or focus is necessary relative to other areas of such research.

(B) Federal agency nonresearch programs and activities that address prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including an assessment of the effectiveness of such programs and activities in preventing substance use by and substance use disorders among adolescents and young adults, treating such adolescents and young adults in a way that accounts for any unique circumstances faced by adolescents and young adults, and supports long-term recovery among adolescents and young adults.

(C) Gaps that have been identified by officials of Federal agencies or experts in the efforts supported by grant programs operated by Federal agencies relating to prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including gaps in research, data collection, and measures to evaluate the effectiveness of such efforts, and the reasons for such gaps.

(2) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of the Congress a report containing the results of the study conducted under paragraph (1), including—

(A) a summary of the findings of the study; and

(B) recommendations based on the results of the study, including recommendations for such areas of research and legislative and administrative action as the Comptroller General determines appropriate.

SEC. 202. FIRST RESPONDER TRAINING.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by section 110, is further amended by adding at the end the following:

“SEC. 546. FIRST RESPONDER TRAINING.

“(a) PROGRAM AUTHORIZED.—The Secretary shall make grants to States, local governmental entities, and Indian tribes and tribal

organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) to allow first responders and members of other key community sectors to administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

“(b) APPLICATION.—

“(1) IN GENERAL.—An 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 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 with which the entity will coordinate to implement the program; and

“(D) describe how the entity will ensure that 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.

“(c) USE OF FUNDS.—An entity shall use a grant received under this section to—

“(1) make a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose available to be carried and administered by first responders and members of other key community sectors;

“(2) train and provide resources for first responders and members of other key community sectors on carrying and administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid 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 followup services.

“(d) TECHNICAL ASSISTANCE GRANTS.—The Secretary shall make a grant for the purpose of providing technical assistance and training on the use of a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, and mechanisms for referral to appropriate treatment for an entity receiving a grant under this section.

“(e) GEOGRAPHIC DISTRIBUTION.—In making grants under this section, the Secretary shall ensure that not less than 20 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). The Secretary shall take into account the unique needs of rural communities, including communities with an incidence of individuals with opioid use disorder that is above the national average and communities with a shortage of prevention and treatment services.

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

“(1) the number of first responders and members of other key community sectors equipped with a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

“(2) the number of opioid and heroin overdoses reversed by first responders and members of other key community sectors receiving training and supplies of a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, through a grant received under this section;

“(3) the number of responses to requests for services by the entity or subgrantee, to opioid and heroin overdose; and

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

“(g) **AUTHORIZATION OF APPROPRIATIONS.**—To carry out this section, there are authorized to be appropriated \$12,000,000 for each of fiscal years 2017 through 2021.”

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.

TITLE III—TREATMENT AND RECOVERY

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

Subpart 1 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.) is amended by adding at the end the following:

“SEC. 514B. EVIDENCE-BASED PRESCRIPTION OPIOID AND HEROIN TREATMENT AND INTERVENTIONS DEMONSTRATION.

“(a) **GRANTS TO EXPAND ACCESS.**—

“(1) **AUTHORITY TO AWARD GRANTS.**—The Secretary shall award grants, contracts, or cooperative agreements to State substance abuse agencies, units of local government, nonprofit organizations, and Indian tribes and tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) 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 evidence-based 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, such as in rural areas.

“(2) **NATURE OF ACTIVITIES.**—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.

“(b) **APPLICATION.**—To be eligible for a grant, contract, or cooperative agreement under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

“(c) **EVALUATION.**—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or agreement a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and an evaluation at the completion of such project as the Secretary determines to be appropriate.

“(d) **GEOGRAPHIC DISTRIBUTION.**—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall ensure that not less than 15 percent of funds are awarded to eligible entities that are not located in metropolitan statistical areas (as defined by the Office of Management and Budget). The Secretary shall take into account the unique needs of rural communities, including communities with an incidence of individuals with opioid use disorder that is above the national average and communities with a shortage of prevention and treatment services.

“(e) **ADDITIONAL ACTIVITIES.**—In administering grants, contracts, and cooperative agreements under subsection (a), the Secretary shall—

“(1) evaluate the activities supported under such subsection;

“(2) disseminate information, as appropriate, derived from evaluations 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 program involved.

“(f) **AUTHORIZATION OF APPROPRIATIONS.**—To carry out this section, there are authorized to be appropriated \$25,000,000 for each of fiscal years 2017 through 2021.”

SEC. 302. BUILDING COMMUNITIES OF RECOVERY.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by section 202, is further amended by adding at the end the following:

“SEC. 547. 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 shall 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) build connections between recovery networks, between recovery community organizations, and with other recovery support services, including—

“(i) behavioral health providers;

“(ii) primary care providers and physicians;

“(iii) the criminal justice system;

“(iv) employers;

“(v) housing services;

“(vi) child welfare agencies; and

“(vii) other recovery support services that facilitate recovery from substance use disorders;

“(B) reduce the stigma associated with substance use disorders; and

“(C) conduct outreach on issues relating to substance use disorders and recovery, including—

“(i) identifying the signs of addiction;

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

“(iii) the resources available to help support individuals in recovery; and

“(iv) related medical outcomes of substance use disorders, the potential of acquiring an infectious disease from intravenous drug use, and neonatal abstinence syndrome among infants exposed to opioids during pregnancy.

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section \$1,000,000 for each of fiscal years 2017 through 2021.”

SEC. 303. MEDICATION-ASSISTED TREATMENT FOR RECOVERY FROM ADDICTION.

(a) **IN GENERAL.**—

(1) **IN GENERAL.**—Section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is amended—

(A) in subparagraph (B), by striking clauses (i), (ii), and (iii) and inserting the following:

“(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

“(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

“(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

“(II) appropriate counseling and other appropriate ancillary services.

“(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

“(II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.

“(III) The Secretary may by regulation change such applicable number.

“(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.”;

(B) in subparagraph (D)—

(i) in clause (ii), by striking “Upon receiving a notification under subparagraph (B)” and inserting “Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)”;

and

(ii) in clause (iii)—

(I) by inserting “and shall forward such determination to the Attorney General” before the period at the end of the first sentence; and

(II) by striking “physician” and inserting “practitioner”;

(C) in subparagraph (G)—

(i) by amending clause (ii)(I) to read as follows:

“(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.”;

(ii) by amending clause (ii)(II) to read as follows:

“(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.”;

(iii) in clause (ii)(III), by striking “subspecialty”;

(iv) by amending clause (ii)(IV) to read as follows:
“(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

- “(aa) opioid maintenance and detoxification;
- “(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
- “(cc) initial and periodic patient assessments (including substance use monitoring);
- “(dd) individualized treatment planning, overdose reversal, and relapse prevention;
- “(ee) counseling and recovery support services;
- “(ff) staffing roles and considerations;
- “(gg) diversion control; and
- “(hh) other best practices, as identified by the Secretary.”; and

(v) by adding at the end the following:

“(iii) The term ‘qualifying practitioner’ means—

“(I) a qualifying physician, as defined in clause (ii);

or

“(II) during the period beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2016 and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).

“(iv) The term ‘qualifying other practitioner’ means a nurse practitioner or physician assistant who satisfies each of the following:

“(I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

“(II) The nurse practitioner or physician assistant has—

“(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

“(bb) has such other training or experience as the Secretary determines will demonstrate the ability of

the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

“(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.”; and (D) in subparagraph (H)—

(i) in clause (i), by inserting after subclause (II) the following:

“(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.”; and

(ii) by amending clause (ii) to read as follows:

“(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.”

(2) OPIOID DEFINED.—Section 102(18) of the Controlled Substances Act (21 U.S.C. 802(18)) is amended by inserting “or ‘opiod’” after “The term ‘opiate’”.

(3) REPORTS TO CONGRESS.—

(A) IN GENERAL.—Not later than 3 years after the date of enactment of this Act and not later than 3 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

(i) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

(ii) submit a report to the Congress on the findings and conclusions of such review.

(B) CONTENTS.—Each report under subparagraph (A) shall include an assessment of—

(i) compliance with the requirements of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), as amended by this section;

(ii) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

(iii) whether there is further need to increase or decrease the number of patients a practitioner, pursuant to a waiver under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), is permitted to treat;

(iv) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used

in routine health care settings and specialty substance use disorder treatment settings;

(v) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

(vi) changes in State or local policies and legislation relating to opioid use disorder treatment;

(vii) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver described in clause (iii);

(viii) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in clause (vii); and

(ix) the effectiveness of cross-agency collaboration between Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.

(b) **STATE FLEXIBILITY.**—Section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is amended by striking subparagraphs (I) and (J), and inserting the following:

“(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

“(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

“(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.”

(c) **UPDATE REGULATIONS.**—Not later than 18 months after the date of enactment of this Act, the Attorney General and the Secretary of Health and Human Services, as appropriate, shall update regulations regarding practitioners described in subsection (a)(3)(B)(vii) (as amended by this section) to include nurse practitioners and physician assistants to ensure the quality of patient care and prevent diversion.

TITLE IV—ADDRESSING COLLATERAL CONSEQUENCES

SEC. 401. GAO REPORT ON RECOVERY AND COLLATERAL CONSEQUENCES.

(a) **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 the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that—

(1) describes the collateral consequences for individuals with convictions for nonviolent drug-related offenses;

(2) describes the effect of the collateral consequences described in paragraph (1) on individuals in resuming their personal and professional activities, especially, to the extent data are available, the effect on individuals who are participating in or have completed a recovery program for a substance use disorder;

(3) discusses policy bases and justifications for imposing collateral consequences on individuals convicted of nonviolent drug-related offenses identified under paragraph (1); and

(4) provides perspectives on the potential for mitigating the effect of the collateral consequences described in paragraph (1) on individuals who are participating in or have completed a recovery program, while also taking into account the policy interests described in paragraph (3).

(b) DEFINITION.—In this section, the term “collateral consequence”—

(1) means a penalty, disability, or disadvantage imposed upon an individual as a result of a criminal conviction for a drug-related offense—

(A) automatically by operation of law; or

(B) by authorized action of an administrative agency or court on a case-by-case basis; and

(2) does not include a direct consequence imposed as part of the judgment of a court at sentencing, including a term of imprisonment or community supervision, or a fine.

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

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

(a) GENERAL AMENDMENTS TO THE RESIDENTIAL TREATMENT PROGRAM FOR PREGNANT AND POSTPARTUM WOMEN.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb-1) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1)—

(i) by inserting “(referred to in this section as the Director)” after “Substance Abuse Treatment”;

(ii) by striking “grants, cooperative agreement,” and inserting “grants, including the grants under subsection (r), cooperative agreements”; and

(iii) by striking “for substance abuse” and inserting “for substance use disorders”; and

(B) in paragraph (1), by inserting “or receive outpatient treatment services from” after “reside in”;

(2) in subsection (b)(2), by inserting “and her children” before the period at the end;

(3) in subsection (c)—

(A) in paragraph (1), by striking “to the woman of the services” and inserting “of services for the woman and her children”; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking “substance abuse” and inserting “substance use disorders”; and
 (ii) in subparagraph (B), by striking “such abuse” and inserting “such a disorder”;

(4) in subsection (d)—

(A) in paragraph (3)(A), by striking “maternal substance abuse” and inserting “a maternal substance use disorder”;

(B) by amending paragraph (4) to read as follows:

“(4) Providing therapeutic, comprehensive child care for children during the periods in which the woman is engaged in therapy or in other necessary health and rehabilitative activities.”;

(C) in paragraphs (9), (10), and (11), by striking “women” each place such term appears and inserting “woman”;

(D) in paragraph (9), by striking “units” and inserting “unit”; and

(E) in paragraph (11)—

(i) in subparagraph (A), by striking “their children” and inserting “any child of such woman”;

(ii) in subparagraph (B), by striking “; and” and inserting a semicolon;

(iii) in subparagraph (C), by striking the period and inserting “; and”; and

(iv) by adding at the end the following:

“(D) family reunification with children in kinship or foster care arrangements, where safe and appropriate.”;

(5) in subsection (e)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking “substance abuse” and inserting “substance use disorders”; and

(ii) in subparagraph (B), by striking “substance abuse” and inserting “substance use disorders”; and
 (B) in paragraph (2)—

(i) by striking “(A) Subject” and inserting the following:

“(A) IN GENERAL.—Subject”;

(ii) in subparagraph (B)—

(I) by striking “(B)(i) In the case” and inserting the following:

“(B) WAIVER OF PARTICIPATION AGREEMENTS.—

“(i) IN GENERAL.—In the case”; and

(II) by striking “(ii) A determination” and inserting the following:

“(ii) DONATIONS.—A determination”; and

(iii) by striking “(C) With respect” and inserting the following:

“(C) NONAPPLICATION OF CERTAIN REQUIREMENTS.—
 With respect”;

(6) in subsection (g)—

(A) by striking “who are engaging in substance abuse” and inserting “who have a substance use disorder”; and

(B) by striking “such abuse” and inserting “such disorder”;

(7) in subsection (j)—

(A) in the matter preceding paragraph (1), by striking “to on” and inserting “to or on”; and

(B) in paragraph (3), by striking “Office for” and inserting “Office of”;

(8) by amending subsection (m) to read as follows:

“(m) ALLOCATION OF AWARDS.—In making awards under subsection (a), the Director shall give priority to an applicant that agrees to use the award for a program serving an area that is a rural area, an area designated under section 332 by the Secretary as a health professional shortage area, or an area determined by the Director to have a shortage of family-based substance use disorder treatment options.”; and

(9) in subsection (q)—

(A) in paragraph (3), by striking “funding agreement under subsection (a)” and inserting “funding agreement”; and

(B) in paragraph (4), by striking “substance abuse” and inserting “a substance use disorder”.

(b) REAUTHORIZATION OF PROGRAM.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb-1), as amended by subsection (a), is further amended—

(1) in subsection (p), in the first sentence, by inserting “(other than subsection (r))” after “section”; and

(2) in subsection (r), by striking “such sums” and all that follows through “2003” and inserting “\$16,900,000 for each of fiscal years 2017 through 2021”.

(c) PILOT PROGRAM GRANTS FOR STATE SUBSTANCE ABUSE AGENCIES.—

(1) IN GENERAL.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb-1), as amended by subsections (a) and (b), is further amended—

(A) by redesignating subsection (r), as amended by subsection (b), as subsection (s); and

(B) by inserting after subsection (q) the following new subsection:

“(r) PILOT PROGRAM FOR STATE SUBSTANCE ABUSE AGENCIES.—

“(1) IN GENERAL.—From amounts made available under subsection (s), the Director of the Center for Substance Abuse Treatment shall carry out a pilot program under which competitive grants are made by the Director to State substance abuse agencies—

“(A) to 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) to 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 nonresidential-based settings; and

“(C) to promote a coordinated, effective, and efficient State system managed by State substance abuse agencies by encouraging new approaches and models of service delivery.

“(2) REQUIREMENTS.—In carrying out the pilot program under this subsection, the Director shall—

“(A) 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) identify, based on such submitted applications, State substance abuse agencies that are eligible for such grants;

“(C) 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) not require that services furnished through such a grant be provided solely to women that reside in facilities;

“(E) not require that grant recipients under the program make available through use of the grant all the services described in subsection (d); and

“(F) consider not applying the requirements described in paragraphs (1) and (2) of subsection (f) to an applicant, depending on the circumstances of the applicant.

“(3) REQUIRED SERVICES.—

“(A) IN GENERAL.—The Director shall specify a minimum set of services required to be made available to eligible women through a grant awarded under the pilot program under this subsection. Such minimum set of services—

“(i) shall include the services requirements described in subsection (c) and be based on the recommendations submitted under subparagraph (B); and

“(ii) may be selected from among the services described in subsection (d) and include other services as appropriate.

“(B) STAKEHOLDER INPUT.—The Director shall convene and solicit recommendations from stakeholders, including State substance abuse agencies, health care providers, persons in recovery from substance abuse, and other appropriate individuals, for the minimum set of 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.—The Director of the Center for Behavioral Health Statistics and Quality shall evaluate the pilot program at the conclusion of the first grant cycle funded by the pilot program.

“(B) REPORT.—The Director of the Center for Behavioral Health Statistics and Quality, in coordination with the Director of the Center for Substance Abuse Treatment shall submit to the relevant committees of jurisdiction of the House of Representatives and the Senate a report on the evaluation under subparagraph (A). The report shall include, at a minimum—

“(i) outcomes information from the pilot program, including any resulting reductions in the use of alcohol and other drugs;

“(ii) engagement in treatment services;

“(iii) retention in the appropriate level and duration of services;

“(iv) increased access to the use of medications approved by the Food and Drug Administration for the treatment of substance use disorders in combination with counseling; and

“(v) other appropriate measures.

“(C) RECOMMENDATION.—The report under subparagraph (B) shall include a recommendation by the Director of the Center for Substance Abuse Treatment as to whether the pilot program under this subsection should be extended.

“(6) STATE SUBSTANCE ABUSE AGENCIES DEFINED.—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 under part B of title XIX.”

(2) FUNDING.—Subsection (s) of section 508 of the Public Health Service Act (42 U.S.C. 290bb-1), as amended by subsection (a) and redesignated by paragraph (1), is further amended by adding at the end the following new sentences: “Of the amounts made available for a year pursuant to the previous sentence to carry out this section, not more than 25 percent of such amounts shall be made available for such year to carry out subsection (r), other than paragraph (5) of such subsection. Notwithstanding the preceding sentence, no funds shall be made available to carry out subsection (r) for a fiscal year unless the amount made available to carry out this section for such fiscal year is more than the amount made available to carry out this section for fiscal year 2016.”

SEC. 502. VETERANS TREATMENT COURTS.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended—

(1) by redesignating subsection (i) as subsection (j); and
(2) by inserting after subsection (h) the following:

“(i) ASSISTING VETERANS.—

“(1) DEFINITIONS.—In this subsection:

“(A) PEER-TO-PEER SERVICES OR PROGRAMS.—The term ‘peer-to-peer services or programs’ means services or programs that connect qualified veterans with other veterans for the purpose of providing support and mentorship to assist qualified veterans in obtaining treatment, recovery, stabilization, or rehabilitation.

“(B) QUALIFIED VETERAN.—The term ‘qualified veteran’ means a preliminarily qualified offender who—

“(i) served on active duty in any branch of the Armed Forces, including the National Guard or Reserves; and

“(ii) was discharged or released from such service under conditions other than dishonorable, unless the reason for the dishonorable discharge was attributable to a substance abuse disorder.

“(C) VETERANS TREATMENT COURT PROGRAM.—The term ‘veterans treatment court program’ means a court program involving collaboration among criminal justice, veterans, and mental health and substance abuse agencies that provides qualified veterans with—

“(i) intensive judicial supervision and case management, which may include random and frequent drug testing where appropriate;

“(ii) a full continuum of treatment services, including mental health services, substance abuse services, medical services, and services to address trauma;

“(iii) alternatives to incarceration; or

“(iv) other appropriate services, including housing, transportation, mentoring, employment, job training, education, or assistance in applying for and obtaining available benefits.

“(2) VETERANS ASSISTANCE PROGRAM.—

“(A) IN GENERAL.—The Attorney General, in consultation with the Secretary of Veterans Affairs, may award grants under this subsection to applicants to establish or expand—

“(i) veterans treatment court programs;

“(ii) peer-to-peer services or programs for qualified veterans;

“(iii) practices that identify and provide treatment, rehabilitation, legal, transitional, and other appropriate services to qualified veterans who have been incarcerated; or

“(iv) training programs to teach criminal justice, law enforcement, corrections, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving qualified veterans.

“(B) PRIORITY.—In awarding grants under this subsection, the Attorney General shall give priority to applications that—

“(i) demonstrate collaboration between and joint investments by criminal justice, mental health, substance abuse, and veterans service agencies;

“(ii) promote effective strategies to identify and reduce the risk of harm to qualified veterans and public safety; and

“(iii) propose interventions with empirical support to improve outcomes for qualified veterans.”.

SEC. 503. INFANT PLAN OF SAFE CARE.

(a) **BEST PRACTICES FOR DEVELOPMENT OF PLANS OF SAFE CARE.**—Section 103(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5104(b)) is amended—

(1) by redesignating paragraphs (5) through (8) as paragraphs (6) through (9), respectively; and

(2) by inserting after paragraph (4) the following:

“(5) maintain and disseminate information about the requirements of section 106(b)(2)(B)(iii) and best practices relating to the development of plans of safe care as described in such section for infants born and identified as being affected by substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder;”.

(b) **STATE PLANS.**—Section 106(b)(2)(B) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(b)(2)(B)) is amended—

(1) in clause (ii), by striking “illegal substance abuse” and inserting “substance abuse”; and

(2) in clause (iii)—

(A) by striking “illegal substance abuse” and inserting “substance abuse”; and

(B) by inserting before the semicolon at the end the following: “to ensure the safety and well-being of such infant following release from the care of health care providers, including through—

“(I) addressing the health and substance use disorder treatment needs of the infant and affected family or caregiver; and

“(II) the development and implementation by the State of monitoring systems regarding the implementation of such plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver”.

(c) DATA REPORTS.—

(1) IN GENERAL.—Section 106(d) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(d)) is amended by adding at the end of the following:

“(17) The number of infants—

“(A) identified under subsection (b)(2)(B)(ii);

“(B) for whom a plan of safe care was developed under subsection (b)(2)(B)(iii); and

“(C) for whom a referral was made for appropriate services, including services for the affected family or caregiver, under subsection (b)(2)(B)(iii).”.

(2) REDESIGNATION.—Effective on May 29, 2017, section 106(d) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(d)) is amended by redesignating paragraph (17) (as added by paragraph (1)) as paragraph (18).

(d) MONITORING AND OVERSIGHT.—

(1) AMENDMENT.—Title I of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 et seq.) is amended by adding at the end the following:

“SEC. 114. MONITORING AND OVERSIGHT.

“The Secretary shall conduct monitoring to ensure that each State that receives a grant under section 106 is in compliance with the requirements of section 106(b), which—

“(1) shall—

“(A) be in addition to the review of the State plan upon its submission under section 106(b)(1)(A); and

“(B) include monitoring of State policies and procedures required under clauses (ii) and (iii) of section 106(b)(2)(B); and

“(2) may include—

“(A) a comparison of activities carried out by the State to comply with the requirements of section 106(b) with the State plan most recently approved under section 432 of the Social Security Act;

“(B) a review of information available on the website of the State relating to its compliance with the requirements of section 106(b);

“(C) site visits, as may be necessary to carry out such monitoring; and

“(D) a review of information available in the State’s Annual Progress and Services Report most recently submitted under section 1357.16 of title 45, Code of Federal Regulations (or successor regulations).”.

(2) TABLE OF CONTENTS.—The table of contents in section 1(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 note) is amended by inserting after the item relating to section 113, the following:

“Sec. 114. Monitoring and oversight.”.

(e) RULE OF CONSTRUCTION.—Nothing in this section, or the amendments made by this section, shall be construed to authorize the Secretary of Health and Human Services or any other officer of the Federal Government to add new requirements to section 106(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(b)), as amended by this section.

SEC. 504. GAO REPORT ON NEONATAL ABSTINENCE SYNDROME (NAS).

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate a report on neonatal abstinence syndrome (in this section referred to as “NAS”) in the United States.

(b) INFORMATION TO BE INCLUDED IN REPORT.—Such report shall include information on the following:

(1) The prevalence of NAS in the United States, including the proportion of children born in the United States with NAS who are eligible for medical assistance under State Medicaid programs under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) at birth, and the costs associated with coverage under such programs for treatment of infants with NAS.

(2) The services for which coverage is available under State Medicaid programs for treatment of infants with NAS.

(3) The settings (including inpatient, outpatient, hospital-based, and other settings) for the treatment of infants with NAS and the reimbursement methodologies and costs associated with such treatment in such settings.

(4) The prevalence of utilization of various care settings under State Medicaid programs for treatment of infants with NAS and any Federal barriers to treating such infants under such programs, particularly in non-hospital-based settings.

(5) What is known about best practices for treating infants with NAS.

(c) RECOMMENDATIONS.—Such report also shall include such recommendations as the Comptroller General determines appropriate for improvements that will ensure access to treatment for infants with NAS under State Medicaid programs.

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

SEC. 601. STATE DEMONSTRATION GRANTS FOR COMPREHENSIVE OPIOID ABUSE RESPONSE.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by section 302, is further amended by adding at the end the following:

“SEC. 548. STATE DEMONSTRATION GRANTS FOR COMPREHENSIVE OPIOID ABUSE RESPONSE.

“(a) DEFINITIONS.—In this section:

“(1) DISPENSER.—The term ‘dispenser’ has the meaning given the term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

“(2) PRESCRIBER.—The term ‘prescriber’ means a dispenser who prescribes a controlled substance, or the agent of such a dispenser.

“(3) PRESCRIBER OF A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE.—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 Secretary may reasonably determine.

“(4) SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE.—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.

“(b) GRANTS FOR COMPREHENSIVE OPIOID ABUSE RESPONSE.—

“(1) IN GENERAL.—The Secretary shall award grants to States, and combinations of States, to implement an integrated opioid abuse response initiative.

“(2) PURPOSES.—A State receiving a grant under this section shall establish a comprehensive response plan to opioid abuse, which may include—

“(A) education efforts around opioid use, treatment, and addiction recovery, including education of residents, medical students, and physicians and other prescribers of schedule II, III, or IV controlled substances on relevant prescribing guidelines, the prescription drug monitoring program of the State described in subparagraph (B), and overdose prevention methods;

“(B) establishing, maintaining, or improving a comprehensive prescription drug monitoring program to track dispensing of schedule II, III, or IV controlled substances, which may—

“(i) provide for data sharing with other States; and

“(ii) allow all individuals authorized by the State to write prescriptions for schedule II, III, or IV controlled substances to access the prescription drug monitoring program of the State;

“(C) developing, implementing, or expanding prescription drug and opioid addiction treatment programs by—

“(i) expanding the availability of treatment for prescription drug and opioid addiction, including medication-assisted treatment and behavioral health therapy, as appropriate;

“(ii) developing, implementing, or expanding screening for individuals in treatment for prescription drug and opioid addiction for hepatitis C and HIV, and treating or referring those individuals if clinically appropriate; or

“(iii) developing, implementing, or expanding recovery support services and programs at high schools or institutions of higher education;

“(D) developing, implementing, and expanding efforts to prevent overdose death from opioid abuse or addiction to prescription medications and opioids; and

“(E) advancing the education and awareness of the public, providers, patients, consumers, and other appropriate entities regarding the dangers of opioid abuse, safe disposal of prescription medications, and detection of early warning signs of opioid use disorders.

“(3) APPLICATION.—A State seeking a grant under this section shall submit to the Secretary an application in such form, and containing such information, as the Secretary may reasonably require.

“(4) USE OF FUNDS.—A State that receives a grant under this section shall use the grant for the cost, including the cost for technical assistance, training, and administration expenses, of carrying out an integrated opioid abuse response initiative as outlined by the State’s comprehensive response plan to opioid abuse established under paragraph (2).

“(5) PRIORITY CONSIDERATIONS.—In awarding grants under this section, the Secretary shall, as appropriate, 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 administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

“(i) 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—

“(aa) have received appropriate training in administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act

for emergency treatment of known or suspected opioid overdose; and

“(bb) may administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

“(II) concluded that the law described in subclause (I) provides adequate civil liability protection applicable to such persons;

“(B) 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;

“(C) ensures the capability of data sharing with other States, where applicable, such as by making data available to a prescription monitoring hub;

“(D) ensures that data recorded in the prescription drug monitoring program database of the State are regularly updated, to the extent possible;

“(E) 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; and

“(F) has in effect one or more statutes or implements policies that maximize use of prescription drug monitoring programs by individuals authorized by the State to prescribe schedule II, III, or IV controlled substances.

“(6) EVALUATION.—In conducting an evaluation of the program under this section pursuant to section 701 of the Comprehensive Addiction and Recovery Act of 2016, with respect to a State, the Secretary shall report on State legislation or policies related to maximizing the use of prescription drug monitoring programs and the incidence of opioid use disorders and overdose deaths in such State.

“(7) STATES WITH LOCAL PRESCRIPTION DRUG MONITORING PROGRAMS.—

“(A) IN GENERAL.—In the case of a State that does not have a prescription drug monitoring program, a county or other unit of local government within the State that has a prescription drug monitoring program shall be treated as a State for purposes of this section, including for purposes of eligibility for grants under paragraph (1).

“(B) PLAN FOR INTEROPERABILITY.—In submitting an application to the Secretary under paragraph (3), a county or other unit of local government shall submit a plan outlining the methods such county or unit of local government shall use to ensure the capability of data sharing with other counties and units of local government within the state and with other States, as applicable.

“(c) AUTHORIZATION OF FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated \$5,000,000 for each of fiscal years 2017 through 2021.”.

TITLE VII—MISCELLANEOUS

SEC. 701. GRANT ACCOUNTABILITY AND EVALUATIONS.

(a) DEPARTMENT OF JUSTICE GRANT ACCOUNTABILITY.—Part LL of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.), as added by section 201, is amended by adding at the end the following:

“SEC. 3026. GRANT ACCOUNTABILITY.

“(a) DEFINITION OF APPLICABLE COMMITTEES.—In this section, the term ‘applicable committees’ means—

“(1) the Committee on the Judiciary of the Senate; and

“(2) the Committee on the Judiciary of the House of Representatives.

“(b) ACCOUNTABILITY.—All grants awarded by the Attorney General 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 the Department of Justice 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 the Department of Justice shall conduct audits of recipients of grants awarded by the Attorney General 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, the Attorney General 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 Attorney General 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 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 may not—

“(i) be party to a contract entered into under section 3021(b); or

“(ii) receive a subaward under section 3021(b).

“(C) DISCLOSURE.—Each nonprofit organization that receives a subaward or is party to a contract entered into under section 3021(b) 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, in the application for such contract or subaward, 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, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

“(3) CONFERENCE EXPENDITURES.—

“(A) LIMITATION.—No amounts made available to the Attorney General under this part may be used by the Attorney General, or by any State, unit of local government, or entity awarded a grant, subaward, or contract under this part, to host or support any expenditure for conferences that uses more than \$20,000 in funds made available by the Attorney General, unless the head of the relevant agency, bureau, or program office provides prior written authorization that the funds may be expended to host or support 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.—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.

“(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this section, the Attorney General shall submit to the applicable committees an annual certification—

“(A) indicating whether—

“(i) all audits issued by the Inspector General of the Department of Justice under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

“(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 the Attorney General awards a grant to an applicant under this part, the Attorney General shall compare potential grant awards with other grants awarded under this part by the Attorney General to determine if duplicate grant awards are awarded for the same purpose.

“(2) REPORT.—If the Attorney General awards duplicate grants under this part to the same applicant for the same purpose, the Attorney General shall submit to the applicable committees a report that includes—

“(A) a list of all duplicate grants awarded under this part, including the total dollar amount of any duplicate grants awarded; and

“(B) the reason the Attorney General awarded the duplicate grants.”

(b) EVALUATION OF PERFORMANCE OF DEPARTMENT OF JUSTICE PROGRAMS.—

(1) EVALUATION OF JUSTICE DEPARTMENT COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.—Not later than 5 years after the date of enactment of this Act, the Attorney General shall complete an evaluation of the effectiveness of the Comprehensive Opioid Abuse Grant Program under part LL of title I of the Omnibus Crime Control and Safe Streets Act of 1968, as added by section 201, administered by the Department of Justice based upon the information reported under paragraph (4).

(2) INTERIM EVALUATION.—Not later than 3 years after the date of enactment of this Act, the Attorney General shall complete an interim evaluation assessing the nature and extent of the incidence of opioid abuse and illegal opioid distribution in the United States.

(3) METRICS AND OUTCOMES FOR EVALUATION.—Not later than 180 days after the date of enactment of this Act, the Attorney General shall identify outcomes that are to be achieved by activities funded by the Comprehensive Opioid Abuse Grant Program and the metrics by which the achievement of such outcomes shall be determined.

(4) METRICS DATA COLLECTION.—The Attorney General shall require grantees under the Comprehensive Opioid Abuse Grant Program (and those receiving subawards under section 3021(b) of part LL of title I of the Omnibus Crime Control and Safe Streets Act of 1968, as added by section 201) to collect and annually report to the Department of Justice data based upon the metrics identified under paragraph (3).

(5) PUBLICATION OF DATA AND FINDINGS.—

(A) PUBLICATION OF OUTCOMES AND METRICS.—The Attorney General shall, not later than 30 days after completion of the requirement under paragraph (3), publish the outcomes and metrics identified under that paragraph.

(B) PUBLICATION OF EVALUATION.—In the case of the interim evaluation under paragraph (2), and the final

evaluation under paragraph (1), the entity conducting the evaluation shall, not later than 90 days after such an evaluation is completed, publish the results of such evaluation and issue a report on such evaluation to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate. Such report shall also be published along with the data used to make such evaluation.

(6) INDEPENDENT EVALUATION.—For purposes of paragraphs (1), (2), and (3), the Attorney General shall—

(A) enter into an arrangement with the National Academy of Sciences; or

(B) enter into a contract or cooperative agreement with an entity that is not an agency of the Federal Government, and is qualified to conduct and evaluate research pertaining to opioid use and abuse, and draw conclusions about overall opioid use and abuse on the basis of that research.

(c) DEPARTMENT OF HEALTH AND HUMAN SERVICES GRANT ACCOUNTABILITY.—

(1) DEFINITIONS.—In this subsection:

(A) APPLICABLE COMMITTEES.—The term “applicable committees” 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) COVERED GRANT.—The term “covered grant” means a grant awarded by the Secretary under a program established under this Act (or an amendment made by this Act, other than sections 703 through 707), including any grant administered by the Administrator of the Substance Abuse and Mental Health Services Administration under section 103.

(C) GRANTEE.—The term “grantee” means the recipient of a covered grant.

(D) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(2) ACCOUNTABILITY MEASURES.—Each covered grant shall be subject to the following accountability requirements:

(A) EFFECTIVENESS REPORT.—The Secretary shall require grantees to report on the effectiveness of the activities carried out with amounts made available to carry out the program under which the covered grant is awarded, including the number of persons served by such grant, if applicable, the number of persons seeking services who could not be served by such grant, and such other information as the Secretary may prescribe.

(B) REPORT ON PREVENTION OF FRAUD, WASTE, AND ABUSE.—

(i) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in coordination with the Inspector General of the Department of Health and Human Services, shall submit to the applicable committees a report on the policies and procedures the Department has in place to prevent waste, fraud, and abuse in the administration of covered grants.

(ii) **CONTENTS.**—The policies and procedures referred to in clause (i) shall include policies and procedures that are designed to—

(I) prevent grantees from utilizing funds awarded through a covered grant for unauthorized expenditures or otherwise unallowable costs; and

(II) ensure grantees will not receive unwarranted duplicate grants for the same purpose.

(C) **CONFERENCE EXPENDITURES.**—

(i) **IN GENERAL.**—No amounts made available to the Secretary under this Act (or in a provision of law amended by this Act, other than sections 703 through 707) may be used by the Secretary, or by any individual or entity awarded discretionary funds through a cooperative agreement under a program established under this Act (or in a provision of law amended by this Act), to host or support any expenditure for conferences that uses more than \$20,000 in funds made available by the Secretary, unless the head of the relevant operating division or program office provides prior written authorization that the funds may be expended to host or support the conference. Such written authorization 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.

(ii) **REPORT.**—The Secretary (or the Secretary's designee) shall submit to the applicable committees an annual report on all conference expenditures approved by the Secretary under this subparagraph.

(d) **EVALUATION OF PERFORMANCE OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS.**—

(1) **EVALUATIONS.**—

(A) **IN GENERAL.**—Not later than 5 years after the date of enactment of this Act, except as otherwise provided in this section, the Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall complete an evaluation of any program administered by the Secretary included in this Act (or an amendment made by this Act, excluding sections 703 through 707), including any grant administered by the Administrator of the Substance Abuse and Mental Health Services Administration under section 103, that provides grants for the primary purpose of providing assistance in addressing problems pertaining to opioid abuse based upon the outcomes and metrics identified under paragraph (2).

(B) **PUBLICATION.**—With respect to each evaluation completed under subparagraph (A), the Secretary shall, not later than 90 days after the date on which such evaluation is completed, publish the results of such evaluation and issue a report on such evaluation to the appropriate committees. Such report shall also be published along with the data used to make such evaluation.

(2) **METRICS AND OUTCOMES.**—

(A) **IN GENERAL.**—Not later than 180 days after the date of enactment of this Act, the Secretary shall identify—

(i) outcomes that are to be achieved by activities funded by the programs described in paragraph (1)(A); and

(ii) the metrics by which the achievement of such outcomes shall be determined.

(B) PUBLICATION.—The Secretary shall, not later than 30 days after completion of the requirement under subparagraph (A), publish the outcomes and metrics identified under such subparagraph.

(3) METRICS DATA COLLECTION.—The Secretary shall require grantees under the programs described in paragraph (1)(A) to collect, and annually report to the Secretary, data based upon the metrics identified under paragraph (2)(A).

(4) INDEPENDENT EVALUATION.—For purposes of paragraph (1), the Secretary shall—

(A) enter into an arrangement with the National Academy of Sciences; or

(B) enter into a contract or cooperative agreement with an entity that—

(i) is not an agency of the Federal Government; and

(ii) is qualified to conduct and evaluate research pertaining to opioid use and abuse and draw conclusions about overall opioid use and abuse on the basis of that research.

(5) EXCEPTION.—If a program described in paragraph (1)(A) is subject to an evaluation similar to the evaluation required under such paragraph pursuant to another provision of Federal law, the Secretary may opt not to conduct an evaluation under such paragraph with respect to such program.

(e) ADDITIONAL REPORT.—In the case of a report submitted under subsection (c) to the applicable committees, if such report pertains to a grant under section 103, that report shall also be submitted, in the same manner and at the same time, to the Committee on Oversight and Government Reform of the House of Representatives and to the Committee on the Judiciary of the Senate.

(f) NO ADDITIONAL FUNDS AUTHORIZED.—No additional funds are authorized to be appropriated to carry out this section.

SEC. 702. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

“(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

“(1) PARTIAL FILLS.—A prescription for a controlled substance in schedule II may be partially filled if—

“(A) it is not prohibited by State law;

“(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

“(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

“(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

“(2) REMAINING PORTIONS.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

“(i) may be filled; and

“(ii) shall be filled not later than 30 days after the date on which the prescription is written.

“(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

“(i) may be filled; and

“(ii) shall be filled not later than 72 hours after the prescription is issued.

“(3) CURRENTLY LAWFUL PARTIAL FILLS.—Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled.”

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

SEC. 703. GOOD SAMARITAN ASSESSMENT.

(a) FINDING.—The Congress finds that the executive branch, including the Office of National Drug Control Policy, has a policy focus on preventing and addressing prescription drug misuse and heroin use, and has worked with States and municipalities to enact Good Samaritan laws that would protect caregivers, law enforcement personnel, and first responders who administer opioid overdose reversal drugs or devices.

(b) GAO STUDY ON GOOD SAMARITAN LAWS PERTAINING TO TREATMENT OF OPIOID OVERDOSES.—The Comptroller General of the United States shall submit to the Committee on the Judiciary of the House of Representatives, the Committee on Oversight and Government Reform of the House of Representatives, the Committee on the Judiciary of the Senate, and the Committee on Homeland Security and Governmental Affairs of the Senate a report on—

(1) the extent to which the Director of National Drug Control Policy has reviewed Good Samaritan laws, and any findings from such a review, including findings related to the potential effects of such laws, if available;

(2) efforts by the Director to encourage the enactment of Good Samaritan laws; and

(3) a compilation of Good Samaritan laws in effect in the States, the territories, and the District of Columbia.

(c) DEFINITIONS.—In this section—

(1) the term “Good Samaritan law” means a law of a State or unit of local government that exempts from criminal or civil liability any individual who administers an opioid overdose reversal drug or device, or who contacts emergency services providers in response to an overdose; and

(2) the term “opioid” means any drug, including heroin, 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.

SEC. 704. PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER MEDICARE PARTS C AND D.

(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–10(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 one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more 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.

“(ii) INITIAL NOTICE.—An initial 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 describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

“(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

“(IV) 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);

“(V) 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);

“(VI) 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; and

“(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

“(iii) SECOND NOTICE.—A second 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 is 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 (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

“(IV) of, and information about, the beneficiary’s right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

“(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.

“(iv) TIMING OF NOTICES.—

“(I) IN GENERAL.—Subject to subclause (II), a second 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 (I), the PDP sponsor may provide such second notice on such earlier date.

“(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 as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers; 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 the prescription drug plan in which such individual was most recently 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) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a 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 guidelines 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 AND PHARMACIES.—
“(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)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) 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.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

“(ii) **REASONABLE ACCESS.**—In making the selections under this subparagraph—

“(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

“(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

“(iii) **BENEFICIARY PREFERENCES.**—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—

“(I) review such preferences;

“(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

“(III) inform the beneficiary of such selection or change of selection.

“(iv) **EXCEPTION REGARDING BENEFICIARY PREFERENCES.**—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) 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 prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

“(I) at least 30 days written notice of the change of selection; and

“(II) a rationale for the change.

“(v) 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) TERMINATIONS AND 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, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

“(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); and

“(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 a controlled substance that the Secretary determines to be frequently abused or diverted.

“(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 the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the 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 by Medicare administrative contractors 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) APPLICATION UNDER MA-PD PLANS.—Pursuant to section 1860D–21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA-PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

“(M) 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 further 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 (6)(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 (and an MA organization offering an MA-PD 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 (or organization) 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 compliance reviews and program audits biennially include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.”

(c) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICs).—

(1) IN GENERAL.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

“(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICs).—

“(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors (including any successor entity to a Medicare drug integrity contractor), the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD plans, and physicians with respect to an individual in order for such contractors to provide information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug abuse, as defined in section 1860D–4(c)(5)(C).

“(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization refers information to a contractor described in paragraph (1) in order for such contractor to assist in the determination described in such paragraph, the contractor shall—

“(A) acknowledge to the sponsor or organization receipt of the referral; and

“(B) in the case that any PDP sponsor or MA organization contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described in such paragraph, shall inform such sponsor or organization of such determination on a date that is not later than 15 days after the date on which the sponsor or organization contacts the contractor.

“(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—

“(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations using available programs and systems in the effort to prevent fraud, waste, and abuse.

“(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of

individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).”.

(2) **OIG STUDY AND REPORT ON EFFECTIVENESS OF MEDICS.**—

(A) **STUDY.**—The Inspector General of the Department of Health and Human Services shall conduct a study on the effectiveness of Medicare drug integrity contractors with which the Secretary of Health and Human Services has entered into a contract under section 1893 of the Social Security Act (42 U.S.C. 1395ddd) in identifying, combating, and preventing fraud under the Medicare program, including under the authority provided under section 1893(j) of the Social Security Act, added by paragraph (1).

(B) **REPORT.**—Not later than 24 months after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A). Such report shall include such recommendations for improvements in the effectiveness of such contractors as the Inspector General determines appropriate.

(d) **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.”.

(e) **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.

(f) **REPORTS.**—

(1) **REPORT BY SECRETARY ON APPEALS PROCESS.**—

(A) **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.

(B) **FEEDBACK.**—In development of the report described in subparagraph (A), 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.

(2) GAO STUDY AND REPORT.—

(A) 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—

(i) 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;

(ii) 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;

(iii) the types of—

(I) individuals who, in the implementation of such section, are determined to be individuals described in such subparagraph (C); and

(II) prescribers and pharmacies that are selected under subparagraph (D) of such section; and

(iv) other areas determined appropriate by the Comptroller General.

(B) 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 subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines to be appropriate.

(g) EFFECTIVE DATE; RULEMAKING.—

(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans (and MA–PD plans) for plan years beginning on or after January 1, 2019.

(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, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, 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 paragraph (3).

(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

(i) the anticipated impact of drug management programs for at-risk beneficiaries under paragraph (5) of section 1860D-4(c) of the Social Security Act (42 U.S.C. 1395w-104(c)) on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA-PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of such paragraph);

(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 that allow an automatic escalation to external review of claims submitted under such part);

(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;

(iv) the manner in which terms and definitions in such paragraph 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;

(v) the information to be included in the notices described in subparagraph (B) of such paragraph and the standardization of such notices;

(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) 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 of title XVIII of the Social Security Act with PDP sponsors.

(3) RULEMAKING.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall, taking into account the input gathered pursuant to paragraph (2)(A) and after providing notice and an opportunity to comment, promulgate regulations to carry out the provisions of, and amendments made by this section.

(h) DEPOSIT OF SAVINGS INTO MEDICARE IMPROVEMENT FUND.—Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking “during and after fiscal year 2020, \$0” and inserting “during and after fiscal year 2021, \$140,000,000”.

SEC. 705. EXCLUDING ABUSE-DETERRENT FORMULATIONS OF PRESCRIPTION DRUGS FROM THE MEDICAID ADDITIONAL REBATE REQUIREMENT FOR NEW FORMULATIONS OF PRESCRIPTION DRUGS.

(a) **IN GENERAL.**—The last sentence of section 1927(c)(2)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is amended by inserting before the period at the end the following: “, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply to drugs that are paid for by a State in calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 706. LIMITING DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

(a) **IN GENERAL.**—Title XI of the Social Security Act is amended by inserting after section 1128J (42 U.S.C. 1320a–7k) the following new section:

“SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

“(a) **REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.**—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

“(b) **LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.**—In implementing such provisions under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

“(1) **NONAPPLICATION OF FOIA.**—The covered algorithms used or developed for purposes of such section 4241 (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

“(2) **LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.**—

“(A) **IN GENERAL.**—A State agency may not use or disclose covered algorithms used or developed for purposes of such section 4241 except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children’s Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a State to assist the State to identify or prevent waste, fraud, and abuse with respect to such programs.

“(B) **INFORMATION SECURITY.**—A State agency shall have in effect data security and control policies that the Secretary finds adequate to ensure the security of covered

algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

“(C) PROCEDURAL REQUIREMENTS.—State agencies to which information is disclosed pursuant to such section 4241 shall adhere to uniform procedures established by the Secretary.

“(c) COVERED ALGORITHM DEFINED.—In this section, the term ‘covered algorithm’—

“(1) means a predictive modeling or other analytics technology, as used for purposes of section 4241(a) of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m(a)) to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children’s Health Insurance Program under title XXI; and

“(2) includes the mathematical expressions utilized in the application of such technology and the means by which such technology is developed.”

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(A) in paragraph (80), by striking “and” at the end;

(B) in paragraph (81), by striking the period at the end and inserting “; and”; and

(C) by inserting after paragraph (81) the following new paragraph:

“(82) provide that the State agency responsible for administering the State plan under this title provides assurances to the Secretary that the State agency is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).”

(2) STATE CHILD HEALTH PLAN REQUIREMENT.—Section 2102(a)(7) of the Social Security Act (42 U.S.C. 1397bb(a)(7)) is amended—

(A) in subparagraph (A), by striking “, and” at the end and inserting a semicolon;

(B) in subparagraph (B), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(C) to ensure that the State agency involved is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).”

SEC. 707. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended to read as follows:

“(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for fiscal year 2021 and thereafter, \$5,000,000.”

SEC. 708. SENSE OF THE CONGRESS REGARDING TREATMENT OF SUBSTANCE ABUSE EPIDEMICS.

It is the sense of the Congress that decades of experience and research have demonstrated that a fiscally responsible approach to addressing the opioid abuse epidemic and other substance abuse

epidemics requires treating such epidemics as a public health emergency emphasizing prevention, treatment, and recovery.

TITLE VIII—KINGPIN DESIGNATION IMPROVEMENT

SEC. 801. PROTECTION OF CLASSIFIED INFORMATION IN FEDERAL COURT CHALLENGES RELATING TO DESIGNATIONS UNDER THE NARCOTICS KINGPIN DESIGNATION ACT.

Section 804 of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1903) is amended by adding at the end the following:

“(i) **PROTECTION OF CLASSIFIED INFORMATION IN FEDERAL COURT CHALLENGES RELATING TO DESIGNATIONS.**—In any judicial review of a determination made under this section, if the determination was based on classified information (as defined in section 1(a) of the Classified Information Procedures Act) such information may be submitted to the reviewing court *ex parte* and *in camera*. This subsection does not confer or imply any right to judicial review.”.

TITLE IX—DEPARTMENT OF VETERANS AFFAIRS

SEC. 901. SHORT TITLE.

This title may be cited as the “Jason Simcakoski Memorial and Promise Act”.

SEC. 902. DEFINITIONS.

In this title:

(1) The term “controlled substance” has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term “State” means each of the several States, territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) The term “complementary and integrative health” has the meaning given that term, or any successor term, by the National Institutes of Health.

(4) The term “opioid receptor antagonist” means a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose.

Subtitle A—Opioid Therapy and Pain Management

SEC. 911. IMPROVEMENT OF OPIOID SAFETY MEASURES BY DEPARTMENT OF VETERANS AFFAIRS.

(a) **EXPANSION OF OPIOID SAFETY INITIATIVE.**—

(1) **INCLUSION OF ALL MEDICAL FACILITIES.**—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall expand the Opioid Safety

Initiative of the Department of Veterans Affairs to include all medical facilities of the Department.

(2) **GUIDANCE.**—The Secretary shall establish guidance that each health care provider of the Department of Veterans Affairs, before initiating opioid therapy to treat a patient as part of the comprehensive assessment conducted by the health care provider, use the Opioid Therapy Risk Report tool of the Department of Veterans Affairs (or any subsequent tool), which shall include information from the prescription drug monitoring program of each participating State as applicable, that includes the most recent information to date relating to the patient that accessed such program to assess the risk for adverse outcomes of opioid therapy for the patient, including the concurrent use of controlled substances such as benzodiazepines, as part of the comprehensive assessment conducted by the health care provider.

(3) **ENHANCED STANDARDS.**—The Secretary shall establish enhanced standards with respect to the use of routine and random urine drug tests for all patients before and during opioid therapy to help prevent substance abuse, dependence, and diversion, including—

(A) that such tests occur not less frequently than once each year or as otherwise determined according to treatment protocols; and

(B) that health care providers appropriately order, interpret and respond to the results from such tests to tailor pain therapy, safeguards, and risk management strategies to each patient.

(b) **PAIN MANAGEMENT EDUCATION AND TRAINING.**—

(1) **IN GENERAL.**—In carrying out the Opioid Safety Initiative of the Department, the Secretary shall require all employees of the Department responsible for prescribing opioids to receive education and training described in paragraph (2).

(2) **EDUCATION AND TRAINING.**—Education and training described in this paragraph is education and training on pain management and safe opioid prescribing practices for purposes of safely and effectively managing patients with chronic pain, including education and training on the following:

(A) The implementation of and full compliance with the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, including any update to such guideline.

(B) The use of evidence-based pain management therapies and complementary and integrative health services, including cognitive-behavioral therapy, non-opioid alternatives, and non-drug methods and procedures to managing pain and related health conditions including, to the extent practicable, medical devices approved or cleared by the Food and Drug Administration for the treatment of patients with chronic pain and related health conditions.

(C) Screening and identification of patients with substance use disorder, including drug-seeking behavior, before prescribing opioids, assessment of risk potential for patients developing an addiction, and referral of patients to appropriate addiction treatment professionals if addiction is identified or strongly suspected.

(D) Communication with patients on the potential harm associated with the use of opioids and other controlled substances, including the need to safely store and dispose of supplies relating to the use of opioids and other controlled substances.

(E) Such other education and training as the Secretary considers appropriate to ensure that veterans receive safe and high-quality pain management care from the Department.

(3) USE OF EXISTING PROGRAM.—In providing education and training described in paragraph (2), the Secretary shall use the Interdisciplinary Chronic Pain Management Training Team Program of the Department (or successor program).

(c) PAIN MANAGEMENT TEAMS.—

(1) IN GENERAL.—In carrying out the Opioid Safety Initiative of the Department, the director of each medical facility of the Department shall identify and designate a pain management team of health care professionals, which may include board certified pain medicine specialists, responsible for coordinating and overseeing pain management therapy at such facility for patients experiencing acute and chronic pain that is non-cancer related.

(2) ESTABLISHMENT OF PROTOCOLS.—

(A) IN GENERAL.—In consultation with the Directors of each Veterans Integrated Service Network, the Secretary shall establish standard protocols for the designation of pain management teams at each medical facility within the Department.

(B) CONSULTATION ON PRESCRIPTION OF OPIOIDS.—Each protocol established under subparagraph (A) shall ensure that any health care provider without expertise in prescribing analgesics or who has not completed the education and training under subsection (b), including a mental health care provider, does not prescribe opioids to a patient unless that health care provider—

(i) consults with a health care provider with pain management expertise or who is on the pain management team of the medical facility; and

(ii) refers the patient to the pain management team for any subsequent prescriptions and related therapy.

(3) REPORT.—

(A) IN GENERAL.—Not later than one year after the date of enactment of this Act, the director of each medical facility of the Department shall submit to the Under Secretary for Health and the director of the Veterans Integrated Service Network in which the medical facility is located a report identifying the health care professionals that have been designated as members of the pain management team at the medical facility pursuant to paragraph (1).

(B) ELEMENTS.—Each report submitted under subparagraph (A) with respect to a medical facility of the Department shall include—

(i) a certification as to whether all members of the pain management team at the medical facility have

completed the education and training required under subsection (b);

(ii) a plan for the management and referral of patients to such pain management team if health care providers without expertise in prescribing analgesics prescribe opioid medications to treat acute and chronic pain that is non-cancer related; and

(iii) a certification as to whether the medical facility—

(I) fully complies with the stepped-care model, or successor models, of pain management and other pain management policies of the Department; or

(II) does not fully comply with such stepped-care model, or successor models, of pain management and other pain management policies but is carrying out a corrective plan of action to ensure such full compliance.

(d) TRACKING AND MONITORING OF OPIOID USE.—

(1) PRESCRIPTION DRUG MONITORING PROGRAMS OF STATES.—In carrying out the Opioid Safety Initiative and the Opioid Therapy Risk Report tool of the Department, the Secretary shall—

(A) ensure access by health care providers of the Department to information on controlled substances, including opioids and benzodiazepines, prescribed to veterans who receive care outside the Department through the prescription drug monitoring program of each State with such a program, including by seeking to enter into memoranda of understanding with States to allow shared access of such information between States and the Department;

(B) include such information in the Opioid Therapy Risk Report tool; and

(C) require health care providers of the Department to submit to the prescription drug monitoring program of each State with such a program information on prescriptions of controlled substances received by veterans in that State under the laws administered by the Secretary.

(2) REPORT ON TRACKING OF DATA ON OPIOID USE.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the feasibility and advisability of improving the Opioid Therapy Risk Report tool of the Department to allow for more advanced real-time tracking of and access to data on—

(A) the key clinical indicators with respect to the totality of opioid use by veterans;

(B) concurrent prescribing by health care providers of the Department of opioids in different health care settings, including data on concurrent prescribing of opioids to treat mental health disorders other than opioid use disorder; and

(C) mail-order prescriptions of opioids prescribed to veterans under the laws administered by the Secretary.

(e) AVAILABILITY OF OPIOID RECEPTOR ANTAGONISTS.—

(1) INCREASED AVAILABILITY AND USE.—

(A) IN GENERAL.—The Secretary shall maximize the availability of opioid receptor antagonists, including naloxone, to veterans.

(B) AVAILABILITY, TRAINING, AND DISTRIBUTING.—In carrying out subparagraph (A), not later than 90 days after the date of the enactment of this Act, the Secretary shall—

(i) equip each pharmacy of the Department with opioid receptor antagonists to be dispensed to outpatients as needed; and

(ii) expand the Overdose Education and Naloxone Distribution program of the Department to ensure that all veterans in receipt of health care under laws administered by the Secretary who are at risk of opioid overdose may access such opioid receptor antagonists and training on the proper administration of such opioid receptor antagonists.

(C) VETERANS WHO ARE AT RISK.—For purposes of subparagraph (B), veterans who are at risk of opioid overdose include—

(i) veterans receiving long-term opioid therapy;

(ii) veterans receiving opioid therapy who have a history of substance use disorder or prior instances of overdose; and

(iii) veterans who are at risk as determined by a health care provider who is treating the veteran.

(2) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on carrying out paragraph (1), including an assessment of any remaining steps to be carried out by the Secretary to carry out such paragraph.

(f) INCLUSION OF CERTAIN INFORMATION AND CAPABILITIES IN OPIOID THERAPY RISK REPORT TOOL OF THE DEPARTMENT.—

(1) INFORMATION.—The Secretary shall include in the Opioid Therapy Risk Report tool of the Department—

(A) information on the most recent time the tool was accessed by a health care provider of the Department with respect to each veteran; and

(B) information on the results of the most recent urine drug test for each veteran.

(2) CAPABILITIES.—The Secretary shall include in the Opioid Therapy Risk Report tool the ability of the health care providers of the Department to determine whether a health care provider of the Department prescribed opioids to a veteran without checking the information in the tool with respect to the veteran.

(g) NOTIFICATIONS OF RISK IN COMPUTERIZED HEALTH RECORD.—The Secretary shall modify the computerized patient record system of the Department to ensure that any health care provider that accesses the record of a veteran, regardless of the reason the veteran seeks care from the health care provider, will be immediately notified whether the veteran—

(1) is receiving opioid therapy and has a history of substance use disorder or prior instances of overdose;

- (2) has a history of opioid abuse; or
- (3) is at risk of developing an opioid use disorder, as determined by a health care provider who is treating the veteran.

SEC. 912. STRENGTHENING OF JOINT WORKING GROUP ON PAIN MANAGEMENT OF THE DEPARTMENT OF VETERANS AFFAIRS AND THE DEPARTMENT OF DEFENSE.

(a) **IN GENERAL.**—Not later than 90 days after the date of enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the Pain Management Working Group of the Health Executive Committee of the Department of Veterans Affairs—Department of Defense Joint Executive Committee (Pain Management Working Group) established under section 320 of title 38, United States Code, includes a focus on the following:

(1) The opioid prescribing practices of health care providers of each Department.

(2) The ability of each Department to manage acute and chronic pain among individuals receiving health care from the Department, including training health care providers with respect to pain management.

(3) The use by each Department of complementary and integrative health in treating such individuals.

(4) The concurrent use and practice by health care providers of each Department of opioids and prescription drugs to treat mental health disorders, including benzodiazepines.

(5) The use of care transition plans by health care providers of each Department to address case management issues for patients receiving opioid therapy who transition between inpatient and outpatient care.

(6) The coordination in coverage of and consistent access to medications prescribed for patients transitioning from receiving health care from the Department of Defense to receiving health care from the Department of Veterans Affairs.

(7) The ability of each Department to properly screen, identify, refer, and treat patients with substance use disorders who are seeking treatment for acute and chronic pain management conditions.

(b) **COORDINATION AND CONSULTATION.**—The Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the working group described in subsection (a)—

(1) coordinates the activities of the working group with other relevant working groups established under section 320 of title 38, United States Code;

(2) consults with other relevant Federal agencies, including the Centers for Disease Control and Prevention, with respect to the activities of the working group; and

(3) consults with the Department of Veterans Affairs and the Department of Defense with respect to the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, or any successor guideline, and reviews and provides comments before any update to the guideline is released.

(c) **CLINICAL PRACTICE GUIDELINES.**—

(1) **IN GENERAL.**—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall issue an update to the

VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(2) **MATTERS INCLUDED.**—In conducting the update under paragraph (1), the Pain Management Working Group, in coordination with the Clinical Practice Guideline VA/DoD Management of Opioid Therapy for Chronic Pain Working Group, shall work to ensure that the Clinical Practical Guideline includes the following:

(A) Enhanced guidance with respect to—

(i) the co-administration of an opioid and other drugs, including benzodiazepines, that may result in life-limiting drug interactions;

(ii) the treatment of patients with current acute psychiatric instability or substance use disorder or patients at risk of suicide; and

(iii) the use of opioid therapy to treat mental health disorders other than opioid use disorder.

(B) Enhanced guidance with respect to the treatment of patients with behaviors or comorbidities, such as post-traumatic stress disorder or other psychiatric disorders, or a history of substance abuse or addiction, that requires a consultation or co-management of opioid therapy with one or more specialists in pain management, mental health, or addictions.

(C) Enhanced guidance with respect to health care providers—

(i) conducting an effective assessment for patients beginning or continuing opioid therapy, including understanding and setting realistic goals with respect to achieving and maintaining an expected level of pain relief, improved function, or a clinically appropriate combination of both; and

(ii) effectively assessing whether opioid therapy is achieving or maintaining the established treatment goals of the patient or whether the patient and health care provider should discuss adjusting, augmenting, or discontinuing the opioid therapy.

(D) Guidelines to inform the methodologies used by health care providers of the Department of Veterans Affairs and the Department of Defense to safely taper opioid therapy when adjusting or discontinuing the use of opioid therapy, including—

(i) prescription of the lowest effective dose based on patient need;

(ii) use of opioids only for a limited time; and

(iii) augmentation of opioid therapy with other pain management therapies and modalities.

(E) Guidelines with respect to appropriate case management for patients receiving opioid therapy who transition between inpatient and outpatient health care settings, which may include the use of care transition plans.

(F) Guidelines with respect to appropriate case management for patients receiving opioid therapy who transition from receiving care during active duty to post-military health care networks.

(G) Guidelines with respect to providing options, before initiating opioid therapy, for pain management therapies

without the use of opioids and options to augment opioid therapy with other clinical and complementary and integrative health services to minimize opioid dependence.

(H) Guidelines with respect to the provision of evidence-based non-opioid treatments within the Department of Veterans Affairs and the Department of Defense, including medical devices and other therapies approved or cleared by the Food and Drug Administration for the treatment of chronic pain as an alternative to or to augment opioid therapy.

(I) Guidelines developed by the Centers for Disease Control and Prevention for safely prescribing opioids for the treatment of chronic, non-cancer related pain in outpatient settings.

(3) **RULE OF CONSTRUCTION.**—Nothing in this subsection shall be construed to prevent the Secretary of Veterans Affairs and the Secretary of Defense from considering all relevant evidence, as appropriate, in updating the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, as required under paragraph (1), or from ensuring that the final clinical practice guideline updated under such paragraph remains applicable to the patient populations of the Department of Veterans Affairs and the Department of Defense.

SEC. 913. REVIEW, INVESTIGATION, AND REPORT ON USE OF OPIOIDS IN TREATMENT BY DEPARTMENT OF VETERANS AFFAIRS.

(a) COMPTROLLER GENERAL REPORT.—

(1) **IN GENERAL.**—Not later than two years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the Opioid Safety Initiative of the Department of Veterans Affairs and the opioid prescribing practices of health care providers of the Department.

(2) **ELEMENTS.**—The report submitted under paragraph (1) shall include the following:

(A) An assessment of the implementation and monitoring by the Veterans Health Administration of the Opioid Safety Initiative of the Department, including examining, as appropriate, the following:

(i) How the Department monitors the key clinical outcomes of such safety initiative (for example, the percentage of unique veterans visiting each medical center of the Department that are prescribed an opioid or an opioid and benzodiazepine concurrently) and how the Department uses that information—

(I) to improve prescribing practices; and

(II) to identify high prescribing or otherwise inappropriate prescribing practices by health care providers.

(ii) How the Department monitors the use of the Opioid Therapy Risk Report tool of the Department (as developed through such safety initiative) and compliance with such tool by medical facilities and health care providers of the Department, including

any findings by the Department of prescription rates or prescription practices by medical facilities or health care providers that are inappropriate.

(iii) The implementation of academic detailing programs within the Veterans Integrated Service Networks of the Department and how such programs are being used to improve opioid prescribing practices.

(iv) Recommendations on such improvements to the Opioid Safety Initiative of the Department as the Comptroller General considers appropriate.

(B) Information made available under the Opioid Therapy Risk Report tool with respect to—

(i) deaths resulting from sentinel events involving veterans prescribed opioids by a health care provider;

(ii) overall prescription rates and, if applicable, indications used by health care providers for prescribing chronic opioid therapy to treat non-cancer, non-palliative, and non-hospice care patients;

(iii) the prescription rates and indications used by health care providers for prescribing benzodiazepines and opioids concomitantly;

(iv) the practice by health care providers of prescribing opioids to treat patients without any pain, including to treat patients with mental health disorders other than opioid use disorder; and

(v) the effectiveness of opioid therapy for patients receiving such therapy, including the effectiveness of long-term opioid therapy.

(C) An evaluation of processes of the Department in place to oversee opioid use among veterans, including procedures to identify and remedy potential over-prescribing of opioids by health care providers of the Department.

(D) An assessment of the implementation by the Secretary of Veterans Affairs of the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, including any figures or approaches used by the Department to assess compliance with such guidelines by medical centers of the Department and identify any medical centers of the Department operating action plans to improve compliance with such guidelines.

(E) An assessment of the data that the Department has developed to review the opioid prescribing practices of health care providers of the Department, as required by this subtitle, including a review of how the Department identifies the practices of individual health care providers that warrant further review based on prescribing levels, health conditions for which the health care provider is prescribing opioids or opioids and benzodiazepines concurrently, or other practices of the health care provider.

(b) SEMI-ANNUAL PROGRESS REPORT ON IMPLEMENTATION OF COMPTROLLER GENERAL RECOMMENDATIONS.—Not later than 180 days after the date of the submittal of the report required under subsection (a), and not less frequently than annually thereafter until the Comptroller General of the United States determines that all recommended actions are closed, the Secretary of Veterans Affairs shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of

Representatives a progress report detailing the actions by the Secretary to address any outstanding findings and recommendations by the Comptroller General of the United States under subsection (a) with respect to the Veterans Health Administration.

(c) ANNUAL REPORT ON OPIOID THERAPY AND PRESCRIPTION RATES.—Not later than one year after the date of the enactment of this Act, and not less frequently than annually for the following five years, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on opioid therapy and prescription rates for the one-year period preceding the date of the submission of the report. Each such report shall include each of the following:

(1) The number of patients and the percentage of the patient population of the Department who were prescribed benzodiazepines and opioids concurrently by a health care provider of the Department.

(2) The number of patients and the percentage of the patient population of the Department without any pain who were prescribed opioids by a health care provider of the Department, including those who were prescribed benzodiazepines and opioids concurrently.

(3) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were treated with opioids by a health care provider of the Department on an inpatient-basis and who also received prescription opioids by mail from the Department while being treated on an inpatient-basis.

(4) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were prescribed opioids concurrently by a health care provider of the Department and a health care provider that is not a health care provider of the Department.

(5) With respect to each medical facility of the Department, the collected and reviewed information on opioids prescribed by health care providers at the facility to treat non-cancer, non-palliative, and non-hospice care patients, including—

(A) the prescription rate at which each health care provider at the facility prescribed benzodiazepines and opioids concurrently to such patients and the aggregate of such prescription rate for all health care providers at the facility;

(B) the prescription rate at which each health care provider at the facility prescribed benzodiazepines or opioids to such patients to treat conditions for which benzodiazepines or opioids are not approved treatment and the aggregate of such prescription rate for all health care providers at the facility;

(C) the prescription rate at which each health care provider at the facility prescribed or dispensed mail-order prescriptions of opioids to such patients while such patients were being treated with opioids on an inpatient-basis and the aggregate of such prescription rate for all health care providers at the facility; and

(D) the prescription rate at which each health care provider at the facility prescribed opioids to such patients who were also concurrently prescribed opioids by a health

care provider that is not a health care provider of the Department and the aggregate of such prescription rates for all health care providers at the facility.

(6) With respect to each medical facility of the Department, the number of times a pharmacist at the facility overrode a critical drug interaction warning with respect to an interaction between opioids and another medication before dispensing such medication to a veteran.

(d) INVESTIGATION OF PRESCRIPTION RATES.—If the Secretary determines that a prescription rate with respect to a health care provider or medical facility of the Department conflicts with or is otherwise inconsistent with the standards of appropriate and safe care, the Secretary shall—

(1) immediately notify the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives of such determination, including information relating to such determination, prescription rate, and health care provider or medical facility, as the case may be; and

(2) through the Office of the Medical Inspector of the Veterans Health Administration, conduct a full investigation of the health care provider or medical facility, as the case may be.

(e) PRESCRIPTION RATE DEFINED.—In this section, the term “prescription rate” means, with respect to a health care provider or medical facility of the Department, each of the following:

(1) The number of patients treated with opioids by the health care provider or at the medical facility, as the case may be, divided by the total number of pharmacy users of that health care provider or medical facility.

(2) The average number of morphine equivalents per day prescribed by the health care provider or at the medical facility, as the case may be, to patients being treated with opioids.

(3) Of the patients being treated with opioids by the health care provider or at the medical facility, as the case may be, the average number of prescriptions of opioids per patient.

SEC. 914. MANDATORY DISCLOSURE OF CERTAIN VETERAN INFORMATION TO STATE CONTROLLED SUBSTANCE MONITORING PROGRAMS.

Section 5701(l) of title 38, United States Code, is amended by striking “may” and inserting “shall”.

SEC. 915. ELIMINATION OF COPAYMENT REQUIREMENT FOR VETERANS RECEIVING OPIOID ANTAGONISTS OR EDUCATION ON USE OF OPIOID ANTAGONISTS.

(a) COPAYMENT FOR OPIOID ANTAGONISTS.—Section 1722A(a) of title 38, United States Code, is amended by adding at the end the following new paragraph:

“(4) Paragraph (1) does not apply to opioid antagonists furnished under this chapter to a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose.”

(b) COPAYMENT FOR EDUCATION ON USE OF OPIOID ANTAGONISTS.—Section 1710(g)(3) of such title is amended—

(1) by striking “with respect to home health services” and inserting “with respect to the following:”

“(A) Home health services”; and

(2) by adding at the end the following subparagraph:
“(B) Education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances.”.

Subtitle B—Patient Advocacy

SEC. 921. COMMUNITY MEETINGS ON IMPROVING CARE FURNISHED BY DEPARTMENT OF VETERANS AFFAIRS.

(a) **COMMUNITY MEETINGS.**—

(1) **MEDICAL CENTERS.**—Not later than 90 days after the date of the enactment of this Act, and not less frequently than once every 90 days thereafter, the Secretary shall ensure that each medical facility of the Department of Veterans Affairs hosts a community meeting open to the public on improving health care furnished by the Secretary.

(2) **COMMUNITY-BASED OUTPATIENT CLINICS.**—Not later than one year after the date of the enactment of this Act, and not less frequently than annually thereafter, the Secretary shall ensure that each community-based outpatient clinic of the Department hosts a community meeting open to the public on improving health care furnished by the Secretary.

(b) **ATTENDANCE BY DIRECTOR OF VETERANS INTEGRATED SERVICE NETWORK OR DESIGNEE.**—

(1) **IN GENERAL.**—Each community meeting hosted by a medical facility or community-based outpatient clinic under subsection (a) shall be attended by the Director of the Veterans Integrated Service Network in which the medical facility or community-based outpatient clinic, as the case may be, is located. Subject to paragraph (2), the Director may delegate such attendance only to an employee who works in the Office of the Director.

(2) **ATTENDANCE BY DIRECTOR.**—Each Director of a Veterans Integrated Service Network shall personally attend not less than one community meeting under subsection (a) hosted by each medical facility located in the Veterans Integrated Service Network each year.

(c) **NOTICE.**—The Secretary shall notify the Committee on Veterans' Affairs of the Senate, the Committee on Veterans' Affairs of the House of Representatives, and each Member of Congress (as defined in section 902) who represents the area in which the medical facility is located of a community meeting under subsection (a) by not later than 10 days before such community meeting occurs.

SEC. 922. IMPROVEMENT OF AWARENESS OF PATIENT ADVOCACY PROGRAM AND PATIENT BILL OF RIGHTS OF DEPARTMENT OF VETERANS AFFAIRS.

Not later than 90 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall, in as many prominent locations as the Secretary determines appropriate to be seen by the largest percentage of patients and family members of patients at each medical facility of the Department of Veterans Affairs—

(1) display the purposes of the Patient Advocacy Program of the Department and the contact information for the patient advocate at such medical facility; and

(2) display the rights and responsibilities of—

- (A) patients and family members of patients at such medical facility; and
- (B) with respect to community living centers and other residential facilities of the Department, residents and family members of residents at such medical facility.

SEC. 923. COMPTROLLER GENERAL REPORT ON PATIENT ADVOCACY PROGRAM OF DEPARTMENT OF VETERANS AFFAIRS.

(a) **IN GENERAL.**—Not later than two years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the Patient Advocacy Program of the Department of Veterans Affairs (in this section referred to as the "Program").

(b) **ELEMENTS.**—The report required by subsection (a) shall include the following:

- (1) A description of the Program, including—
 - (A) the purpose of the Program;
 - (B) the activities carried out under the Program; and
 - (C) the sufficiency of the Program in achieving the purpose of the Program.
- (2) An assessment of the sufficiency of staffing of employees of the Department responsible for carrying out the Program.
- (3) An assessment of the sufficiency of the training of such employees.
- (4) An assessment of—
 - (A) the awareness of the Program among veterans and family members of veterans; and
 - (B) the use of the Program by veterans and family members of veterans.
- (5) Such recommendations and proposals for improving or modifying the Program as the Comptroller General considers appropriate.
- (6) Such other information with respect to the Program as the Comptroller General considers appropriate.

SEC. 924. ESTABLISHMENT OF OFFICE OF PATIENT ADVOCACY OF THE DEPARTMENT OF VETERANS AFFAIRS.

(a) **IN GENERAL.**—Subchapter I of chapter 73 of title 38, United States Code, is amended by adding at the end the following new section:

“§ 7309A. Office of Patient Advocacy

“(a) **ESTABLISHMENT.**—There is established in the Department within the Office of the Under Secretary for Health an office to be known as the ‘Office of Patient Advocacy’ (in this section referred to as the ‘Office’).

“(b) **HEAD.**—(1) The Director of the Office of Patient Advocacy shall be the head of the Office.

“(2) The Director of the Office of Patient Advocacy shall be appointed by the Under Secretary for Health from among individuals qualified to perform the duties of the position and shall report directly to the Under Secretary for Health.

“(c) **FUNCTION.**—(1) The function of the Office is to carry out the Patient Advocacy Program of the Department.

“(2) In carrying out the Patient Advocacy Program of the Department, the Director shall ensure that patient advocates of the Department—

“(A) advocate on behalf of veterans with respect to health care received and sought by veterans under the laws administered by the Secretary;

“(B) carry out the responsibilities specified in subsection (d); and

“(C) receive training in patient advocacy.

“(d) PATIENT ADVOCACY RESPONSIBILITIES.—The responsibilities of each patient advocate at a medical facility of the Department are the following:

“(1) To resolve complaints by veterans with respect to health care furnished under the laws administered by the Secretary that cannot be resolved at the point of service or at a higher level easily accessible to the veteran.

“(2) To present at various meetings and to various committees the issues experienced by veterans in receiving such health care at such medical facility.

“(3) To express to veterans their rights and responsibilities as patients in receiving such health care.

“(4) To manage the Patient Advocate Tracking System of the Department at such medical facility.

“(5) To compile data at such medical facility of complaints made by veterans with respect to the receipt of such health care at such medical facility and the satisfaction of veterans with such health care at such medical facility to determine whether there are trends in such data.

“(6) To ensure that a process is in place for the distribution of the data compiled under paragraph (5) to appropriate leaders, committees, services, and staff of the Department.

“(7) To identify, not less frequently than quarterly, opportunities for improvements in the furnishing of such health care to veterans at such medical facility based on complaints by veterans.

“(8) To ensure that any significant complaint by a veteran with respect to such health care is brought to the attention of appropriate staff of the Department to trigger an assessment of whether there needs to be a further analysis of the problem at the facility-wide level.

“(9) To support any patient advocacy programs carried out by the Department.

“(10) To ensure that all appeals and final decisions with respect to the receipt of such health care are entered into the Patient Advocate Tracking System of the Department.

“(11) To understand all laws, directives, and other rules with respect to the rights and responsibilities of veterans in receiving such health care, including the appeals processes available to veterans.

“(12) To ensure that veterans receiving mental health care, or the surrogate decision-makers for such veterans, are aware of the rights of veterans to seek representation from systems established under section 103 of the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C. 10803) to protect and advocate the rights of individuals with mental illness and to investigate incidents of abuse and neglect of such individuals.

“(13) To fulfill requirements established by the Secretary with respect to the inspection of controlled substances.

“(14) To document potentially threatening behavior and report such behavior to appropriate authorities.

“(e) TRAINING.—In providing training to patient advocates under subsection (c)(2)(C), the Director shall ensure that such training is consistent throughout the Department.

“(f) CONTROLLED SUBSTANCE DEFINED.—In this section, the term ‘controlled substance’ has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).”.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 73 of such title is amended by inserting after the item relating to section 7309 the following new item:

“7309A. Office of Patient Advocacy.”.

(c) DATE FULLY OPERATIONAL.—The Secretary of Veterans Affairs shall ensure that the Office of Patient Advocacy established under section 7309A of title 38, United States Code, as added by subsection (a), is fully operational not later than the date that is one year after the date of the enactment of this Act.

Subtitle C—Complementary and Integrative Health

SEC. 931. EXPANSION OF RESEARCH AND EDUCATION ON AND DELIVERY OF COMPLEMENTARY AND INTEGRATIVE HEALTH TO VETERANS.

(a) ESTABLISHMENT.—There is established a commission to be known as the “Creating Options for Veterans’ Expedited Recovery” or the “COVER Commission” (in this section referred to as the “Commission”). The Commission shall examine the evidence-based therapy treatment model used by the Secretary of Veterans Affairs for treating mental health conditions of veterans and the potential benefits of incorporating complementary and integrative health treatments available in non-Department facilities (as defined in section 1701 of title 38, United States Code).

(b) DUTIES.—The Commission shall perform the following duties:

(1) Examine the efficacy of the evidence-based therapy model used by the Secretary for treating mental health illnesses of veterans and identify areas to improve wellness-based outcomes.

(2) Conduct a patient-centered survey within each of the Veterans Integrated Service Networks to examine—

(A) the experience of veterans with the Department of Veterans Affairs when seeking medical assistance for mental health issues through the health care system of the Department;

(B) the experience of veterans with non-Department facilities and health professionals for treating mental health issues;

(C) the preference of veterans regarding available treatment for mental health issues and which methods the veterans believe to be most effective;

(D) the experience, if any, of veterans with respect to the complementary and integrative health treatment therapies described in paragraph (3);

(E) the prevalence of prescribing prescription medication among veterans seeking treatment through the health care system of the Department as remedies for addressing mental health issues; and

(F) the outreach efforts of the Secretary regarding the availability of benefits and treatments for veterans for addressing mental health issues, including by identifying ways to reduce barriers to gaps in such benefits and treatments.

(3) Examine available research on complementary and integrative health treatment therapies for mental health issues and identify what benefits could be made with the inclusion of such treatments for veterans, including with respect to—

(A) music therapy;

(B) equine therapy;

(C) training and caring for service dogs;

(D) yoga therapy;

(E) acupuncture therapy;

(F) meditation therapy;

(G) outdoor sports therapy;

(H) hyperbaric oxygen therapy;

(I) accelerated resolution therapy;

(J) art therapy;

(K) magnetic resonance therapy; and

(L) other therapies the Commission determines appropriate.

(4) Study the sufficiency of the resources of the Department to ensure the delivery of quality health care for mental health issues among veterans seeking treatment within the Department.

(5) Study the current treatments and resources available within the Department and assess—

(A) the effectiveness of such treatments and resources in decreasing the number of suicides per day by veterans;

(B) the number of veterans who have been diagnosed with mental health issues;

(C) the percentage of veterans using the resources of the Department who have been diagnosed with mental health issues;

(D) the percentage of veterans who have completed counseling sessions offered by the Department; and

(E) the efforts of the Department to expand complementary and integrative health treatments viable to the recovery of veterans with mental health issues as determined by the Secretary to improve the effectiveness of treatments offered by the Department.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Commission shall be composed of 10 members, appointed as follows:

(A) Two members appointed by the Speaker of the House of Representatives, at least one of whom shall be a veteran.

(B) Two members appointed by the minority leader of the House of Representatives, at least one of whom shall be a veteran.

(C) Two members appointed by the majority leader of the Senate, at least one of whom shall be a veteran.

(D) Two members appointed by the minority leader of the Senate, at least one of whom shall be a veteran.

(E) Two members appointed by the President, at least one of whom shall be a veteran.

(2) **QUALIFICATIONS.**—Members of the Commission shall be individuals who—

(A) are of recognized standing and distinction within the medical community with a background in treating mental health;

(B) have experience working with the military and veteran population; and

(C) do not have a financial interest in any of the complementary and integrative health treatments reviewed by the Commission.

(3) **CHAIRMAN.**—The President shall designate a member of the Commission to be the Chairman.

(4) **PERIOD OF APPOINTMENT.**—Members of the Commission shall be appointed for the life of the Commission.

(5) **VACANCY.**—A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(6) **APPOINTMENT DEADLINE.**—The appointment of members of the Commission in this section shall be made not later than 90 days after the date of the enactment of this Act.

(d) **POWERS OF COMMISSION.**—

(1) **MEETINGS.**—

(A) **INITIAL MEETING.**—The Commission shall hold its first meeting not later than 30 days after a majority of members are appointed to the Commission.

(B) **MEETING.**—The Commission shall regularly meet at the call of the Chairman. Such meetings may be carried out through the use of telephonic or other appropriate telecommunication technology if the Commission determines that such technology will allow the members to communicate simultaneously.

(2) **HEARINGS.**—The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive evidence as the Commission considers advisable to carry out the responsibilities of the Commission.

(3) **INFORMATION FROM FEDERAL AGENCIES.**—The Commission may secure directly from any department or agency of the Federal Government such information as the Commission considers necessary to carry out the duties of the Commission.

(4) **INFORMATION FROM NONGOVERNMENTAL ORGANIZATIONS.**—In carrying out its duties, the Commission may seek guidance through consultation with foundations, veteran service organizations, nonprofit groups, faith-based organizations, private and public institutions of higher education, and other organizations as the Commission determines appropriate.

(5) **COMMISSION RECORDS.**—The Commission shall keep an accurate and complete record of the actions and meetings of the Commission. Such record shall be made available for public

inspection and the Comptroller General of the United States may audit and examine such record.

(6) PERSONNEL RECORDS.—The Commission shall keep an accurate and complete record of the actions and meetings of the Commission. Such record shall be made available for public inspection and the Comptroller General of the United States may audit and examine such records.

(7) COMPENSATION OF MEMBERS; TRAVEL EXPENSES.—Each member shall serve without pay but shall receive travel expenses to perform the duties of the Commission, including per diem in lieu of substances, at rates authorized under subchapter I of chapter 57 of title 5, United States Code.

(8) STAFF.—The Chairman, in accordance with rules agreed upon the Commission, may appoint and fix the compensation of a staff director and such other personnel as may be necessary to enable the Commission to carry out its functions, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, without regard to the provision of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, except that no rate of pay fixed under this paragraph may exceed the equivalent of that payable for a position at level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(9) PERSONNEL AS FEDERAL EMPLOYEES.—

(A) IN GENERAL.—The executive director and any personnel of the Commission are employees under section 2105 of title 5, United States Code, for purpose of chapters 63, 81, 83, 84, 85, 87, 89, and 90 of such title.

(B) MEMBERS OF THE COMMISSION.—Subparagraph (A) shall not be construed to apply to members of the Commission.

(10) CONTRACTING.—The Commission may, to such extent and in such amounts as are provided in appropriations Acts, enter into contracts to enable the Commission to discharge the duties of the Commission under this Act.

(11) EXPERT AND CONSULTANT SERVICE.—The Commission may procure the services of experts and consultants in accordance with section 3109 of title 5, United States Code, at rates not to exceed the daily rate paid to a person occupying a position at level IV of the Executive Schedule under section 5315 of title 5, United States Code.

(12) POSTAL SERVICE.—The Commission may use the United States mails in the same manner and under the same conditions as departments and agencies of the United States.

(13) PHYSICAL FACILITIES AND EQUIPMENT.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this Act. These administrative services may include human resource management, budget, leasing accounting, and payroll services.

(e) REPORT.—

(1) INTERIM REPORTS.—

(A) IN GENERAL.—Not later than 60 days after the date on which the Commission first meets, and each 30-day period thereafter ending on the date on which the

Commission submits the final report under paragraph (2), the Commission shall submit to the Committees on Veterans' Affairs of the House of Representatives and the Senate and the President a report detailing the level of cooperation the Secretary of Veterans Affairs (and the heads of other departments or agencies of the Federal Government) has provided to the Commission.

(B) OTHER REPORTS.—In carrying out its duties, at times that the Commission determines appropriate, the Commission shall submit to the Committees on Veterans' Affairs of the House of Representatives and the Senate and any other appropriate entities an interim report with respect to the findings identified by the Commission.

(2) FINAL REPORT.—Not later than 18 months after the first meeting of the Commission, the Commission shall submit to the Committee on Veterans' Affairs of the House of Representatives and the Senate, the President, and the Secretary of Veterans Affairs a final report on the findings of the Commission. Such report shall include the following:

(A) Recommendations to implement in a feasible, timely, and cost-efficient manner the solutions and remedies identified within the findings of the Commission pursuant to subsection (b).

(B) An analysis of the evidence-based therapy model used by the Secretary of Veterans Affairs for treating veterans with mental health care issues, and an examination of the prevalence and efficacy of prescription drugs as a means for treatment.

(C) The findings of the patient-centered survey conducted within each of the Veterans Integrated Service Networks pursuant to subsection (b)(2).

(D) An examination of complementary and integrative health treatments described in subsection (b)(3) and the potential benefits of incorporating such treatments in the therapy models used by the Secretary for treating veterans with mental health issues.

(3) PLAN.—Not later than 90 days after the date on which the Commission submits the final report under paragraph (2), the Secretary of Veterans Affairs shall submit to the Committees on Veterans' Affairs of the House of Representatives and the Senate a report on the following:

(A) An action plan for implementing the recommendations established by the Commission on such solutions and remedies for improving wellness-based outcomes for veterans with mental health care issues.

(B) A feasible timeframe on when the complementary and integrative health treatments described in subsection (b)(3) can be implemented Department-wide.

(C) With respect to each recommendation established by the Commission, including any complementary and integrative health treatment, that the Secretary determines is not appropriate or feasible to implement, a justification for such determination and an alternative solution to improve the efficacy of the therapy models used by the Secretary for treating veterans with mental health issues.

(f) **TERMINATION OF COMMISSION.**—The Commission shall terminate 30 days after the Commission submits the final report under subsection (e)(2).

SEC. 932. EXPANSION OF RESEARCH AND EDUCATION ON AND DELIVERY OF COMPLEMENTARY AND INTEGRATIVE HEALTH TO VETERANS.

(a) **DEVELOPMENT OF PLAN TO EXPAND RESEARCH, EDUCATION, AND DELIVERY.**—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall develop a plan to expand materially and substantially the scope of the effectiveness of research and education on, and delivery and integration of, complementary and integrative health services into the health care services provided to veterans.

(b) **ELEMENTS.**—The plan required by subsection (a) shall provide for the following:

(1) Research on the following:

(A) The effectiveness of various complementary and integrative health services, including the effectiveness of such services integrated with clinical services.

(B) Approaches to integrating complementary and integrative health services into other health care services provided by the Department of Veterans Affairs.

(2) Education and training for health care professionals of the Department on the following:

(A) Complementary and integrative health services selected by the Secretary for purposes of the plan.

(B) Appropriate uses of such services.

(C) Integration of such services into the delivery of health care to veterans.

(3) Research, education, and clinical activities on complementary and integrative health at centers of innovation at medical centers of the Department.

(4) Identification or development of metrics and outcome measures to evaluate the effectiveness of the provision and integration of complementary and integrative health services into the delivery of health care to veterans.

(5) Integration and delivery of complementary and integrative health services with other health care services provided by the Department.

(c) **CONSULTATION.**—

(1) **IN GENERAL.**—In carrying out subsection (a), the Secretary shall consult with the following:

(A) The Director of the National Center for Complementary and Integrative Health of the National Institutes of Health.

(B) The Commissioner of Food and Drugs.

(C) Institutions of higher education, private research institutes, and individual researchers with extensive experience in complementary and integrative health and the integration of complementary and integrative health practices into the delivery of health care.

(D) Nationally recognized providers of complementary and integrative health.

(E) Such other officials, entities, and individuals with expertise on complementary and integrative health as the Secretary considers appropriate.

(2) **SCOPE OF CONSULTATION.**—The Secretary shall undertake consultation under paragraph (1) in carrying out subsection (a) with respect to the following:

(A) To develop the plan.

(B) To identify specific complementary and integrative health practices that, on the basis of research findings or promising clinical interventions, are appropriate to include as services to veterans.

(C) To identify barriers to the effective provision and integration of complementary and integrative health services into the delivery of health care to veterans, and to identify mechanisms for overcoming such barriers.

SEC. 933. PILOT PROGRAM ON INTEGRATION OF COMPLEMENTARY AND INTEGRATIVE HEALTH AND RELATED ISSUES FOR VETERANS AND FAMILY MEMBERS OF VETERANS.

(a) **PILOT PROGRAM.**—

(1) **IN GENERAL.**—Not later than 180 days after the date on which the Secretary of Veterans Affairs receives the final report under section 931(e)(2), the Secretary shall commence a pilot program to assess the feasibility and advisability of using complementary and integrative health and wellness-based programs (as defined by the Secretary) to complement the provision of pain management and related health care services, including mental health care services, to veterans.

(2) **MATTERS ADDRESSED.**—In carrying out the pilot program, the Secretary shall assess the following:

(A) Means of improving coordination between Federal, State, local, and community providers of health care in the provision of pain management and related health care services to veterans.

(B) Means of enhancing outreach, and coordination of outreach, by and among providers of health care referred to in subparagraph (A) on the pain management and related health care services available to veterans.

(C) Means of using complementary and integrative health and wellness-based programs of providers of health care referred to in subparagraph (A) as complements to the provision by the Department of Veterans Affairs of pain management and related health care services to veterans.

(D) Whether complementary and integrative health and wellness-based programs described in subparagraph (C)—

(i) are effective in enhancing the quality of life and well-being of veterans;

(ii) are effective in increasing the adherence of veterans to the primary pain management and related health care services provided such veterans by the Department;

(iii) have an effect on the sense of well-being of veterans who receive primary pain management and related health care services from the Department; and

(iv) are effective in encouraging veterans receiving health care from the Department to adopt a more healthy lifestyle.

(b) DURATION.—The Secretary shall carry out the pilot program under subsection (a)(1) for a period of three years.

(c) LOCATIONS.—

(1) FACILITIES.—The Secretary shall carry out the pilot program under subsection (a)(1) at facilities of the Department providing pain management and related health care services, including mental health care services, to veterans. In selecting such facilities to carry out the pilot program, the Secretary shall select not fewer than 15 geographically diverse medical centers of the Department, of which not fewer than two shall be polytrauma rehabilitation centers of the Department.

(2) MEDICAL CENTERS WITH PRESCRIPTION RATES OF OPIOIDS THAT CONFLICT WITH CARE STANDARDS.—In selecting the medical centers under paragraph (1), the Secretary shall give priority to medical centers of the Department at which there is a prescription rate of opioids that conflicts with or is otherwise inconsistent with the standards of appropriate and safe care.

(d) PROVISION OF SERVICES.—Under the pilot program under subsection (a)(1), the Secretary shall provide covered services to covered veterans by integrating complementary and integrative health services with other services provided by the Department at the medical centers selected under subsection (c).

(e) COVERED VETERANS.—For purposes of the pilot program under subsection (a)(1), a covered veteran is any veteran who—

(1) has a mental health condition diagnosed by a clinician of the Department;

(2) experiences chronic pain;

(3) has a chronic condition being treated by a clinician of the Department; or

(4) is not described in paragraph (1), (2), or (3) and requests to participate in the pilot program or is referred by a clinician of the Department who is treating the veteran.

(f) COVERED SERVICES.—

(1) IN GENERAL.—For purposes of the pilot program, covered services are services consisting of complementary and integrative health services as selected by the Secretary.

(2) ADMINISTRATION OF SERVICES.—Covered services shall be administered under the pilot program as follows:

(A) Covered services shall be administered by professionals or other instructors with appropriate training and expertise in complementary and integrative health services who are employees of the Department or with whom the Department enters into an agreement to provide such services.

(B) Covered services shall be included as part of the Patient Aligned Care Teams initiative of the Office of Patient Care Services, Primary Care Program Office, in coordination with the Office of Patient Centered Care and Cultural Transformation.

(C) Covered services shall be made available to—

(i) covered veterans who have received conventional treatments from the Department for the conditions for which the covered veteran seeks complementary and integrative health services under the pilot program; and

(ii) covered veterans who have not received conventional treatments from the Department for such conditions.

(g) **REPORTS.**—

(1) **IN GENERAL.**—Not later than 30 months after the date on which the Secretary commences the pilot program under subsection (a)(1), the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the pilot program.

(2) **ELEMENTS.**—The report under paragraph (1) shall include the following:

(A) The findings and conclusions of the Secretary with respect to the pilot program under subsection (a)(1), including with respect to—

(i) the use and efficacy of the complementary and integrative health services established under the pilot program;

(ii) the outreach conducted by the Secretary to inform veterans and community organizations about the pilot program; and

(iii) an assessment of the benefit of the pilot program to covered veterans in mental health diagnoses, pain management, and treatment of chronic illness.

(B) Identification of any unresolved barriers that impede the ability of the Secretary to incorporate complementary and integrative health services with other health care services provided by the Department.

(C) Such recommendations for the continuation or expansion of the pilot program as the Secretary considers appropriate.

Subtitle D—Fitness of Health Care Providers

SEC. 941. ADDITIONAL REQUIREMENTS FOR HIRING OF HEALTH CARE PROVIDERS BY DEPARTMENT OF VETERANS AFFAIRS.

As part of the hiring process for each health care provider considered for a position at the Department of Veterans Affairs after the date of the enactment of the Act, the Secretary of Veterans Affairs shall require from the medical board of each State in which the health care provider has or had a medical license—

(1) information on any violation of the requirements of the medical license of the health care provider during the 20-year period preceding the consideration of the health care provider by the Department; and

(2) information on whether the health care provider has entered into any settlement agreement for a disciplinary charge relating to the practice of medicine by the health care provider.

SEC. 942. PROVISION OF INFORMATION ON HEALTH CARE PROVIDERS OF DEPARTMENT OF VETERANS AFFAIRS TO STATE MEDICAL BOARDS.

Notwithstanding section 552a of title 5, United States Code, with respect to each health care provider of the Department of Veterans Affairs who has violated a requirement of the medical

license of the health care provider, the Secretary of Veterans Affairs shall provide to the medical board of each State in which the health care provider is licensed detailed information with respect to such violation, regardless of whether such board has formally requested such information.

SEC. 943. REPORT ON COMPLIANCE BY DEPARTMENT OF VETERANS AFFAIRS WITH REVIEWS OF HEALTH CARE PROVIDERS LEAVING THE DEPARTMENT OR TRANSFERRING TO OTHER FACILITIES.

Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the compliance by the Department of Veterans Affairs with the policy of the Department—

(1) to conduct a review of each health care provider of the Department who transfers to another medical facility of the Department, resigns, retires, or is terminated to determine whether there are any concerns, complaints, or allegations of violations relating to the medical practice of the health care provider; and

(2) to take appropriate action with respect to any such concern, complaint, or allegation.

Subtitle E—Other Matters

SEC. 951. MODIFICATION TO LIMITATION ON AWARDS AND BONUSES.

Section 705 of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113–146; 38 U.S.C. 703 note) is amended to read as follows:

“SEC. 705. LIMITATION ON AWARDS AND BONUSES PAID TO EMPLOYEES OF DEPARTMENT OF VETERANS AFFAIRS.

“(a) **LIMITATION.**—The Secretary of Veterans Affairs shall ensure that the aggregate amount of awards and bonuses paid by the Secretary in a fiscal year under chapter 45 or 53 of title 5, United States Code, or any other awards or bonuses authorized under such title or title 38, United States Code, does not exceed the following amounts:

“(1) With respect to each of fiscal years 2017 through 2018, \$230,000,000.

“(2) With respect to each of fiscal years 2019 through 2021, \$225,000,000.

“(3) With respect to each of fiscal years 2022 through 2024, \$360,000,000.

“(b) **SENSE OF CONGRESS.**—It is the sense of Congress that the limitation under subsection (a) should not disproportionately impact lower-wage employees and that the Department of Veterans

S. 524—85

Affairs is encouraged to use bonuses to incentivize high-performing employees in areas in which retention is challenging.”.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*

**Lali's Law of the
Comprehensive
Addiction and
Recovery Act**

**CARA) 2016
Press Release**

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JUL 22 2016

Dold's Bipartisan Bill to Prevent Drug Overdoses Signed Into Law

*Comprehensive Addiction and Recovery Act Includes Dold's Lali's Law
Lali's Law Named in Memory of Alex Laliberte from Buffalo Grove*

WASHINGTON, D.C. - U.S. Congressman Robert Dold (IL-10) today celebrated the signing of the Comprehensive Addiction and Recovery Act, which included Rep. Dold's bipartisan bill Lali's Law. Earlier this month, the House passed the Comprehensive Addiction and Recovery Act 407 to 5 and the Senate passed the bill 92 to 2.

"Working with the Laliberte family from Buffalo Grove, we wrote and passed Lali's Law to help save lives and spare families from the pain of losing a child," Rep. Dold said. "Getting this bill signed into law with overwhelming bipartisan support is a perfect example of what we can achieve when we set aside partisan differences to help families. Together, we've ensured that Alex's lasting legacy includes helping others get a second chance at recovery and saving their families from heartbreak."

On May 12, 2016, Rep. Dold's bipartisan legislation Lali's Law passed the United States House of Representatives, 415 to 4. Because of his leadership on the issue, Rep. Dold was then named to a conference committee to reach a compromise between the senate version of the Comprehensive Addiction and Recovery Act of 2016 and the House version. Rep. Dold secured Lali's Law's inclusion in the final package that was signed into law today.

"The Comprehensive Addiction and Recovery Act is a game changer for the millions of Americans struggling with substance use. I am elated that Lali's Law is a part of this incredibly thoughtful and intelligent bill," **Alex Laliberte's sister Chelsea Laliberte said.** "With the President's signature, change around behavioral health will begin, stigma will reduce, and those impacted can slowly heal from the destruction caused by this epidemic. By making substance use a top priority, Americans will be able to access affordable, evidence-based, individualized care, and states will no longer be dependent on their budgets alone to provide basic public health education and supplies such as naloxone."

Between 2001 and 2014, there was a three-fold increase in prescription drug overdoses and a six-fold increase in heroin overdoses in the United States. Heroin now takes a life every three days in Chicago's collar counties and takes more than one life every day in Cook County.

Lali's Law is named in memory of Alex Laliberte, a Buffalo Grove, Ill. resident and Stevenson High School graduate, who passed away seven years ago from a drug overdose. Laliberte played sports at Stevenson High School, did well in school and cared about his friends and family, but during his sophomore year of college he began being hospitalized for a mysterious illness. Unknown to his family and doctors, Laliberte had an addiction to prescription drugs and was being hospitalized for his withdrawal. He would stay in the hospital until his symptoms subsided only to

leave the hospital and repeat the cycle. Liliberto continued this pattern until he died of a heroin and prescription drug overdose a few days before his final exams.

Rep. Dold's bipartisan Lili's Law will increase access to the life-saving antidote naloxone throughout the United States. Naloxone has proven to be hugely successful as a life-saving antidote. When used, naloxone helps restore breathing that has been stopped by an overdose. In Lake County, Ill., 94 lives have been saved with naloxone since a new program developed by the Lake County Opioid Initiative was introduced equipping first responders with the overdose antidote. With increased access, the World Health Organization predicts naloxone could save another 20,000 lives every year.

Rep. Dold is a co-chair of the Suburban Anti-Heroin Task Force and also a member of the Congressional Bipartisan Task Force to Combat the Heroin Epidemic.

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<http://dold.house.gov/2016/7/dold-s-bipartisan-bill-to-prevent-drug-overdoses-signed-into-law>

Attachment 3

**Summary of Training & Continuing Education
Required by Protocols in 16 CCR § 1746.1, 1746.2, 1746.3, and 1746.4**

Section	Topic	Training Requirement Prior to Protocol Initiation	Continuing Education Requirement to Maintain Protocol
1746.1	Self-Administered Hormonal Contraception	(b) (12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.	n/a
1746.2	Nicotine Replacement Therapy Products	(b) (8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.	(b) (8) (continued) Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

**Summary of Training & Continuing Education
Required by Protocols in 16 CCR § 1746.1, 1746.2, 1746.3, and 1746.4**

Section	Topic	Training Requirement Prior to Protocol Initiation	Continuing Education Requirement to Maintain Protocol
1746.3	Naloxone Hydrochloride	(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.	n/a
1746.4	Pharmacists Initiating and Administering Vaccines	(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: A pharmacist must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

[Home Table of Contents](#)**§ 1746.1. Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.**

16 CA ADC § 1746.1

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations [Currentness](#)
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 5. Dangerous Drugs (Refs & Annos)

16 CCR § 1746.1

§ 1746.1. Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

(A) Oral;

(B) Transdermal;

(C) Vaginal;

(D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

(A) Ask the patient to use and complete the self-screening tool;

(B) Review the self-screening answers and clarify responses if needed;

(C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended;

(D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

1. Dosage;
2. Effectiveness;
3. Potential side effects;
4. Safety;
5. The importance of receiving recommended preventative health screenings;
6. That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheets:

(A) The pharmacist should provide the patient with a copy of a current, consumer-friendly, comprehensive birth control guide such as that created by the Food and Drug Administration (FDA). Examples of appropriate guides are available on the Board of Pharmacy's website.

(B) The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

(C) The pharmacist should provide the patient with a copy of an administration-specific factsheet. Examples of appropriate factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: 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 laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS

1	What was the first date of your last menstrual period?	/ /	
2a	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2b	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2c	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19a	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19b	If yes, list them here:		
20a	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
20b	If yes, list them here:		

Note: Authority cited: Sections 4005 and 4052.3, Business and Professions Code. Reference: Sections 733, 4052, 4052.3 and 4103, Business and Professions Code.

HISTORY

1. New section filed 4-8-2016; operative 4-8-2016 pursuant to Government Code section 11343.4(b)(3) (Register 2016, No. 15).

This database is current through 9/23/16 Register 2016, No. 39

16 CCR § 1746.1, 16 CA ADC § 1746.1

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[Home Table of Contents](#)**§ 1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products.**

16 CA ADC § 1746.2

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations [Currentness](#)
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 5. Dangerous Drugs (Refs & Annos)

16 CCR § 1746.2

§ 1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products.

(a) A pharmacist furnishing nicotine replacement products pursuant to Section 4052.9 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Nicotine Replacement Products

(1) Authority: section 4052.9(a) of the California Business and Professions Code authorizes a pharmacist to furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to nicotine replacement products and to ensure that the patient receives information to appropriately initiate smoking cessation medication therapy.

(3) Explanation of Products Covered: Prescription nicotine replacement products approved by the federal Food and Drug Administration and provided by a pharmacist for smoking cessation are covered under this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

(4) Procedure: When a patient requests nicotine replacement therapy or other smoking cessation medication, or when a pharmacist in his or her professional judgment decides to initiate smoking cessation treatment and counseling, the pharmacist shall complete the following steps:

(A) Review the patient's current tobacco use and past quit attempts.

(B) Ask the patient the following screening questions:

(i) Are you pregnant or plan to become pregnant? (If yes do not furnish and refer to an appropriate health care provider)

(ii) Have you had a heart attack within the last 2 weeks? (If yes, furnish with caution and refer to an appropriate health care provider)

(iii) Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia? (If yes, furnish with caution and refer to an appropriate health care provider)

(iv) Do you currently experience frequent chest pain or have you been diagnosed with unstable angina? (If yes, furnish with caution and refer to an appropriate health care provider)

(v) Do you have any history of allergic rhinitis (e.g., nasal allergies)? (If yes, avoid nasal spray)

(vi) Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction? (If yes, avoid nicotine gum)

These screening questions shall be made available in alternate languages for patients whose primary language is not English.

(C) When a nicotine replacement product is furnished:

(i) The pharmacist shall review the instructions for use with every patient using a nicotine replacement product.

(ii) Pharmacists should recommend the patient seek additional assistance for behavior change, including but not limited to the California Smokers' Helpline (1-800-NO-BUTTS), web-based programs (e.g., <http://smokefree.gov>), apps, and local cessation programs.

(D) The pharmacist shall answer any questions the patient may have regarding smoking cessation therapy and/or nicotine replacement products.

(5) Product Selection: The pharmacist, in consultation with the patient, may select any nicotine replacement product (alone or in combination) from the list of therapies specified in this protocol in the Table "Nicotine Replacement Therapy Medications for Smoking Cessation." This list shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(6) Notifications: The pharmacist shall notify the patient's primary care provider of any prescription drug(s) and/or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. 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 provide the patient with a written record of the prescription drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(7) Documentation: Each nicotine replacement product provided for smoking cessation and furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(8) Training: Prior to furnishing prescription nicotine replacement products, pharmacists who participate in this protocol must have completed a minimum of two hours of an approved continuing education program specific to smoking cessation therapy and nicotine replacement therapy, or an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.

Additionally, pharmacists who participate in this protocol must complete ongoing continuing education focused on smoking cessation therapy from an approved provider once every two years.

(9) Patient Privacy: All pharmacists furnishing nicotine replacement products in a pharmacy or health care facility shall operate under the pharmacy's or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(10) Nicotine Replacement Therapy Medications for Smoking Cessation

[Image 1 within § 1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products.](#)

[Home](#) [Table of Contents](#)**§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.**

16 CA ADC § 1746.3

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations [Currentness](#)
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 5. Dangerous Drugs (Refs & Annos)

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

HISTORY

1. New section filed 4-10-2015 as a deemed emergency exempt from OAL review pursuant to Business and Professions Code section 4052.01(e); operative 4-10-2015 (Register 2015, No. 15). A Certificate of Compliance must be transmitted to OAL by 10-7-2015, pursuant to Business and Professions Code section 4052.01(e), or emergency language will be repealed by operation of law on the following day.

2. New section refiled 9-29-2015 as a deemed emergency exempt from OAL review pursuant to Business and Professions Code section 4052.01(e); operative 10-8-2015 pursuant to Government Code section 11346.1(d) (Register 2015, No. 40). A Certificate of Compliance must be transmitted to OAL by 4-5-2016, pursuant to Business and Professions Code section 4052.01(e), or emergency language will be repealed by operation of law on the following day.

3. Certificate of Compliance as to 9-29-2015 order, including further amendment of section, transmitted to OAL 12-15-2015 and filed 1-27-2016; amendments effective 1-27-2016 pursuant to Government Code section 11343.4(b)(3) (Register 2016, No. 5).

This database is current through 9/23/16 Register 2016, No. 39

16 CCR § 1746.3, 16 CA ADC § 1746.3

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[Home](#) [Table of Contents](#)**§ 1746.4. Pharmacists Initiating and Administering Vaccines.**

16 CA ADC § 1746.4

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations [Currentness](#)

Title 16. Professional and Vocational Regulations

Division 17. California State Board of Pharmacy

Article 5. Dangerous Drugs (Refs & Annos)

16 CCR § 1746.4

§ 1746.4. Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering any vaccine pursuant to section 4052 or 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: A pharmacist must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: A pharmacist shall notify, each patient's primary care provider of any vaccine 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 a 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. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (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 information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each 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, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United States Code.

HISTORY

1. New section filed 8-25-2016; operative 8-25-2016 pursuant to Government Code section 11343.4(b)(3) (Register 2016, No. 35).

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16 CCR § 1746.4, 16 CA ADC § 1746.4

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Attachment 4



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

California State Board of Pharmacy's Website Guidelines Developed by the Communication and Public Education Committee

The following are guidelines to be used in determining appropriateness of website links posted at the California State Board of Pharmacy's website.

The board will utilize the following guidelines when determining what outside links to provide on the board's website – www.pharmacy.ca.gov

Links should be provided when they benefit consumers, applicants, licensees and other board stakeholders who utilize the board's website as a resource for information and reference in accordance with the board's mission statement:

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

Additionally, all links posted to the board's website in accordance with these guidelines should uphold the board's statutory mandate of public protection as referenced in Business and Professions Code section 4001.1:

“Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”

Examples of appropriate links include:

- Local, State, Federal Agencies/Governments
- Consumer Protection Entities
- National Association of Boards of Pharmacy
- Accrediting Entities Referenced in Statute or Regulation
- Industry Associations
- Industry Related Organizations or Non-Profit Organizations
- Licensing Entities for other US States or Territories
- Links to media sites with consumer/licensee appropriate information, new stories, journals, etc.

Examples of links that are not appropriate:

- Commercial websites endorsing a product/concept/class for sale to a consumer/licensee population
- Links to websites of licensees
- Any link whereby posting it to the board's website would provide an unfair competitive real or perceived benefit to an entity.

Attachment 5

CA State Board of Pharmacy





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Attachment 6

Communication and Public Education Communication Plan

The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

2017-2021

4.1 Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.

Task

a. Develop plan and bring to committee for approval.	Licensees and Consumers	List of tasks with corresponding: audiences, content/method, purpose, responsible parties and timing	To improve communication and keep stakeholders better informed	Board staff C&PE Committee	September 2016
b.					

4.2 Identify and use additional resources for public and licensee outreach services to implement a communication plan.

Task

a. Website	Consumer/ Licensee	Update board website	Implement a communication plan	Board staff C&PE Committee	TBD
b.					

Communication and Public Education Communication Plan

The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

2017-2021

4.3 Establish a process to collect email addresses and mobile numbers for text messaging, from all licensees for better ability to improve communications.

Task					
a. Research means to collect email addresses	Licensees	Mechanism to collect email addresses	To distribute information to licensees	Board staff C&PE Committee	TBD
b. Research means to collect mobile telephone numbers	Licensees	Mechanism to collect mobile telephone numbers	To distribute information to licensees	Board staff C&PE Committee	TBD
c.					

4.4 Educate licensees about the board's regulations by publishing summaries of all newly issued regulations and explain implementation tactics.

Task					
a. Inform licensees of new regulations	Licensees	Website Subscriber alert Newsletter	Disseminate information about new regulations	Board staff	TBD
b.					

Communication and Public Education Communication Plan

The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

2017-2021

4.5 Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Inspect pharmacies at least once every four years b.	Licensee – pharmacies	Inspection	Forum for licensee-inspector interaction	Inspectors Board staff	TBD

4.6 Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Naloxone availability at pharmacies b.	Consumers	Website	Inform the public	Board staff	TBD

4.7 Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Notice to Consumers	Consumers	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD
b. Point-to-your-language notice c.	Consumer	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD

Attachment 7

Edward P. O'Brien, J.D.
Chairman

Y. Jennifer Ahn, Pharm.D.
Executive Officer



Panel Members

David A. Baron, DO, MSED
C. Angie Chen, MD, FACP
Patrick R. Finley, Pharm.D.
Andrew S. Kayser, MD, PhD
Anna Lembke, M.D.
Laurence R. Upjohn, Pharm.D.

**RESEARCH ADVISORY PANEL
OF CALIFORNIA**

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jennifer.ahn@doj.ca.gov

MEMORANDUM

Date: July 19, 2016

To: Recipients - Research Advisory Panel Annual Report

From: Y. Jennifer Ahn, Pharm.D.
Panel Executive Officer

Subject: Forty-fifth Annual Report of the Research
Advisory Panel of California 2015

The Research Advisory Panel of California has recently submitted its annual report to the Legislature and Governor. Enclosed is a copy of this report, which provides a summary of the Panel's activities for the year 2015. Also, the PDF version of the report can be found at our website: oag.ca.gov/research under Appendices section.

FORTY-FIFTH ANNUAL REPORT
of the
RESEARCH ADVISORY PANEL
OF CALIFORNIA
2015



PREPARED FOR THE
LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

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TABLE OF CONTENTS

	Page
LIST OF 2015 PANEL MEMBERS	2
SUMMARY OF 2015 PANEL ACTIVITIES and SELECTED RESEARCH FINDINGS	3
TABLE 1 - Research Studies approved in 2015	9
TABLE 2 - Research Studies closed in 2015	17
APPENDICES	
Appendix A - Currently Open Schedule I and II Non-Human & Academic Human Studies	21
Appendix B - Currently Open Schedule II Clinical Drug Trial Studies	31
Appendix C - Currently Open Research Studies on the Treatment of Controlled Substance Abuse	43
Appendix D - Pertinent Sections - California Health and Safety Code	
§ 11213 - Persons and researches using controlled substances	45
§ 11480 & 11481 - Research Advisory Panel	45
§ 11603 & 11604 - Attorney General	46
§ 24172 - Experimental subject's bill of rights	47
§ 24173 - Informed consent	48

2015 PANEL MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

The Research Advisory Panel of California (RAPC) consists of the Panel chairman, Executive officer, and the Panel members.

Edward P. O'Brien, J.D.

Deputy Attorney General IV, State of California AG's Office, San Francisco
Panel Chairman, Appointed by the State of California Attorney General

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This report represents a consensus among Panel members acting as individual experts.
It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

SUMMARY OF 2015 PANEL ACTIVITIES

During 2015 the Panel reviewed forty-five research study submissions. Forty-three were approved by the Panel. Among the approved studies, fourteen studies were Academic research studies, two studies were Substance Abuse Treatment research studies, and twenty-seven studies were Multi-Center Clinical Drug Trial research studies.

Thirteen research studies were completed or, in a few cases, terminated in 2014, and they were closed on the Panel's records.

At the end of 2015 the Panel was monitoring one hundred and twenty-one research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2015 and Table 2 is a list of the studies closed by the Panel in 2015.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance research projects currently ongoing in California:

Dr. Barth Wilsey, M.D. and colleagues at University of California Davis Medical Center, Department of Physical Medicine and Rehabilitation have provided the Panel with the following summary of research titled "A Randomized, Cross-Over Controlled Trial of Dronabinol and Vaporized Cannabis in Neuropathic Low Back Pain".

Our primary objective is to assess whether treatment with vaporized whole plant cannabis or oral $\Delta 9$ -THC reduces spontaneous and evoked pain more than placebo, and whether there are differences between the two active treatments in terms of interference with activities of daily living. The primary outcome will be measured using self-reported average numerical pain intensity during the past 24 hours. A secondary outcome measure will be level of use of breakthrough pain medication. To determine if whole plant cannabis or oral $\Delta 9$ -THC have a more general analgesic effect above and

beyond medication induced changes in subjective pain intensity, pain tolerance and sensitivity will be experimentally induced using the cold pressor test (evoked pain). The secondary outcome measure of pain interference will be measured from the Repeated Measures Recommended Minimal Dataset (NIH Task Force on chronic low back pain).

Our secondary objective is to examine the effects of vaporized whole plant cannabis and oral Δ -THC (dronabinol) on mood, neuropsychological function, and psychomimetic side-effects (high, stoned, etc.) compared to placebo and to each other. The secondary outcome mood will be determined using the Profile of Mood States. The secondary outcome measures of attention, verbal learning and fine motor coordination will be determined using the Digit Symbol test, the Hopkins Verbal Learning Test, and the Grooved Pegboard Test, respectively.

Our tertiary objective is to examine the acute effects (after receiving stable treatment for 4 weeks) of vaporized whole plant cannabis and oral Δ -THC compared to placebo and each other on driving skills. Using a driving simulator, we will examine the effects of treatment on driving performance, as well as the rate at which the effects dissipate over time. We will verify the recommendation that patients who use medicinal cannabis should wait at least three to four hours before driving. This will be evaluated, for the first time, in a cohort of patients who have been treated for a month (rather than in a group of novice or recreational users). It will also be the first time that driving simulation is studied in patients taking oral Δ -THC.

The present proposal builds upon previous work funded by the University of California Center for Medicinal Cannabis Research (CMCR). In our first study, thirty-eight patients with a heterogeneous collection of neuropathic pain conditions (e.g., spinal cord injury pain, central post-stroke pain, peripheral neuropathy, post-herpetic neuralgia, and complex regional pain syndrome) resistant to standard pharmacologic treatments were recruited 32. Subjects underwent a standardized procedure for smoking high dose (7% Δ -THC), medium dose (3.5% Δ -THC), or placebo Δ -THC while continuing to use their regularly prescribed treatments. A mixed linear model demonstrated an equivalent analgesic response to smoking cannabis with both the high and medium doses. Psychoactive effects were minimal and well-tolerated, with some acute cognitive effects, particularly with memory, at the high dose (7% Δ -THC)

The present study is designed to evaluate whether or not the medium dose of cannabis (3.5%) can maintain an analgesic response over an eight week period. In addition, a direct comparison of this vaporized preparation will be made with dronabinol and placebo.

Dr. Robert C. Malenka, MD, PhD and colleagues at Stanford University, School of Medicine have submitted Annual Progress Report titled “The Role of Oxytocin in the Pathogenesis of Autism”.

As described in our initial protocol application, we aim to define the pathogenesis of social dysfunction in autistic spectrum disorders (ASDs) using an array of mouse models. Genetic ASD syndromes in humans, when modeled in mice, give us some

insight into abnormal social behavior. However, acute MDMA administration is entirely unique in its ability to promote pro-social and empathic behavior in humans, potentially pointing to therapeutic avenues for human ASDs. In the course of our studies, we have identified assays of mouse social behavior reflecting these pro-social, “affiliative” human behaviors, specifically we are using a previously validated three-chamber social interaction test, wherein mice prefer to spend time with a confined mouse over spending time with a similar confining enclosure without a mouse. We have found a statistically significant enhancement of sociability with this assay at an MDMA dose of 7.5mg/kg, which has minimal effects on locomotor activation, and does not possess strong rewarding properties *per se*.

In the past year, we have extended these results by examining the molecular mechanism of this MDMA effect. We have found an important role for the serotonin transporter, SERT, as well as receptor for oxytocin. We have identified the nucleus accumbens as an important brain area mediating MDMA’s pro-social effect, and have done preliminary electrophysiological experiments to define MDMA’s effect on synaptic function in this brain area.

In the coming year, we will assess the role of other brain areas and of specific serotonin receptors in mediating MDMA’s pro-social effect. These experiments will take advantage of my lab’s expertise with transgenic mice and viral-mediated gene transfer.

Dr. Steven Shoptaw, M.D. and colleagues at University of California, Los Angeles have submitted Annual Progress Report titled “Phase I Safety Interaction Trial of Ibudilast with Methamphetamine”.

Summary and Findings: As detailed in the last annual report submitted 23 Feb 2015, enrollment to this trial has been completed, all subjects have completed study procedures, and research activities are limited to data analysis. This phase 1 study aimed to recruit and enroll 12 non-treatment seeking methamphetamine dependent research participants when recruitment opened in February 2011. Of the 110 subjects consented to the trial, 18 were eligible for study participation. Screen failures were primarily due to medical or psychiatric ineligibility. Of the 18 eligible, 11 participants were admitted to the hospital and completed all inpatient procedures; 4 participants were admitted to the hospital, randomized, and withdrew; 3 participants were admitted to the hospital and withdrew pre-randomization. All 4 of the non-completers voluntarily withdrew from the study stating unwillingness to remain in the unit for 27 days and none withdrew due to study related adverse events. One participant who completed the inpatient component did not complete the 14-day follow up. Nine of the completed subjects are male; two are female. Both female completers are white. Study completers are approximately 43 years old. Three of the four female subjects who terminated early are white, the other Native Hawaiian/Other Pacific Islander. Their ages are 27, 33, 35, and 27 years old. Of the three males who terminated early, two are white, one is Hispanic. Their ages are 28, 52 and 50. Demographic characteristics of the 11 completers are summarized in Table 1. Eleven non-treatment seeking methamphetamine dependent volunteers resided in a

research facility for 27 days and nights during which they received infusions with methamphetamine (0 mg, 15mg, and 30 mg) under placebo, ibudilast 20 mg BID, and ibudilast 50 mg BID conditions using a randomized double-blind, placebo-controlled within-subjects crossover design. Participants were randomly assigned to medication dosing order (placebo, ibudilast 20 mg BID, ibudilast 50 mg BID versus ibudilast 20 mg BID, ibudilast 50 mg BID, placebo) in a counter-balanced fashion.

Aim 1: To determine whether ibudilast (20 mg BID or 50 mg BID) alters the cardiovascular response to IV methamphetamine. As described in the previous annual report submitted on 23 Feb 2015, mean changes in heart rate and blood pressure following saline or methamphetamine infusion with both doses of ibudilast and placebo were measured, shown in Figure 1. Using a linear regression model controlling for age, gender, study day, and baseline methamphetamine use, methamphetamine infusion was associated with increased heart rate, systolic blood pressure, and diastolic blood pressure, with a higher methamphetamine dose (30 mg vs. 15 mg) associated with greater increases in all 3 cardiovascular measures ($p < 0.001$.) There was no statistically significant main effect of ibudilast at either dose on mean change in heart rate ($p = 0.76$ for ibudilast 20 mg BID, $p = 0.42$ for ibudilast 50 mg BID), systolic blood pressure ($p = 0.68$ for ibudilast 20 mg BID, $p = 0.76$ for ibudilast 50 mg BID), or diastolic blood pressure ($p = 0.81$ for ibudilast 20 mg BID, $p = 0.80$ for ibudilast 50 mg BID) compared to placebo. Nor were there any significant interactions between ibudilast dose and methamphetamine dose on any of the cardiovascular measures (all $p > 0.05$).

Aim 2: To determine whether ibudilast (20 mg BID or 50 mg BID) alters the subjective effects of IV methamphetamine. The effects of ibudilast compared to placebo were assessed on self-reports of subjective effects of 15 mg, 30 mg IV methamphetamine using visual analogue and standard scales assessing responses over time. Analysis of whether ibudilast (20 mg BID or 50 mg BID) alters the subjective effects of IV methamphetamine was analyzed. Participants rated the subjective intensity of 12 drug effects (Morean et al., 2013) on a visual analog scale (VAS) ranging from 0 (Not at all) to 100 (Extremely). At 15 minutes pre-infusion and eight times post-infusion, participants rated “Effect” (Any drug effect?), “High” (How high are you?), “Good” (Any good effects?), “Like” (How much do you like the drug?), “Stimulated” (How stimulated do you feel?), “Want” (How much do you want the drug?), “Use” (How likely would you use the drug?), “Bad” (Any bad effects?), “Nervous” (How nervous do you feel?), “Sad” (How sad do you feel?), “Crave” (How much do you crave the drug?), and “Refuse” (How easily could you refuse the drug?). Subjective effect models first examined MA condition main effects and potential interactions with time and ibudilast sequence, which were retained if statistically significant ($p < .05$). Primary models then tested ibudilast X MA condition interactions, with statistically-significant interactions ($p < .05$) probed by testing the simple ibudilast effect within each MA condition. Planned contrasts compared each ibudilast condition to placebo, using an alpha (.025) and confidence interval (97.5% CI) adjusted for multiple comparisons. Ibudilast X MA condition interactions were statistically-significant for several positive subjective drug effects including “Effect” (Wald $X^2(4) = 20.76, p < .001$), “High” (Wald $X^2(4) = 12.19, p < .05$), “Good” (Wald $X^2(4) = 14.17, p < .01$), “Like” (Wald $X^2(4) = 12.68, p < .05$).

Aim 3: To determine whether ibudilast alters the pharmacokinetics of IV methamphetamine. Based on data obtained from the 11 completers, we have been able to determine there were no clinically significant changes in methamphetamine or amphetamine pharmacokinetic parameters with ibudilast. Methamphetamine challenge sessions occurred after treatment conditions had reached steady state (ibudilast 20 mg twice daily, ibudilast 50 mg twice daily, and placebo) with sessions separated by 2 days to allow for pharmacokinetic analysis. During methamphetamine challenge sessions, participants were given either a 15 mg or 30 mg infusion of methamphetamine administered via IV push over 2 minutes using an automatic pump. Samples were collected for methamphetamine pharmacokinetic analysis following each infusion at regular intervals. Plasma levels of methamphetamine and its major metabolite, amphetamine, were assessed via liquid chromatographic-tandem mass spectrometry to determine if ibudilast alters the pharmacokinetics of intravenous methamphetamine. For pharmacokinetic analysis, methamphetamine and amphetamine were analyzed. Peak concentration (C_{max}) was the observed maximum value during the collection period of 0 (pre-dose) to 18 hours. The time to peak concentration (T_{max}) was the time at which C_{max} was observed. The area under the curve represents the total drug exposure over time, either to the last sample time (AUC) or the estimated total drug exposure (AUC_{∞}). Pharmacokinetic parameters (AUC, T_{max} , C_{max} , and elimination rates) were calculated using the times of sample collection reported by the Investigator. There were no significant differences in C_{max} of methamphetamine, T_{max} of methamphetamine, or methamphetamine $T_{1/2}$ for either ibudilast dose compared to placebo following the 15 and 30 mg methamphetamine infusions. As a metabolite of methamphetamine, amphetamine pharmacokinetic analysis was also performed for C_{max} , T_{max} , and AUC_{∞} . There were no significant differences in C_{max} , T_{max} , or AUC_{∞} for amphetamine.

In summary, ibudilast was well tolerated in this Phase 1 safety-interaction study among methamphetamine dependent volunteers. There were no Serious Adverse Events and adverse events were mild, similar in frequency during ibudilast and placebo treatment, and typical of methamphetamine clinical trials. Ibudilast did not affect daily morning blood pressure or heart rate among methamphetamine dependent participants nor did it augment or exacerbate the cardiovascular response to methamphetamine. Ibudilast attenuated several of the prototypical subjective effects of MA, most notably "High", "Effect", and "Good", with reductions in "Stimulated" and "Like" that were less robust. There were no clinically significant changes in methamphetamine or amphetamine pharmacokinetic parameters with ibudilast. When measuring sustained attention, ibudilast showed reduced variability in response times and less perseverative responses in contrast to the placebo group. Pharmacogenetic analyses are ongoing.

Research Plans for 2016 Calendar Year: Enrollment to this trial has been completed, all subjects have completed study procedures, and research activities are limited to data analysis only for the 2016 calendar year.

Grunenthal/Janssen Pharmaceuticals has submitted Annual Progress Report titled “an Evaluation of the Efficacy & Safety of Tapentadol Oral Solution in the Treatment of Post-Operative Acute Pain Requiring Opioid Treatment in Pediatric Subjects Aged from Birth to Less than 18 Years old”

A brief summary of research performed and findings made during the year (this requirement may be augmented by including reprints of papers or copies of reports published) The trial KF5503/65 had First Subject In on 19 Feb 2015, and recruited until 31 Dec 2015 50 of the targeted 168 subjects. In parallel to this trial, the Sponsor is performing an Open label evaluation of the population pharmacokinetic profile, safety, tolerability, and efficacy of tapentadol oral solution for the treatment of post surgical pain in children aged from birth to less than 2 years (KF5503/72). The pharmacokinetic data gathered in this trial for a particular age group have been and will continue to be used to confirm the dose to be administered in the same age group in KF5503/65. Given that the age group 6 months to <2 years in KF5503/72 could already be closed and analyzed, the trial KF5503/65 has been amended to include the same age group (Amendment 05). The sponsor letter regarding DMC is included to further clarify the findings for this study by the DMC X

Research plans for the upcoming calendar year (with indication of any additional controlled substances planned for procurement in the upcoming year) It is expected that the trial KF5503/65 will continue to recruit until the end of the year 2016. No new clinical trials with oral solution are planned to start in 2016.

TABLE 1

**RESEARCH STUDIES
APPROVED IN 2015**

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Nicholas Butowski, M.D. UCSF Neurological Surgery San Francisco, CA	CBD Developmental Research Project
Kevin Chu, D.O. Lotus Clinical Research, LLC Pasadena, CA	A Phase 1, Open-Label, Single Ascending Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Fentanyl Sublingual Spray and Fentanyl Citrate Intravenous (IV) in Opioid Naive Subjects
Jay Keasling, Ph.D. Joint Bioenergy Institute Emeryville, CA	Engineering the Industrial Microbe Saccharomyces Cerevisiae for Biosynthesis of Cannabinoids
Christian Adam Kekoa Koch, MD Lotus Clinical Research, Inc. Pasadena, CA	A Phase I, Multiple Ascending Dose Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Fentanyl Sublingual Spray in Opioid Naive Subjects
Daniel Levin, Ph.D. S&B Pharma, Inc. Azusa, CA	Panel Approved Research Study
Sara Mednick, Ph.D. UC Riverside Riverside, CA	The Effects of Zolpidem and Dextroamphetamine on Cognitive Performance

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
David E. Olson, Ph.D. UC Davis Davis, CA	Chemical Modulation of Neural Plasticity, Learning and Memory
Loren Parsons, Ph.D. The Scripps Research Institute La Jolla, CA	Cognitive and Neurochemical Effects of Δ 9-tetrahydrocannabinol and related cannabinoids in rodents
Jeanne Paz, Ph.D. The J. David Gladstone Institutes San Francisco, CA	The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats
Joel E. Schlosburg, Ph.D. The Scripps Research Institute La Jolla, CA	Treatment of Opiate Dependence Through Inhibition of Fatty Acid Amide Hydrolase
Jennifer Thomas, Ph.D. San Diego State University San Diego, CA	The Effects of Developmental Cannabis Exposure on Brain and Behavioral Development in Rats
Friedbert Weiss, Ph.D. The Scripps Research Institute La Jolla, CA	Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol
Bart Wilsey, M.D. UC Davis Medical Center Sacramento, CA	A Randomized, Cross-Over Controlled Trial of Dronabinol and Vaporized Cannabis in Neuropathic Low Back Pain

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Alkermes Waltham, MA	A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALK3831-A303)
Alkermes Waltham, MA	A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects with Acute Exacerbation of Schizophrenia (ALK3831-A305)
Alkermes Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)
Cortbus Norwood, MA	A Phase 2, Double-Blind, randomized, Placebo-Controlled Multicenter Study to Evaluate safety, Tolerability, Efficacy, and Pharmacokinetics of JBT-101 in Cystic Fibrosis (BT101-CF-001)
Cortbus Norwood, MA	A Phase 2, Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Evaluate Safety, Tolerability, Efficacy, and Pharmacokinetics of JBT-101 in Diffuse Cutaneous Systemic Sclerosis (JBT101-SSc-001)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

GW
Cambridge, UK

Panel Approved Research Study

GW
Cambridge, UK

Panel Approved Research Study

GW
Cambridge, UK

Panel Approved Research Study

GW
Cambridge, UK

Panel Approved Research Study

INSYS Therapeutics
Chandler, AZ

A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Lennox-Gastaut Syndrome
(INS011-14-024)

INSYS Therapeutics
Chandler, AZ

A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Dravet Syndrome
(INS011-14-025)

<u>PI/ Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
INSYS Therapeutics Chandler, AZ	A Phase I/II Study to Assess the Pharmacokinetics and Safety of Multiple Doses of Pharmaceutical Cannabidiol Oral Solution in Pediatric Subjects with Treatment-Resistant Seizure Disorders (INS011-14-029)
INSYS Therapeutics Chandler, AZ	A Phase 2 Study to Assess the Efficacy and Safety of Cannabidiol Oral Solution for the Treatment of Refractory Infantile Spasms (NIS011-15-054)
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study
Janssen Raritan, NJ	An Open-Label, Randomized, Single-Application, Two-Period Crossover, Pivotal Bioequivalence Study to Evaluate the Bioequivalence of Fentanyl Transdermal System (JNJ-35685-AAA-G021) Compared with DURAGESIC® Fentanyl Transdermal Patch in Healthy Subjects (FENPA11023)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

Janssen
Raritan, NJ

A Randomized, Partially-Blind, Two-Arm, Single-Application, 3-Way Crossover Study to Evaluate the Adherence of 2 Strengths of Newly Manufactured Samples and Aged Samples of a New Formulation (JNJ-35685-AAA-G016 and JNJ-35685-AAA-G021) of Fentanyl Transdermal System Compared with DURAGESIC® Fentanyl Transdermal Patch in Healthy Subjects
(FENPAI1025)

Nektar
CRO: PRA
Lenexa, KS

A Phase 3, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of NKTR-181 in Opioid-Naive Subjects with Moderate to Severe Chronic Low Back Pain
(14-181-07)

Nektar
CRO: PRA
Lenexa, KS

A Phase 3, Multicenter, Open-Label, 52-Week Study to Evaluate the Long-Term Safety and Tolerability of NKTR-181 in Subjects with Moderate to Severe Chronic Low Back Pain or Chronic Noncancer Pain
(14-181-08)

Pfizer
CRO: ICON
New York, NY

An Open-Label Study to Evaluate the Pharmacokinetics and Safety of ALO-02 (Oxycodone Hydrochloride and Naltrexone Hydrochloride) Extended-Release Capsules in Children and Adolescents 7-17 Years of Age Who Require Opioid Analgesia
(B4531015)

Table 1 Cont.

<u>PI / Sponsor</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Shire CRO: PPD San Diego, CA	A Phase 2, Open-Label, Multicenter, Exploratory Safety, Tolerability, Pharmacokinetic, and Efficacy Study of SPD489 in Preschool Children Aged 4-5 Years with Attention-deficit/Hyperactivity Disorder (SPD489-211)
Shire Wayne, PA	A Phase 3, Randomized, Double-blind, Multi- center, Placebo-controlled, Dose-Optimization, Safety and Efficacy Study of SHP465 in Children and Adolescents Aged 6-17 years with Attention Deficit Hyperactivity Disorder (ADHD) (SHP465-305)
Shire CRO: PPD San Diego, CA	A Phase 3, Open-label, Multicenter, 12-Month Safety and Tolerability Study of SPD489 in Preschool Children Aged 4-5 Years Diagnosed with Attention-Deficit /Hyperactivity Disorder (SPD489-348)
Shire CRO: Premier Research San Diego, CA	A Phase 3, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Forced-Dose Titration, Safety and Efficacy Study of SHP465 in Adults Aged 18-55 Years with Attention-Deficit/Hyperactivity Disorder (ADHD) (SHP465-306)

Table 1 Cont.

PI / Sponsor

Title of Study / Clinical Drug
Trial Protocol

Teva
CRO: INC
Raleigh, NC

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Analgesic Efficacy and Safety of Hydrocodone Bitartrate/Acetaminophen Immediate-Release Tablets (TV-46763) at Doses of 5.0 mg/325 mg, 7.5 mg/325 mg, and 10 mg/325 mg Every 4 to 6 Hours in Patients with Moderate to Severe Pain Following Bunionectomy
(TV46763-CNS-30031)

USWorldMeds
Louisville, KY

A Phase 3, Open-Label, Safety Study of Lofexidine
(USWM-LX1-3003-2)

Alkermes
Waltham, MA

A Phase 3 Study of Evaluate the Safety, Tolerability, and Efficacy of Naltrexone for use in Conjunction with Buprenorphine in Adults with Opioid Use Disorder Prior to First Dose of Vivitrol
(ALK6428-A301)

TABLE 2

RESEARCH STUDIES CLOSED IN 2015

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
Adam Leventhal, Ph.D. USC Keck School of Medicine Los Angeles, CA	Influence of Genes and Emotions on medication Effects
Jennifer Whistler, Ph.D. Ernest Gallo Clinic & Research Center Emeryville, CA 94608	Endocytosis and Opioid Receptors
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA 95817	The Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury
AcelRx Pharmaceuticals, Inc. Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sublingual Sufentanil Tablet 30 mcg for the Treatment of Post-Operative Pain in Patients after Abdominal Surgery (SAP301)
INTRuST Clinical Consortium La Jolla, CA	Randomized Controlled Trial of Galantamine, Methylphenidate, and Placebo for the Treatment of Cognitive Symptoms in Patients with Mild Traumatic Brain Injury (mTBI) and/or Posttraumatic Stress Disorder (PTSD) ("Cognitive REmediation After Trauma Exposure" Trial = CREATE Trial")

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Purdue
CRO: PRA
Lenexa, KS

An Open-Label, Multicenter Study of the Safety of Twice Daily Oxycodone HCl Controlled-Release Tablets in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, with Moderate to Severe Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics (Purdue OTR 3001)

Purdue
CRO: Quintiles
Overland Park, KS

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (Purdue ONU3704)

Table 2 Cont.

<u>Sponsor / PI</u>	<u>Title of Study / Clinical Drug Trial Protocol</u>
<p>Purdue CRO: Quintiles Overland Park, KS</p>	<p>A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (Purdue ONU3705)</p>
<p>Purdue CRO: PRA Charlottesville, VA</p>	<p>An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study (Purdue OTR3002)</p>
<p>Shire CRO: Premier Research Group Bluff City, TN</p>	<p>A Phase 3, Multicenter, Open-Label, 12-Month Extension Safety and Tolerability Study of SPD489 in the Treatment of Adults with Binge Eating Disorder (Shire SPD489-345)</p>
<p>USWorldMeds Louisville, KY</p>	<p>A Phase 3, Open-Label, Safety Study of Lofexidine (USWM-LX1-3003-2)</p>

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Kelly Courtney, MA
UCLA
Los Angeles, CA

Effects of Naltrexone on Methamphetamine
Cue-Induced Brain Activity in
Methamphetamine Dependence

Lara Ray, Ph.D.
UCLA
Los Angeles, CA

Effects of Ivermectin on Non-Treatment
Seeking Patients Who Meet Criteria for
Alcohol Abuse or Dependence

NIDA Clinical Coordinating Center
The EMMES Corporation
Rockville, MD

Accelerated Development of Additive
Pharmacotherapy Treatment (ADAPT)
(NIDA CTN Protocol 0054)

APPENDIX A

CURRENTLY OPEN (*through December 31, 2015*)
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

Principal Investigator

Title of Study

Donald Abrams, M.D.
UCSF / SFGH
San Francisco, CA

Cannabinoid-Based Therapy and Approaches
to Quantify Pain in Sickle Cell Disease

Mark A. Agius, M.D.
UC. Davis
Davis, CA

Cannabis for Spasticity in MS: Placebo-
Controlled Study

Philip E. Bickler, MD, PhD
Dept of Anesthesia, UCSF
San Francisco, CA

Detecting Apnea in Healthy Volunteers
Receiving Opiate or Sedative Medications

Nicholas Butowski, M.D.
UCSF Neurological Surgery
San Francisco, CA

CBD Developmental Research Project

John R. Cashman, Ph.D.
Human BioMolecular
Research Institute
San Diego, CA

Molecular Evolution of Human Cocaine
Catalysis

Kevin Chu, D.O.
Lotus Clinical Research, LLC
Pasadena, CA

A Phase 1, Open-Label, Single Ascending
Dose Study to Evaluate the Pharmacokinetics,
Pharmacodynamics, Safety and Tolerability of
Fentanyl Sublingual Spray and Fentanyl
Citrate Intravenous (IV) in Opioid Naive
Subjects

Appendix A Cont.

Principal Investigator

Title of Study

Laura Colin
Biostride, Inc.
Redwood City, CA

Research of Novel Technologies for
Development of Antibodies and Immunoassay
Techniques to Drugs of Abuse and Controlled
Compounds of Interest

Nissar A. Darmani, Ph.D.
Western University
Pomona, CA

Project 1: mechanisms of vomiting induced by
chemotherapeutics, related emetics, & GI
disorders. Project 2: Dev changes in
monoamine function following prenatal &
early postnatal exposure to serotonergic
altering drugs in mice

Aaron Ettenberg, Ph.D.
UC Santa Barbara
Santa Barbara, CA

Dopamine involvement in Opiate and
Stimulant Reinforcement

Michael Fischbach
UCSF
San Francisco, CA

Engineering a human gut bacteria to produce
dimethyltryptamine

Laura Colin
Biostride, Inc.
Redwood City, CA

Effects of Cannabidiol on Mania-relevant
Locomotor and Investigatory Behavior

Nissar A. Darmani, Ph.D.
Western University
Pomona, CA

Project 1: mechanisms of vomiting induced by
chemotherapeutics, related emetics, & GI
disorders. Project 2: Dev changes in
monoamine function following prenatal &
early postnatal exposure to serotonergic
altering drugs in mice

Principal InvestigatorTitle of Study

Aaron Ettenberg, Ph.D.
UC Santa Barbara
Santa Barbara, CA

Dopamine involvement in Opiate and
Stimulant Reinforcement

Michael Fischbach
UCSF
San Francisco, CA

Engineering a human gut bacteria to produce
dimethyltryptamine

Mark A. Geyer, Ph.D.
Dept of Psychiatry, UCSD
La Jolla, CA

Effects of Cannabidiol on Mania-relevant
Locomotor and Investigatory Behavior

Judith Hellman, M.D.
UCSF
San Francisco, CA

Cannabinoid-Dependent Modulation of the
Innate Immune Response to Infection and
Injury

Kanthi Hettiarachchi, Ph.D.
SRI International
Menlo Park, CA

Analysis of Controlled Substances

Kim D. Janda, Ph.D.
The Scripps Research Institute
La Jolla, CA

Vaccines for the Treatment of Opiate
Addiction

Jay Keasling, Ph.D.
Joint Bioenergy Institute
Emeryville, CA

Engineering the Industrial Microbe
Saccharomyces Cerevisiae for Biosynthesis
of Cannabinoids

Thomas S. Kilduff, Ph.D.
SRI International
Menlo Park, CA

Neurobiological Studies of
Gammahydroxybutyrate (GHB)

Appendix A Cont.

Principal Investigator

Title of Study

Christian Adam Kekoa Koch, MD
Lotus Clinical Research, Inc.
Pasadena, CA

A Phase I, Multiple Ascending Dose Study to
Evaluate the Pharmacokinetics,
Pharmacodynamics, Safety and Tolerability of
Fentanyl Sublingual Spray in Opioid Naive
Subjects

George Koob, Ph.D.
The Scripps Research Institute
La Jolla, CA

Prescription Opioid Addiction: Neurobiological
Mechanisms

Daniel Levin, Ph.D.
S&B Pharma, Inc.
Azusa, CA

Panel Approved Research Project

Daniel Levin, Ph.D.
S&B Pharma, Inc.
Azusa, CA

Panel Approved Research Project

Daniel Levin, Ph.D.
S&B Pharma, Inc.
Azusa, CA

Panel Approved Research Project

Daniel Levin, Ph.D.
S&B Pharma, Inc.
Azusa, CA

Panel Approved Research Project

Principal Investigator

Title of Study

Walter Ling, M.D.
Integrated Substance Abuse
Programs, UCLA
Los Angeles, CA

Analgesic Response to Opioid Analgesics in
Buprenorphine-Maintained Individuals

Robert Malenka, M.D.
School of Medicine
Stanford University
Palo Alto, CA

The Role of Oxytocin in the Pathogenesis of
Autism

Sean D. McAllister, Ph.D.
CPMC Research Institute
San Francisco, CA

Panel Approved Research Project

Sara Mednick, Ph.D.
UC Riverside
Riverside, CA

The Effects of Zolpidem and
Dextroamphetamine on Cognitive
Performance

Ardis Moe, Ph.D.
UCLA Center for AIDS Research
Los Angeles, CA

Phase III, Placebo-Controlled, Double-Blind
Crossover Study of Slow-Release
Methylphenidate (Concerta™) for Treatment
of HIV Dementia

Byung-Sook Moon
ARK
Freemont, CA

Research and Development of in-Vitro
Diagnostic (IVD) Immunoassays for Drug of
Abuse Testing

N.V. Myung, M.D.
Nano Engineered Applications
Riverside, CA

Marijuana Active Ingredient Quantification
via Volatilized Sample

Appendix A Cont.

Principal Investigator

Title of Study

David E. Olson, Ph.D.
UC Davis
Davis, CA

Chemical Modulation of Neural Plasticity,
Learning and Memory

Loren Parsons, Ph.D.
The Scripps Research Institute
La Jolla, CA

Cognitive and Neurochemical Effects of
 Δ^9 -tetrahydrocannabinol and related
cannabinoids in rodents

Jeanne Paz, Ph.D.
The J. David Gladstone Institutes
San Francisco, CA

The Effects of Developmental Cannabis
Exposure on Brain and Behavioral
Development in Rats

Florian Rader, M.D.
Cedars-Sinai Med Center
Los Angeles, CA

Mechanisms and Modulation of Cocaine
Effects on Blood Flow to the Heart

Richard Reznicek, M.D.
Harbor-UCLA
Los Angeles, CA

Panel approved research

Paolo Sassone-Corsi, Ph.D.
UC Irvine
Irvine, CA

The Role of Liver CB1 Receptor in
Regulation of the Circadian Metabolism

Principal InvestigatorTitle of Study

Joel E. Schlosburg, Ph.D.
The Scripps Research Institute
La Jolla, CA

Treatment of Opiate Dependence Through
Inhibition of Fatty Acid Amide Hydrolase

Douglas Sears, M.D.
Encino, CA

A Double-Blind, Placebo-Controlled Study of
Combination Therapy in Children with
ADHD

Rajkumar J. Sevak, Ph.D.
UCLA
Los Angeles, CA

Human Methamphetamine Self-
Administration in a Progressive-Ratio
Paradigm

Rajkumar J. Sevak, Ph.D.
UCLA
Los Angeles, CA

Safety and Initial Efficacy of
Lisdexamfetamine for Modifying the
Behavioral Effects of Intravenous
Methamphetamine in Humans

Neil Singla, M.D.
Lotus Clinical Research, LLC
Pasadena, CA

A Randomized, Open Label, Prospective
Study of the Analgesic Efficacy of Oral
MNK795 Compared to Generic
Oxycodone/APAP in the Treatment of Mod to
Severe Post Operative Pain

Matthew L. Springer, Ph.D.
UCSF
San Francisco, CA

Assessment of Impairment of Vascular
Function in Rats by Environmental Exposure
to Marijuana Second Hand Smoke

Appendix A Cont.

Principal Investigator

Title of Study

Raymond Stevens, Ph.D.
The Scripps Research Institute
La Jolla, CA

Structure Determination of the Hallucinogens
LSD and Psilocin Bound to the Serotonin
Receptor 5-HT_{2B}

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral and Physiological Toxicities of
Cannabinoids: Effects of Cannabidiol

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral Toxicities of Amphetamine and
Cathinone Stimulant Drugs

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral Toxicities of Amphetamine and
Cathinone Stimulant Drugs

Michael Taffe, Ph.D.
The Scripps Research Institute
La Jolla, CA

Behavioral and Physiological Toxicities of
Cannabinoids: Effects of Cannabidiol

Jennifer Thomas, Ph.D.
San Diego State University
San Diego, CA

The Effects of Developmental Cannabis
Exposure on Brain and Behavioral
Development in Rats

Stephen Van Dien, Ph.D.
Genomatica, Inc.
San Diego, CA

Panel Approved Research Project

Principal Investigator

Title of Study

Ronald Victor, M.D.
Cedars-Sinai Med Center
Los Angeles, CA

Effects of Cocaine on Blood Flow to the Heart

Tanya Wallace, Ph.D.
SRI International
Menlo Park, CA

Cannabinoid Regulation of Cognition

Friedbert Weiss, Ph.D.
The Scripps Research Institute
La Jolla, CA

Ethanol Seeking and Relapse: Therapeutic Potential of Transdermal Cannabidiol

Friedbert Weiss, Ph.D.
The Scripps Research Institute
La Jolla, CA

Implementation of Novel Methodology to Study the Anti-Relapse Potential of Cannabidiol

Timothy Wigal, Ph.D.
UC Irvine
Irvine, CA

Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)

Bart Wilsey, M.D.
UC Davis Medical Center
Sacramento, CA

A Randomized, Cross-Over Controlled Trial of Dronabinol and Vaporized Cannabis in Neuropathic Low Back Pain

Roya Yumul, MD, PhD
Cedars-Sinai Med Center
Los Angeles, CA

Intra-operative ketamine and methadone for laminectomy: effect on recovery, post-operative pain, and opioid requirements

APPENDIX B

CURRENTLY OPEN (*through December 31, 2015*)
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Multicenter, Safety, Tolerability, and Dose-Ranging Study of Samidorphan, A Component of ALKS 383, in Adults with Schizophrenia Treated with Olanzapine (ALK3831-302)
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Treatment of Major Depressive Disorder (Study I) (ALKS5461-205)
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALK5461 for the Adjunctive Treatment of Major Depressive Disorder (Study II) (ALKS5461-206)
Alkermes, Inc. Waltham, MA	A Phase 2, Randomized, Double-Blind Study to Evaluate Efficacy, Safety, and Tolerability of ALKS3831 in Subjects with Schizophrenia with Alcohol Use Disorder (ALKS3831-401)

Appendix B Cont.

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Alkermes, Inc. Waltham, MA	A Phase 3 Efficacy & Safety Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-207)
Alkermes, Inc. Waltham, MA	A Phase 3 E & S Study of ALKS5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-5 Study) (ALKS5461-208)
Alkermes, Inc. Waltham, MA	A Phase 3 Study to Evaluate Weight Gain of ALKS 3831 Compared to Olanzapine in Adults with Schizophrenia (ALK3831-A303)
Alkermes Waltham, MA	A Phase 3 Study to Determine the Antipsychotic Efficacy and Safety of ALKS 3831 in Adult Subjects with Acute Exacerbation of Schizophrenia (ALK3831-A305)
Alkermes Waltham, MA	A Phase 3, Multicenter Study to Assess the Long Term Safety and Tolerability of ALKS 3831 in Subjects with Schizophrenia (ALK3831-A306)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Braeburn Pharmaceuticals Princeton, NJ	A Randomized, Double-Blind, Double-Dummy, Active-Controlled Multi-Center Study of Adult Outpatients with Opioid Dependence Transitioned from a Daily Maintenance Dose of 8mg or Less of SL Buprenorphine or Buprenorphine/Naloxone to Four Probuphine Subdermal Implants (PRO-814)
CNS Therapeutics CRO: Social & Scientific Systems	A Controlled, Two-Arm Parallel Group, Randomized Withdrawal Study to Assess the Safety and Efficacy of Hydromorphone HCl Delivered by intrathecal Administration a Programmable Implantable Pump (HYD201US)
CNS Therapeutics CRO: Social & Scientific Systems	A Phase 3 Open-Label, Single-Arm Study To Assess The Safety of Hydromorphone HCl Delivered by Intrathecal Administration (HYD202US)
Collegium CRO : INC Research	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of Oxycodone DETERx™ Versus Placebo in Opioid-Experienced and Opioid-Naïve Subjects with Moderate-to-Severe Chronic Low Back Pain (CO-OXYDET-08)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Cortbus
Norwood, MA

A Phase 2, Double-Blind, randomized,
Placebo-Controlled Multicenter Study to
Evaluate safety, Tolerability, Efficacy, and
Pharmacokinetics of JBT-101 in Cystic
Fibrosis
(BT101-CF-001)

Cortbus
Norwood, MA

A Phase 2, Double-Blind, Randomized,
Placebo-Controlled Multicenter Study to
Evaluate Safety, Tolerability, Efficacy, and
Pharmacokinetics of JBT-101 in Diffuse
Cutaneous Systemic Sclerosis
(JBT101-SSc-001)

Grunenthal/Janssen
CRO : inVentiv
Cary, NC

An Evaluation of the Efficacy & Safety of
Tapentadol Oral Solution in the Treatment of
Post-Operative Acute Pain Requiring Opioid
Treatment in Pediatric Subjects Aged from
Birth to Less than 18 Years old
(KF5503/65)

GW
Cambridge, UK

Panel Approved Research Project

GW
Cambridge, UK

Panel Approved Research Project

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project
GW Cambridge, UK	Panel Approved Research Project

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

INSYS Therapeutics
Chandler, AZ

A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Lennox-Gastaut Syndrome
(INS011-14-024)

INSYS Therapeutics
Chandler, AZ

A multicenter, randomized, double-blind, placebo-controlled, interventional study to assess the safety and efficacy of pharmaceutical Cannabidiol Oral Solution as adjunctive therapy for treatment of subjects with inadequately controlled Dravet Syndrome
(INS011-14-025)

INSYS Therapeutics
Chandler, AZ

A multicenter, open-label, flexible dose study to assess the long-term safety of pharmaceutical Cannabidiol Oral Solution as an adjunctive treatment for pediatric and adult subjects with a treatment-resistant seizure disorder who complete INS011-14-024, INS011-14-025, or INS011-14-029
(INS011-14-030)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
INSYS Therapeutics Chandler, AZ	A Phase 2 Study to Assess the Efficacy and Safety of Cannabidiol Oral Solution for the Treatment of Refractory Infantile Spasms (NIS011-15-054)
INSYS Therapeutics Chandler, AZ	A Phase I/II Study to Assess the Pharmacokinetics and Safety of Multiple Doses of Pharmaceutical Cannabidiol Oral Solution in Pediatric Subjects with Treatment-Resistant Seizure Disorders (INS011-14-029)
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study
Ironshore CRO: Rho Chapel Hill, NC	Panel Approved Research Study
Janssen Raritan, NJ	An Open-Label, Randomized, Single-Application, Two-Period Crossover, Pivotal Bioequivalence Study to Evaluate the Bioequivalence of Fentanyl Transdermal System (JNJ-35685-AAA-G021) Compared with DURAGESIC® Fentanyl Transdermal Patch in Healthy Subjects (FENPAI1023)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Janssen
Raritan, NJ

A Randomized, Partially-Blind, Two-Arm, Single-Application, 3-Way Crossover Study to Evaluate the Adherence of 2 Strengths of Newly Manufactured Samples and Aged Samples of a New Formulation (JNJ-35685-AAA-G016 and JNJ-35685-AAA-G021) of Fentanyl Transdermal System Compared with DURAGESIC® Fentanyl Transdermal Patch in Healthy Subjects
(FENPAI1025)

Lannett
CRO : Parexel
Waltham, MA

A Phase 3 Investigation of Topical Application of Cocaine 4% and 10% on Safety & Efficacy in Local Anesthesia for Dx Procedures & Surgeries on or through Accessible Mucous Membranes of the Nasal Cavities
(COCA4vs10-001)

MAPS
Santa Cruz, CA

A Placebo-Controlled, Randomized, Blinded, Dose Finding Phase 2 Pilot Safety Study of MDMA-Assisted Therapy for Social Anxiety in Autistic Adults
(MAA-1)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
MAPS Santa Cruz, CA	A Randomized, Double-Blind, Placebo-Controlled Study of MDMA-Assisted Psychotherapy for Anxiety Associated with a Life-Threatening Illness (MDA-1)
Nektar CRO: PRA Lenexa, KS	A Phase 3, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of NKTR-181 in Opioid-Naive Subjects with Moderate to Severe Chronic Low Back Pain (14-181-07)
Nektar CRO: PRA Lenexa, KS	A Phase 3, Multicenter, Open-Label, 52-Week Study to Evaluate the Long-Term Safety and Tolerability of NKTR-181 in Subjects with Moderate to Severe Chronic Low Back Pain or Chronic Noncancer Pain (14-181-08)
Pfizer CRO: ICON New York, NY	An Open-Label Study to Evaluate the Pharmacokinetics and Safety of ALO-02 (Oxycodone Hydrochloride and Naltrexone Hydrochloride) Extended-Release Capsules in Children and Adolescents 7-17 Years of Age Who Require Opioid Analgesia (B4531015)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Shire
CRO : Premier Research Group
Alexander, NC

A Phase 3, Multicenter, Randomized,
Double-Blind, Parallel-Group,
Placebo-Controlled, Dose-Optimization Study
to Evaluate the Efficacy, Safety, and
Tolerability of SPD489 in Adults Aged 18-55
Years with Moderate to Severe Binge Eating
Disorder
(SPD489-343)

Alkermes
Waltham, MA

Shire
CRO : Premier Research Group
Little Egg Harbor, NJ

A Phase 4, Randomized, Double-blind,
Multicenter, Parallel-group, Active-controlled,
Dose-optimization Safety and Efficacy Study
of SPD489 (Vyvanse®) Compared with
OROS-MPH (Concerta®) with a Placebo
Reference Arm, in Adolescents Aged 13-17
Years with Attention-deficit/Hyperactivity
Disorder (ADHD)
(SPD489-405)

Shire
CRO : Premier Research Group
Little Egg Harbor, NJ

A Phase 4, Randomized, Double-blind,
Multicenter, Parallel-group, Active-controlled,
Forced-dose Titration, Safety and Efficacy
Study of SPD489 (Vyvanse®) Compared with
OROS-MPH (Concerta®) with a Placebo
Reference Arm, in Adolescents Aged 13-17
Years with Attention-deficit/Hyperactivity
Disorder (ADHD)
(SPD489-406)

<u>Sponsor</u>	<u>Description or Title of Clinical Drug Trial Protocol</u>
Shire CRO: PPD San Diego, CA	A Phase 2, Open-Label, Multicenter, Exploratory Safety, Tolerability, Pharmacokinetic, and Efficacy Study of SPD489 in Preschool Children Aged 4-5 Years with Attention-deficit/Hyperactivity Disorder (SPD489-211)
Shire Wayne, PA	A Phase 3, Randomized, Double-blind, Multi-center, Placebo-controlled, Dose-Optimization, Safety and Efficacy Study of SHP465 in Children and Adolescents Aged 6-17 years with Attention Deficit Hyperactivity Disorder (ADHD) (SHP465-305)
Shire CRO: PPD San Diego, CA	A Phase 3, Open-label, Multicenter, 12-Month Safety and Tolerability Study of SPD489 in Preschool Children Aged 4-5 Years Diagnosed with Attention-Deficit /Hyperactivity Disorder (SPD489-348)
Shire CRO: Premier Research San Diego, CA	A Phase 3, Randomized, Double-Blind, Multicenter, Placebo-Controlled, Forced-Dose Titration, Safety and Efficacy Study of SHP465 in Adults Aged 18-55 Years with Attention-Deficit/Hyperactivity Disorder (ADHD) (SHP465-306)

Appendix B Cont.

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Teva
Raleigh, NC

A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Analgesic Efficacy and Safety of Hydrocodone Bitartrate/Acetaminophen Immediate-Release Tablets (TV-46763) at Doses of 5.0 mg/325 mg, 7.5 mg/325 mg, and 10 mg/325 mg Every 4 to 6 Hours in Patients with Moderate to Severe Pain Following Bunionectomy (TV46763-CNS-30031)

Tris
Chapel Hill, NC

Amphetamine Extended-Release Oral Suspension in the Treatment of Children with ADHD: A Laboratory School Study (TRI102-ADD-001)

USWorldMeds
Louisville, KA

A Phase 3, Open-Label, Safety Study of Lofexidine (USWM-LX1-3003-2)

APPENDIX C

CURRENTLY OPEN (*December 31, 2015*)
RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

<u>Investigator or Sponsor</u>	<u>Description or Title of Research Study</u>
Keith Heinzerling, M.D. UCLA Los Angeles, CA	Randomized Trial of Ibudilast for Methamphetamine Dependence
Lara Ray, Ph.D. UCLA Los Angeles, CA	The Effects of Naltrexone on Neural Responses to Methamphetamine Cues
Lara Ray, Ph.D. UCLA Los Angeles, CA	Effects of Ibudilast on Non-treatment Seeking Patients Who Meet Criteria for Alcohol Abuse or Dependence
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline for Methamphetamine Dependence

Appendix C Cont.

Investigator or Sponsor

Description or Title
of Research Project

Alkermes
Waltham, MA

A Phase 3 Study of Evaluate the Safety, Tolerability, and Efficacy of Naltrexone for use in Conjunction with Buprenorphine in Adults with Opioid Use Disorder Prior to First Dose of Vivitrol (ALK6428-A301)

NIDA
Bethesda, MD

Phase 2, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial of Nopicastat for Cocaine Dependence (NIDA/VA CS# 1031)

NIDA
The EMMES Corp.
Rockville, MD

Achieving Cannabis Cessation-Evaluating N-Acetylcysteine Treatment (ACCENT) (NIDA CTN Protocol 0053)

NIDA
The EMMES Corp.
Rockville, MD

Extended-Release Naltrexone vs. Buprenorphine for Opioid Treatment (X:BOT)

APPENDIX D

SECTIONS CONCERNING THE RESEARCH ADVISORY PANEL FROM THE CALIFORNIA HEALTH AND SAFETY CODE

§ 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to § 11480 and § 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

§ 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with § 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

The Panel shall annually select a chairman from among its members.

Appendix D Cont.

§ 11480. Cont.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to § 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

§ 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

§ 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

§ 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in § 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

Appendix D Cont.

§ 24172. Cont.

- (i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.
- (j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to § 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

§ 24173. Cont.

- (2) A description of any attendant discomfort and risks to the subject reasonably to be expected.
- (3) An explanation of any benefits to the subject reasonably to be expected, if applicable.
- (4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
- (5) An estimate of the expected recovery time of the subject after the experiment.
- (6) An offer to answer any inquiries concerning the experiment or the procedures involved.
- (7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.
- (8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.
- (9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
- (10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.
- (11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

Appendix D Cont.

§ 24173. Cont.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

Attachment 8

ORDERING PRESCRIPTION MEDICINES ONLINE

Buying medicine on the Internet can be risky—97 percent of online pharmacies don't comply with pharmacy laws and standards. Here are some tips when purchasing online:

- Check to see if the pharmacy is licensed by the California State Board of Pharmacy at www.pharmacy.ca.gov.
- Use only pharmacy websites displaying the Verified Internet Pharmacy Practice Sites (VIPPS) seal. This guarantees the pharmacy is licensed and sells FDA-approved medicine. To find a VIPPS online pharmacy, go to www.nabp.net.
- Make sure a valid prescription is required and not available from an online doctor who is linked to the site.
- Beware of very low prices and locations outside the United States.
- Make sure a licensed pharmacist is available to answer questions.
- Check if there's a physical address, phone number or other contact information listed. Fifty percent of medicines bought from websites that hide their physical address are counterfeit, according to the World Health Organization. Also, many online pharmacies say they are located in Canada because people assume Canadian medicine is safe, but the pharmacies are really located somewhere else or the medicine is from another country.



LICENSING IS KEY

Buying your prescription medicine from a pharmacy licensed by the California State Board of Pharmacy is the best way to be sure it is safe. All pharmacies, including online pharmacies, that dispense prescription medicine to California patients must be licensed here to protect patients' health and safety.

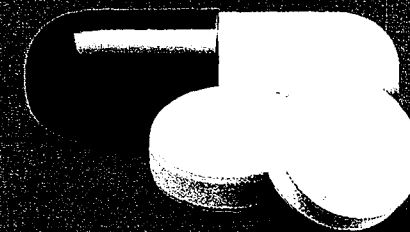


These used bottles and vials, seized during a raid in Colombia, were being washed for reuse to hold counterfeit medicines.

Licensed pharmacies are regulated and inspected. Under California and federal laws, it is illegal to sell prescription medicine without a valid prescription. Also, if a pharmacy is located in a State outside of California and sells to California residents, it must be licensed in both its home state and here.



CALIFORNIA STATE BOARD OF PHARMACY
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov



COUNTERFEIT PRESCRIPTION DRUGS

PROTECT YOURSELF,
YOUR FAMILY
AND YOUR PETS



You see an ad for prescription medicines at half of what you now pay. Sounds tempting, but be careful.

You could be buying counterfeit prescription medicine or medicine that may be expired, contain the wrong dosage or none of the active ingredient. These medicines may not work and could contain toxic ingredients that can cause allergic reactions, harmful side effects or even death.

COUNTERFEIT DRUGS EXPLAINED

Deadly ingredients that have been found in counterfeit medicine include rat poison, floor wax, brick dust, sheet rock, house paint, road paint, paint thinner, boric acid, antifreeze, PCBs, benzopyrenes, mercury, lead, cadmium, arsenic, chrome, uranium, strontium, selenium and aluminum.

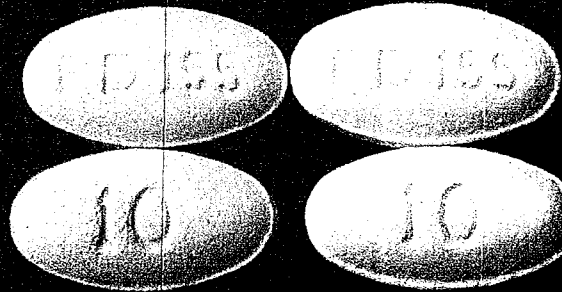
Counterfeit medicine can be generic or brand-name and includes pet medicines, antibiotics, painkillers, and drugs to treat erectile dysfunction, weight-loss, heart conditions, mental health issues, HIV, AIDS, diabetes and cancer.

These fake medicines often come from countries where government enforcement is weak, but they can be manufactured anywhere.

IS IT A FAKE?

Counterfeits often look exactly like real medicine and can even fool health care professionals, but here are some signs that your prescription drugs could be counterfeit:

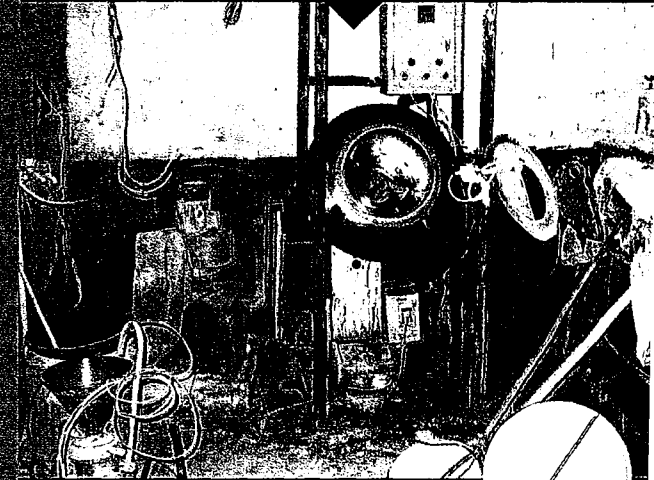
- The container label has a name for a drug you did not order.
- The pills are chipped or cracked.
- The container and packaging have changed.
- The label on the container is crooked.
- Foreign language text appears on the label.
- The medicine is in a baggie, not a prescription container.
- The drug looks or tastes differently than it did before.
- The drug causes a different reaction or does not work as well as the medicine you are used to.



Lipitor, a statin used to control cholesterol, is a Pfizer drug that is often counterfeited. Counterfeit pills, at left, are placed next to real pills, at right, for comparison. It is hard to tell a counterfeit just by looking at it, so only buy from a legitimate pharmacy.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

This counterfeit drug manufacturing site in China produced fake Viagra and other drugs that were sold to customers in Europe and the United States.



LOWER YOUR RISK

Unfortunately, the making and selling of counterfeit medicine happens and it's hard to tell a fake without chemical testing.

Be aware and protect yourself by always getting a prescription from a licensed health care provider and filling it at a licensed pharmacy. Don't buy medicines off of Craigslist or from street vendors.

If you are traveling outside the United States, be sure to bring enough of your prescription medicines. Drugs in foreign countries may be counterfeit or you may receive the wrong drug.

If you suspect you received counterfeit medicine, contact the pharmacy where you purchased it and notify:

- The California State Board of Pharmacy (916) 574-7900
www.pharmacy.ca.gov
- The U.S. Food and Drug Administration (FDA) (800) 332-1088
www.fda.gov

Buying prescription medications online
Are the drugs you buy real or fake?



What you need to know...

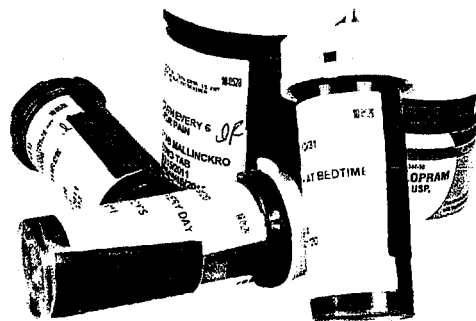
CALIFORNIA STATE BOARD OF PHARMACY

According to the FDA, many online pharmacies sell counterfeit or expired drugs that may not be safe or effective.

Counterfeit drugs have been found that contain:

- ▶ No medicine, just filler
- ▶ Too much medicine
- ▶ The wrong medicine

The result may be failure to treat your medical condition, poisoning, overdose, or even death.



**Buy from the Internet safely
and
protect your health!**

1. Use online pharmacy sites that:

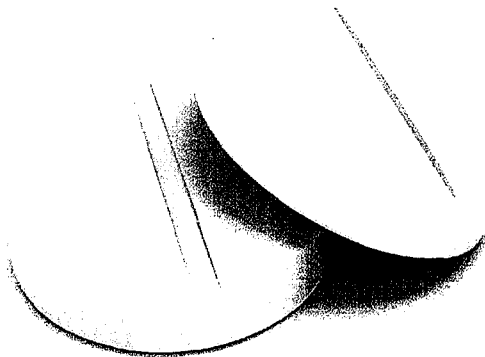
- ▶ Require a prescription from your doctor
- ▶ Display the VIPPS symbol



Verified Internet Pharmacy Practice Sites [VIPPS]
sell federally-approved medications.

2. Make sure the pharmacy is licensed in California:

Go to "Verify a License" at www.pharmacy.ca.gov



**For more consumer tips on safely buying and
taking prescription drugs,**

visit the California State Board of Pharmacy
www.pharmacy.ca.gov

Choose the link to **Information for Consumers**

1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
tel: 916-574-7900

California State
Board of Pharmacy



BE AWARE & TAKE CARE:
Talk to your pharmacist!

PDE 11_201 4.2012

Attachment 9



INTRODUCTION TO PRESCRIBING GUIDELINES COMPARISON



Attached is a comparison between the Centers for Disease Control and Prevention's (CDC) *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's (MBC) *Guidelines for Prescribing Controlled Substances for Pain*. While there are a few differences between these two prescriber guidelines, overall there are many more similarities demonstrating how each complements the other and together can be effective educational tools for prescribers. Differences between the two Guidelines are not due to contradicting opinions/recommendations, but rather to the intended use and audience for each.

BACKGROUND

The Medical Board of California is a state regulatory agency whose mission is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions. The MBC is the only entity who can take disciplinary action against a California physician's license. In prescribing cases, the MBC takes action based upon the standard of care that a physician provides to a specific patient.

The Centers for Disease Control and Prevention is a federal agency that conducts and supports health promotion, prevention and preparedness activities in the United States with the goal of improving overall public health. As the nation's health protection agency, CDC's mission is to save lives and protect people from health threats. CDC's primary role is tackling the biggest health problems causing death and disability for Americans, including reducing deaths due to prescription painkiller abuse and overdose.

INTENDED USE

The MBC Guidelines are **intended for all physicians practicing in California**. They provide a broader range of recommendations for explicit patient populations in specific settings. The MBC Guidelines were designed to educate physicians for improved outcomes of patient care and to prevent overdose deaths due to opioid use. Since the MBC Guidelines' primary goal was to educate physicians, and are based upon the enforcement role of the MBC, the MBC Guidelines do not have the specificity that the CDC Guidelines contain.

http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf

The CDC Prescribing Guidelines were developed to address the opioid epidemic currently sweeping across the United States. The Guidelines are **intended for primary physicians** to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>

PRIMARY DIFFERENCES

1. The MBC Guidelines recommend referral to pain specialists while the CDC Guidelines encourage Primary Care Physicians (PCP) to work with their patients to manage pain.
2. The MBC endorses up to 45 days for initiating opioid trial, with the explanation that after 90 days there is risk. The CDC notes after seven (7) days there is risk with prescribing opioids.
3. The CDC recommends precaution when increasing from 50 MMEs per day and to avoid increasing past 90 MMEs per day. The MBC recommends a physician proceed cautiously once 80 MMEs per day is reached.

CDC and MBC PRESCRIBER GUIDELINES OVERALL OBJECTIVES

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs. Prescribers should be encouraged to use both Guidelines to educate themselves on appropriate prescribing practices.

COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIOIDS) FOR CHRONIC PAIN

Centers for Disease Control and Prevention (CDC) Prescriber Guidelines for Chronic Pain

Medical Board of California (MBC) Prescriber Guidelines for Substances for Pain

Background/Reason for Prescriber Guidelines and Strategy Plan

CDC recommendations are based upon the following assessment:

- No evidence of long-term benefit from opioids in pain and function for chronic pain with outcomes examined at least 1 year later;
- Extensive evidence shows the possible harms of opioids (including abuse and dependence, overdose, myocardial infarction, motor vehicle crashes); and
- Extensive evidence suggests benefits of alternative treatments compared with long-term opioid therapy, including non-pharmacologic therapy and non-opioid pharmacologic therapy, with less harm.

MBC's guidelines are intended to improve outcomes of patient care and to prevent overdose deaths due to opioid use. They particularly address the use of opioids in the long-term treatment of chronic pain.

MBC recommendations are based upon:

Special patient populations including: Emergency Departments, Urgent Care Clinics, Acute Pain, End-of-Life Pain, Cancer Pain, Older Adults, Pediatric Patients, Pregnant Women, Patients Covered by Workers' Compensation, Patients with History of Use Disorder, Psychiatric Patients, Patients Prescribed Benzodiazepines and Patients Prescribed Methadone or Buprenorphine for Treatment of a Substance Use Disorder.

These guidelines are **intended for primary care providers** who are treating patients with chronic pain (i.e., pain lasting longer than three months or past the time of normal tissue healing) in outpatient settings.

The recommendations are not intended: a) for guidance on use of opioids as part of medication-assisted treatment for opioid use disorder; b) for patients who are in active cancer treatment, palliative care, or end-of-life care.

These guidelines are **intended for all physicians** practicing in California.

These guidelines are not meant for the treatment of patients in hospice or palliative care settings or to limit treatment where improved function is not anticipated and pain relief is the primary goal.

The three sections/categories below are based upon CDC recommendations.

DETERMINING WHEN TO INITIATE or CONTINUE OPIOIDS for CHRONIC PAIN

- Non-pharmacologic therapy and non-opioid pharmacologic therapy preferred for chronic pain
- Before starting opioid therapy for pain, providers should establish treatment goals with all patients, including realistic goals for pain and function
- **Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful**
- Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety

Emergency Departments (ED) or Urgent Care Clinics

- **Physicians should avoid the routine prescribing of outpatient opioids for a patient with an acute exacerbation of chronic non-cancer pain seen in the ED**
- **If opioids are prescribed on discharge, the prescription should be for the lowest practical dose for a limited duration e.g., < 1 week.**
- The prescriber should consider the patient's risk for opioid misuse, abuse, or diversion
- **The physician should, if practicable, honor existing patient-physician pain contracts/treatment agreements and consider past prescription patterns from information sources such as prescription drug monitoring programs**

COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIOIDS) FOR CHRONIC PAIN

Centers for Disease Control and Prevention (CDC) Prescriber Guidelines for Chronic Pain

Medical Board of California (MBC) Prescriber Guidelines for Substances for Pain

DETERMINING WHEN TO INITIATE or CONTINUE OPIOIDS for CHRONIC PAIN Continued...

- Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits
- Discuss patient and provider responsibilities for managing therapy.

Acute Pain

- Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants it
- Opioid medications should only be used after determining that other non-opioid pain medications or therapies likely will not prove adequate pain relief

When considering long-term use of opioids for chronic, non-cancer pain, the physician and the patient should develop treatment goals together

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, and DISCONTINUATION

- When starting opioid therapy for chronic pain, providers should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids
- When opioids are started, providers should prescribe the lowest effective dosage
- **Providers should use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥ 90 MME/ day**
- When opioids are used for acute pain, providers 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 or fewer days usually will be sufficient for most non-traumatic pain not related to major surgery**
- Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation
- **Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently**

- When prescribed, the number dispensed should be for a short duration and no more than the number of doses needed based on the usual duration of pain
- Long (and intermediate) duration-of-action opioids or extended-release/long acting opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted
- **Methadone is rarely, if ever, indicated for treatment of acute pain**
- The use of opioids should be re-evaluated carefully if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition
- The American College of Emergency Physicians (ACEP) recommends that the use of a state prescription monitoring program may help identify patients who are at high risk for prescription opioid diversion or doctor shopping
- Treatment plan and goals should be established as early as possible in the process and revisited regularly

COMPARISON OF PRESCRIBING GUIDELINES FOR CONTROLLED SUBSTANCES (OPIOIDS) FOR CHRONIC PAIN

Centers for Disease Control and Prevention (CDC) Prescriber Guidelines for Chronic Pain

Medical Board of California (MBC) Prescriber Guidelines for Substances for Pain

ASSESSING RISK and ADDRESSING HARMS of OPIOID USE

- | | |
|---|---|
| <ul style="list-style-type: none"> • Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms • Providers 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, or higher opioid dosages (≥ 50 MME), are present • Providers 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 high opioid dosages or dangerous combinations that put him or her at high risk for overdose • Providers 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 • When prescribing opioids for chronic pain, providers 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 • Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible • Providers 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 | <ul style="list-style-type: none"> • When considering long-term use of opioids for chronic, non-cancer pain, given the potential risks of opioids, careful and thorough patient assessment is critical • The nature and extent of the clinical assessment depends on pain and the context in which it occurs – this includes: <ul style="list-style-type: none"> ◦ Complete a medical history & physical exam ◦ Performing a psychological evaluation ◦ Establishing a diagnosis and medical necessity including Pain Intensity and Interference (pain scale) and Sheehan Disability Scale ◦ Exploring non-opioid therapeutic options ◦ Evaluating both potential benefits and potential risks of opioid therapy ◦ Being aware of aberrant or drug seeking behaviors ◦ Undertake urine drug testing (as a precaution) ◦ Review the CURES/PDMP report to see if patient is receiving controlled substances from other prescribers in California • The treating physician should seek a consultation, or refer patient to, a pain, psychiatry, or addiction or mental health specialist as needed • Physicians who prescribe long-term opioid therapy should be familiar with treatment options for opioid addiction to be make appropriate referrals as needed • When considering use of opioids physicians should discuss risks/benefits of treatment plan with the patient • If prescribed, the patient and family should be counseled on safe ways to store and dispose of medications • MBC recommends that a patient consent form and pain management agreement be signed • It is important to educate patients and family/caregivers of the danger signs of respiratory depression • Compliance monitoring through CURES/PDMP and drug testing and periodic pill counting is recommended |
|---|---|

Attachment 10



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING MINUTES

Date: September 8, 2016

Location: Department of Consumer Affairs
1st Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

Committee Members Present: Victor Law, RPh, Chair
Debbie Veale, RPh, Vice Chair
Ryan Brooks, Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Debbie Damoth, Staff Services Manager
Bob Dávila, Public Information Officer

1. Call to Order and Establishment of Quorum

The meeting was called to order at 9:34 a.m. Roll call was taken, and a quorum was established.

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

There were no public comments.

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

a. Review and Discussion of Similarly Conducted Surveys on Patient Consultations

Chairperson Law noted that President Gutierrez asked the committee at the October 2015 board meeting to develop a broader survey for licensees about patient consultation. At the July 2016 board meeting, the board directed staff to research previously conducted patient consultation surveys.

Board staff contacted the Institute for Safe Medication Practices (ISMP) and the National Council on Patient Information and Education (NCPIE). Chairperson Law reviewed the following information that was provided by ISMP and NCPIE, which also was included in the meeting materials:

- Pharmaceutical Consultation in UAE Community Pharmacies, N. M. Hamoudi, A. A. Shirwaikar, H. S. Ali, and E. I. Al Ayoubi, *Indian J Pharm Sci.* 2011 Jul-Aug; 73(4): 404–408 – Provides sample questions on pharmacists’ opinions on patient counseling and the use of consumer product information (CPI) and patient information leaflet (PIL).
 - Patient counseling and giving out CPI/PIL is my professional responsibility.
 - PIL and CPIs will ease my counseling tasks.
 - Patient counseling and giving out CPI to customers will enhance my financial costs.
 - I should get paid for counseling and giving out PILs.
 - Counseling and information leaflets have no role in my practice.
 - Counseling will increase my dispensing workload and thus I need extra staff
 - Patient counseling and giving out CPI/PIL is the responsibility of the prescriber.
 - Customers will experience medication side effects when I give out CPI.
 - Patient counseling will improve my sales and reputation of my pharmacy.
 - For effective counseling act, I need training.
 - Customers do not show any interest toward counseling or PIL.
 - Patient counseling and information leaflets contain more information which contradicts with the prescriber’s information.

- Counselling Practices in Community Pharmacies in Riyadh, Saudi Arabia: A Cross-Sectional Study, Sinaa Alaqeel and Norah O. Abanmy, Alaqeel and Abanmy *BMC Health Services Research* (2015) 15:557 – Provides statements from pharmacists regarding barriers to counseling.
 - Pharmacists have limited drug resources.
 - Pharmacists are too busy.
 - Pharmacists do not have the patient history.
 - Pharmacists lack confidence in their knowledge.

- Attitude of Community Pharmacists towards Patient Counseling In Saudi Arabia, *The Internet Journal of Pharmacology.* 2010 Volume 9, Number 2 – Provides several topics of interest.
 - Pharmacists’ attitudes to items about the professional responsibilities of the community pharmacist.

- The pharmacist should counsel patient about prescribed medication.
- The community pharmacist should counsel patients about OTC medication.
- The community pharmacist should keep up-to-date knowledge of current drug information.
- The community pharmacist should attend continuing education regularly.
- The community pharmacist should have good working relationships with health care providers.
- The community pharmacist should be committed with the rules and regulation governing the practice of pharmacy.
- Pharmacists' attitudes towards items about reasons for deciding to counsel.
 - Medications are more likely to be taken as they should be taken.
 - With regular customers, I know enough about them to be able to counsel effectively.
 - I am a respected member of community and expected to give advice.
 - Counseling improves patient compliance.
 - Counseling improves patient/pharmacist relationship.
 - Counseling brings more people into the pharmacy.
 - Counseling increases provisional relationships.
 - Customers appreciate extra care and interest I show in them.
 - Counseling enables me to become an active member of the health care team.
 - Counseling may prevent the patient from experiencing an adverse drug effect.
 - Counseling reduces drug wastage.
 - Counseling increases sales.
 - Counseling increases job satisfaction.
 - Counseling improves my knowledge and practicing ability.
- Pharmacists' attitudes towards items about reasons against deciding to counsel.
 - I should not counsel without adequate medical history.
 - People do not respect the advice of a pharmacist.
 - I am too busy.
 - I am not paid for counseling.
 - I do not like talking to consumers.
 - Counseling does not lead to a significant improvement in health care.
 - Counseling may not be necessary.
 - Counseling is not my responsibility beyond but should be

- performed by the doctor.
 - Counseling increases professional responsibility beyond which I am prepared to accept.
 - I lack confidence in my knowledge.
 - There is a lack of feedback from people.
 - Customers do not perceive the benefit.
 - I do not know enough about drugs and their effects.
 - I do not know how to approach people.
 - I am worried about contradicting doctors.
- A comparison of patients' and pharmacists' satisfaction with medication counseling provided by community pharmacies: a cross-sectional survey, Yang et al. BMC Health Services Research (2016) 16:131 – Provides statements for reasons why community pharmacists' perceive barriers to patient consultation.
 - Pharmacists' lack of time.
 - Patient's lack of time.
 - Low level of patient demand and expectation.
 - Lack of educational programs.
 - Lack of communication skills.
 - Lack of patients' information.
 - Lack of continuing education for counseling.
 - Risk-Informed Interventions in Community Pharmacy: Implementation and Evaluation, Cohen, Michael R. and Judy L. Smetzer, Institute for Safe Medication Practices, September 14, 2009.

Ms. Veale asked if these were the only studies that ISMP and NCPIE could provide and whether any studies of patient consultation were available that were done recently in the United States. Ms. Veale stated the board feels that something must be done to increase pharmacist consultations with patients and that the board was looking for a study that could be the backbone of the board's efforts. Ms. Damoth replied that she could not find studies in her own research, so she reached out to ISMP and NCPIE. She said that the groups directed her to these studies – mostly from ISMP, because information provided by NCPIE was not relevant.

Mr. Brooks said an earlier board survey on why pharmacists do not do consultations provided answers that the board already knew. He asked what jurisdiction the board has other than enforcement and noted that the board cannot force pharmacies to pay more money or change their structure to increase consultations. He expressed uncertainty about where the board was going with this.

Chairperson Law said that the board could enforce patient consultation requirements but has not really done so. He said the licenses of both the pharmacist and the pharmacy could be disciplined if the board found that they were not doing consultations. Mr. Brooks said the board does not need a survey; the board simply needs to enforce the requirement for patient consultations. Chairperson Law agreed but added that board members feel that having a study showing that that doing patient consultations can improve patient compliance and reduce medication errors would be helpful.

Ms. Veale said that the board is doing some enforcement but that members also want to consider legislation. Ms. Herold pointed out that the board already has a requirement in place for consultation.

Ms. Veale said the board is not looking at consultation itself but how to make the pharmacist more available in the pharmacy for patients. She said that the board's study showed that pharmacists feel that they are not available because board regulations are keeping them away from the consultation and forcing them to do tasks that are non-discretionary. She said the purpose of this survey was to look at regulations and that perhaps the issue should be handled by the Licensing Committee. She added that at the last board meeting, members seemed to come to the conclusion that maybe another study is not needed. She said that all the studies seem to reach the same conclusion, so maybe the issue should simply be handed to Licensing.

Chairperson Law said that there is nothing in the board's regulations to impose a severe punishment on violators and asked if the board needs a statutory change. Ms. Herold noted that the board currently has the ability to revoke a license if the board wanted to take formal discipline against a pharmacist for failing to consult or if there were evidence that an error would not have happened if the pharmacist had taken time to consult.

As an example, Ms. Herold cited an example that would not have happened if the pharmacist had provided a patient consultation. She said that, at the board's request, staff has been citing and fining for a long time where there is proof of failure to consult. Staff has cited and fined three chains – Walgreens, CVS and Rite Aid – for failure to consult. She said that eventually it may become more expensive to chains to not consult than to provide consultations. She added that, under a “three strikes and you're out” policy, if there are three violations for failure to consult, the case is referred to the Attorney General's office for formal discipline.

Chairperson Law said that he agreed with a “three strikes” rule because even if the pharmacy or pharmacist or pharmacy management gets a first strike, they would make sure that any pharmacist working on the shift does consultations. In addition, he said, they would tell pharmacists that their main job is giving consultations, not filling prescriptions.

Mr. Brooks asked what barriers are placed on pharmacies that the board could remove or change to make pharmacies more efficient. He said that is the important question and that a questionnaire about patient consultations probably could not provide the answers.

Ms. Veale said that there are some tasks that the board has burdened the pharmacist with that could be offloaded to others. She said that was the reason the board was going through the process of looking for studies to back up the board's efforts. She said that during the last few committee and board meetings, members were getting comfortable with not having a survey to move forward.

Ms. Veale said maybe the board should compile a list of non-discretionary tasks that are keeping pharmacists from providing consultations to patients and consider whether they can be offloaded to the pharmacy technicians. Mr. Brooks suggested that the board direct staff to put together the regulations on one side and recommendations on how to streamline them on the other side, and then the board could act on that.

Ms. Veale said the committee should recommend to the board that the issue be passed to the Licensing Committee to look at the regulations. Chairperson Law said that he agreed and that there is no point in getting more surveys. Mr. Brooks seconded Ms. Veale's proposed recommendation.

Public comment: Paige Talley of the California Council for the Advancement of Pharmacy said that she believes more counseling is done in situations when a parent is picking up medication for a child or at a compounding pharmacy or specialty pharmacy. She also thanked the board for fining chains for not complying with counseling requirement. She said that her pharmacy now gives a consultation each time she picks up medications, and she suggested that pharmacies display signs informing patients that they must be counseled about their medications. Ms. Herold replied that patients will not demand a meaningful consultation until they begin receiving it; once they start demanding it, it will be built into their health care plan.

Lori Hensic of Kaiser Permanente agreed that additional surveys of pharmacists regarding patient consultation would not be helpful for increasing patient consultation. To find ways to ensure that patient consultations are meaningful, she said that it could be more useful instead to collect information from patients. She suggested asking customers why they did not get a consultation when picking up a prescription.

Motion: Recommend that the board re-direct the subject of patient consultation to the Licensing Committee; recommend that the Licensing Committee focus on regulations that could be streamlined to increase pharmacist availability for consultations; and recommend that no survey be conducted.

M/S: Veale/Brooks

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	X			

b. Review and Discussion of the Department of Consumer Affairs Developed Patient Consultation Survey

Chairperson Law reported that, at the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office’s ability to develop the patient consultation survey for the board’s licensees. During the meeting, the committee provided basic parameters to Dr. Montez regarding the survey, including intent, privacy for participants, and various practice settings that must be addressed.

Chairperson Law said the committee directed board staff to work with Dr. Montez’s team on the development, administration and completion of the survey. The committee agreed to a target date of September 2016 for the committee to review the survey.

Chairperson Law noted that, at the July 2016 board meeting, the board directed staff to review the proposal submitted by the Department of Consumer Affairs. Board staff met with Dr. Montez and her team in the beginning of September 2016.

Ms. Herold told the committee that staff contacted various health foundations including the Kaiser Foundation, but none was interested in doing a survey. She said staff also reached out to DCA. Ms. Damoth said DCA estimated a contract price of \$15,000 to \$20,000 for staff work, plus \$1 for each pharmacist surveyed. Ms. Herold said DCA suggested reaching 10,000 to 20,000 pharmacists. Ms. Herold said perhaps the board could use that money to find a better way to encourage patient consultation.

Motion: Recommend canceling the pharmacist survey by the Department of Consumer Affairs.

M/S: Veale/Brooks

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

4. Update and Discussion on the Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including its Impact on Pharmacy Translations and Interpretations

a. Overview and Summary

Chairperson Law said that a new rule issued by the U.S. Department of Health and Human Services requires pharmacies to provide “meaningful access” to customers with limited English proficiency – including posting taglines written in at least 15 languages advising the public that interpreter and translation services are available free of charge.

Chairperson Law said that the regulation implements Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule went into effect on July 18, 2016. A copy of the board’s draft newsletter article on this requirement, the APHA summary documents and Federal Rule itself were included in the committee meeting materials.

Chairperson Law told the committee that the rule appears to pre-empt the board’s rules and regulations on prescription label translations.

b. Board Statutes and Regulations Impacted

Chairperson Law noted that a cursory review indicates the following statutes and regulations may be impacted by the new federal rule:

Business and Professions Code Sections:

- 4076 – Prescription Container – Requirements for Labeling
- 4076.5 – Standardized, Patient-Centered Prescription Labels; Requirements
- 4076.6 – Dispenser Shall Provide Translated Directions for Use Printed on Container Label or Supplemental Document Upon Request; Dispenser Responsible for Accuracy of Translation; Veterinarian Excepted
- 4122 – Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information 16 California Code of Regulations Sections:
- 1707.5 – Patient-Centered Labels for Prescription Drug Containers; Requirements
- 1707.6 – Notice to Consumers

Ms. Freedman asked if there are any pharmacies that do not receive federal funds and therefore would not be affected by the new federal rule. Chairperson Law and Ms. Veale said that some specialty compounding pharmacies might not receive Medicare or

Medicaid funds, but they would constitute a small percentage of all pharmacies. Ms. Herold noted that it would be unfair to have separate standards of care for consumers by defining a benefit based on reimbursement.

In addition, Ms. Herold agreed that the federal rule appears to pre-empt the board's requirements for label translations. She added that, although the effective date was June 19, there is a 90-day implementation period – so the implementation date would be Oct. 19. But she said that she asked a couple of large chains what they were doing to comply with the law, and they told her that they were astounded when the new rule came out because no one saw it coming. She said that the board learned of the new law right before it took effect. She recommended that the board move in the direction of creating a single standard of care for the state, and Ms. Freedman agreed.

Ms. Herold asked Chairperson Law if he were ready to implement the federal rule in his pharmacies. Chairperson Law replied that he was not prepared to handle 15 languages and would need time to work with a software company.

Ms. Veale noted that the federal law refers to the top 15 languages in each state. She noted that the board previously had identified the top 12 languages in the state for Medi-Cal purposes. Ms. Herold said the data on the top 15 languages is available and that the California Pan-Ethnic Health Network has been helpful in this area.

Ms. Herold said that existing telephone interpreter services will help with the oral requirements of the new law, but translated label instructions will require more work. Ms. Veale noted that the board already provides label translations in five languages and asked if the board now must provide them in 15 languages. She suggested that the board could consider doing label translations in 15 languages or simply not provide the label translations for the current five languages anymore.

Ms. Veale said that many pharmacies have access to translation software that could be expanded. She said that perhaps the board should “pull off” the label directions currently provided in five languages and let pharmacies do their own translations.

Ms. Herold suggested that the board invite pharmacists to the October board meeting to talk about how they are complying with the new federal rule. Committee members said that was a good idea and suggested that software vendors also be invited. Ms. Herold said the discussion would give the board time to develop a reasoned approach to complying with the federal rule.

Chairperson Law said that software programs make it easy to translate label directions into other languages. Mr. Brooks noted that Google apps do not always provide accurate language translations. Ms. Veale said that pharmacies generally have translation software systems that are more sophisticated and accurate than Google.

Ms. Veale said she agreed with Ms. Herold that the board should take some time and set up a stakeholder meeting. Ms. Herold said that hearing from pharmacists about what they are doing or plan to do to comply with the federal regulation will give the board information to determine the direction the board would like to go and how to proceed. Ms. Veale said it would be helpful for staff or Ms. Freedman to advise the board on specific board regulations that pose issues for the federal regulation and to draft language for possible solutions.

Mr. Brooks expressed concern that, unlike major chains, small local pharmacies might not be able to afford or might not want to spend money on software translation services and instead rely on Google apps.

Ms. Herold said that a key subject for a board discussion is how pharmacies are complying with the new federal rule – especially since they will be subject to audits to ensure compliance and could be in trouble if they are not in compliance by the October implementation date. She said that she was not aware that any other boards of pharmacy had discussed this issue. She added that complying with the new federal rule would be a major project for pharmacies nationwide as well as other health-care providers who receive federal funding.

Motion: Bring the federal rule implementing Section 1557 of the Affordable Care Act to the board’s attention at the September board meeting and ask the board to invite stakeholders to the October board meeting for a discussion about how they are complying or plan to comply with the rule.

M/S: Brooks/Veale

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

Ms. Freedman clarified with the committee members that the intent of the motion was put the item on the September board agenda to discuss only the logistics – not the substance – of a board meeting with stakeholders that is to be held in October.

c. Development of Prescription Label Translations of Directions for Use Pursuant to Business and Professions Code section 4076.6

Ms. Veale noted that this subject was discussed by the Communication and Public Education Committee in May and reported to the full board in July. A staff report noted

that the far broader provisions in the Affordable Care Act (ACA) now pre-empt the board's planned activities in this area.

Chairperson Law said that any discussion of future public education activities in relation to AB 1073 should be postponed pending the final outcome of the board's discussions on the new federal rule on label translations.

Lori Hensic of Kaiser Permanente asked for clarification on the committee's plan for addressing the issues raised by the new federal rule and bringing those issues to the full board's attention. Ms. Herold replied that before changing any regulations and statutes, board members want to hear from licensees about what they feel is needed, what they can do, and what they can't do to comply with the new federal rule. Ms. Freedman noted that the committee is recommending that in September the board discuss how it would have that meeting in October.

5. Update and Discussion on Development of FAQs Received from ask.inspector@dca.ca.gov

Chairperson Law noted that, currently, the board has available to its licensees and the public 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.

Chairperson Law said that, 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.

Chairperson Law said that board staff had drafted an initial collection of FAQs that were sent for review by the board's legal counsel. Ms. Damoth told the committee that board staff received the FAQs along with comments from counsel. She added that they would be posted on the board's website as soon as the FAQs and comments are synthesized.

Chairperson Law asked if the final FAQs would be posted online without committee members reviewing them first. Ms. Sodergren said that decision was up to the committee. Committee members said that they did not need to see them again before they are posted.

Motion: Direct the Executive Officer to post the FAQs online after staff has finished them.

M/S: Brooks/Veale

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

6. Discussion and Consideration of Naloxone-Related Matters

a. Communication to the California Healing Art Boards Regarding Naloxone

Chairperson Law reported that, at previous committee meetings, committee members have expressed interested in reaching to out to California healing arts boards regarding naloxone access, regulation and protocol.

Chairperson Law told the committee that board staff drafted an article about pharmacists and naloxone to be shared with the other California Healing Arts Boards. He said that the article would be provided to the other California Healing Arts Boards with a cover letter from California State Board of Pharmacy Executive Officer Virginia Herold. A copy of the article was included in the meeting materials.

Ms. Damoth told the committee that the cover letter was under review and that it would be sent to all the healing arts boards. Chairperson Law thanked board staff and said that it is important that other healing arts practitioners know what is going on in the pharmacy profession.

b. Naloxone FAQs

Chairperson Law reported that, at previous committee meetings, committee members have expressed the need for a naloxone FAQ. He said that board staff drafted naloxone FAQs that were under legal review. Ms. Damoth told the committee that the FAQs would be posted as soon as staff has finished synthesizing them with comments from legal counsel. Chairperson Law replied that the committee recommends that the FAQs be posted as soon as they are ready.

c. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

Chairperson Law reported that SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016) requires the State Department of Public Health, subject to an appropriation for this purpose in the Budget Act of 2016, to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide Naloxone to first responders and to at-risk opioid users through programs that serve at-risk drug users, including, but not limited to, syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers.

Chairperson Law said that there is approximately \$3 million available from this law. But he added that the board is not eligible to apply for the funding.

Ms. Herold said that pharmacies that want to provide naloxone should apply to the Department of Public Health for this money. She said that she belongs to a committee with CDPH members and that she would disseminate information about application guidelines to pharmacies as soon as it is available. She urged pharmacists to apply for the money especially now that they have authority to furnish naloxone and added that she also notified the California Pharmacists Association to inform its members about this funding.

Ms. Veale asked if information about the available funding could be disseminated as a subscriber alert. Ms. Herold said yes but added that she wants to wait so that the board can also let subscribers know at the same time how to apply for the funding.

Ms. Veale told the committee that many pharmacies are not dispensing naloxone. She suggested that subscriber alerts also be sent out every so often to remind pharmacists that they now can provide naloxone and direct them to the protocol on the board's website. She said that she recently was at a CE session and that there were a lot of pharmacists who do not know what they are supposed to be doing with naloxone.

Ms. Herold said board staff could develop an article that could be sent out as a subscriber alert to pharmacies about this. She said the article could remind pharmacists that, with an hour of CE, they can dispense naloxone on their own authority. She said staff could develop a statement about it that could be sent out as a subscriber alert and perhaps do the same for immunizations and hormonal

contraceptives.

Ms. Damoth noted that the upcoming issue of *The Script* would include an article about the regulations authorizing pharmacists to furnish naloxone. Ms. Herold said staff could repurpose or refocus the article and send it out as a subscriber alert. She also expressed support for Ms. Veale's suggestion about sending subscriber alerts to remind pharmacists that taking an hour of CE in furnishing naloxone would enable them to meet the health care needs of their patients who are receiving opioids.

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

Chairperson Law reported that, on July 22, 2016, President Obama signed into law US S. 524 – known as the Comprehensive Addiction and Recovery Act (CARA) of 2016 – in an effort to combat the national epidemic of prescription opioid abuse and heroin use. A copy of the enacted law was included in the meeting materials.

There were no comments from committee members or the public.

i. Lali's Law

Chairperson Law reported that, according to Congressman Bob Dold's website, Lali's Law was passed by the House by a vote of 415-4 on May 12, 2016, and the bill was signed into law as part of the Comprehensive Addiction and Recovery Act of 2016 on July 22, 2016. A copy of the press release was included in the meeting materials.

Chairperson Law said that Lali's Law will increase access to naloxone throughout the United States. The bill is named in memory of Alex Laliberte, a Buffalo Grove, Ill., resident and Stevenson High School graduate, who passed away seven years ago from a drug overdose.

Chairperson Law said that Lali's Law creates a competitive grant program that will help states increase access to naloxone. The primary purpose of the grant is to fund state programs that allow pharmacists to distribute naloxone without a prescription. Many states use these programs to allow local law enforcement officers to carry and use naloxone.

Chairperson Law asked if the grants were available to everyone in California and all the states. Ms. Herold said that awarding grants is a competitive process and that state agencies such as the Justice Department and the Department of Public Health both pursue grants for purposes such as this. She said that she did not know if the Board of

Pharmacy would be a potential grantee but added that the board could consider applying.

Ms. Herold asked Ms. Freedman if the board would need status as a 501(c)(3) organization to apply for grants. Ms. Freedman replied that she had not yet reviewed that aspect of the law and whether the board could apply for grants would depend on how the law is written. She said that she also would also want to review the board's authority, because the board is authorized to do only certain things.

Ms. Freedman said that the board might be better suited to facilitate or get the word out about Lali's Law. Ms. Herold said that perhaps staff could add the information to the subscriber alert and suggested contacting the lawmaker's office for information on how they expect grants to be distributed. She added that, if the grants are part of the budget, the federal budget year begins in October.

There were no comments from the public.

ii. Provisions regarding Partial Fills for Schedule II

Chairperson Law reported that, as one of the many provisions of the Comprehensive Addiction and Recovery Act of 2016, the CARA provides for partial fills of Schedule II Controlled Substances as outlined below:

SEC. 702. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.

(a) IN GENERAL.-Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SURSTANCES.

"(1) PARTIAL FILLS.-A prescription for a controlled substance in Schedule II may be partially filled if-

"(A) it is not prohibited by State law;

"(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

"(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(2) REMAINING PORTIONS.-

"(A) IN GENERAL.-Except as provided in subparagraph (B),

remaining portions of a partially filled prescription for a controlled substance in Schedule II

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.-In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in Schedule II-

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.

"(3) CURRENTLY LAWFUL PARTIAL FILLS.-Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before the date of enactment of this subsection, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled."

(b) RULE OF CONSTRUCTION.-Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

Chairperson Law noted that Section 702 (f)(2)(A)(ii) conflicts with California law, which is 6 months or 30 days once partially dispensed.

Ms. Veale said that the federal law is more restrictive but added that California must follow the federal law. Ms. Herold noted that the board also has other provisions dealing with partially filling Schedule II drugs, but the federal law appears to be more restrictive. She added that the board needs to bring this to the attention of pharmacists.

Ms. Herold said that this should be discussed in an article in *The Script* rather than a subscriber alert so that that pharmacist can consult the information on an ongoing basis. She said that *The Script* was expected to be released that day, so the article could be in the next newsletter.

There was no comment from the public.

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

Chairperson Law reported that 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 and other requirements. There were two rulemakings. One was approved by the Office of

Administrative Law (OAL). The other was disapproved and returned to the board for modification.

Chairperson Law said that, 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. Board staff drafted SB 493 FAQs for legal review.

Ms. Damoth told the board that the FAQs would be posted online as soon as possible.

8. Discussion on CE Courses Available for Naloxone, Self-Administered Hormonal Contraception and Nicotine Replacement Therapy under Protocols

Chairperson Law and committee members reviewed a handout chart summarizing options for CE that are available specific to naloxone, self-administered hormonal contraception and nicotine replacement therapy under protocols.

Ms. Veale asked if the handout would be posted somewhere. Chairperson Law said the handout indicates that nicotine replacement therapy requires two hours of CE upon renewal; meanwhile, naloxone and self-administered hormonal contraception do not require CE education – only CE training prior to being allowed to furnish naloxone or self-administered hormonal contraception. Ms. Herold said a statute requires CE education for nicotine replacement.

Ms. Sodergren told the committee that the chart could be updated to show what is required before initiating one of these three tasks – and then, if there are additional requirements as a condition of renewal, those could be added and highlighted in a separate column.

Ms. Herold said the updated chart will be posted on the board's website under the SB 493 Implementation tab. Ms. Damoth asked if the committee wanted to see the chart again or just post it. Committee members directed staff simply to post the information as soon as it is ready.

Public comment: Lori Hensic of Kaiser Permanente said that adding links to CE providers with the chart would be helpful for pharmacists. Ms. Veale replied that adding links to CE providers could be seen as promoting those specific providers, which the board cannot do.

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

Chairperson Law reported that, at prior meetings, the committee reviewed multiple items for posting on the board's website as a resource for consumers and licensees. At the May

2016 meeting, the committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee.

Chairperson Law reported that board staff consulted with other boards within DCA and state agencies and drafted the California State Board of Pharmacy's Website Guidelines: Developed by the Communication and Public Education Committee. A copy of the draft policy was included in the meeting materials.

Ms. Veale explained that the policy issue came up because the board was receiving general requests to post items on the board's website. Chairperson Law agreed that the board should have posting guidelines.

Mr. Brooks said that the draft policy is reasonable, but he added that the challenge for websites is how useable they are: Can users search the site for documents? How long does posted information remain on the site? Is the information relevant? He said that "less is more," and he added that the board's site does not reflect that idea.

Ms. Veale agreed that the board's website has a lot of "stuff" on it, which members tried to address during the recent redesign. She said the problem is that the board does not want to keep things off of the site that should be on it. Ms. Herold said that the board provides both public education and licensee education, which requires the board to maintain a site that is interactive as much as possible.

Committee members agreed that the draft policy is a good place for the board to start and see how it works and make changes as necessary. The committee directed staff to move forward with the policy and post on the board's website.

10. Discussion of a Board-Developed Bulletin Board Message and Related Communication Materials

Staff provided the committee with an overview of a board-developed bulletin board message and related communication materials.

Ms. Herold unveiled photos of two draft concepts for a billboard intended to encourage parents to talk to their children about prescription drug abuse. She said the draft concepts were developed by staff at Mr. Brooks' firm. The first draft included drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids." The second draft featured "Kid KILLER" with capital letters superimposed on a prescription drug pill.

After discussing both concepts, committee members agreed to recommend that the board proceed with the first draft concept, which committee members said was eye-catching and self-explanatory. Committee members also said the billboard should tell the public that the message is sponsored by the Board of Pharmacy and provide information on how to contact the board. Ms. Freedman added that any billboard and message attributed to the

board must be reviewed for compliance with legal requirements.

Public comment: Paige Talley of the California Council for the Advancement of Pharmacy expressed hope that the message not deter parents from getting needed prescription drugs for their children. Committee members replied that the billboard message text refers to “unattended” drugs.

Motion: Add the board’s website and sponsorship to the billboard message and move forward with the concept to the full board.

M/S: Brooks/Veale

Yes: 3 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

11. Update and Discussion on SB 1193 (Hill) Requiring Pharmacists, Intern Pharmacists, Pharmacy Technician and Designated Representatives Licensed in California Join the Board’s E-mail Notification List

Chairman Law reported that, at the April 2016 board meeting, the board requested the Communication and Public Education Committee discuss the possible requirement to collect pharmacists’ email addresses. At the May 2016 committee meeting, the committee directed board staff to draft language for consideration at the July 2016 board meeting to require pharmacists’ emails addresses to be collected at time of renewal.

Chairperson Law said that, at the July 2016 board meeting, the board was advised that this requirement was added to the board’s Sunset bill SB 1193 (Hill) was amended to include this provision. A copy of the relevant provisions of SB 1193 (Hill) as amended in Assembly August 18, 2016, was included in the meeting materials.

Chairperson Law asked for an update on the status SB 1193. Ms. Herold replied that the bill was on the governor’s desk and that he was expected to sign it. She said the bill would give the board authority to require individuals who have email addresses to provide the addresses to the board and to keep the information current.

There were no comments from the public.

12. Communication Plan for Consumers and Licensees

In accordance with the board's strategic plan, staff developed and provided committee members with copies of a draft communication plan that included aspects for both board consumers and licensees.

Chairperson Law complimented the plan. Ms. Veale said the plan was a good start and said the committee would continue working with it. She said the committee should revisit it at the committee's next meeting.

Public comment: Lori Hensic of Kaiser Permanente asked what is the board's plan for communicating impending new pharmacy requirements contained in current legislation. Ms. Herold replied that the board would use subscriber alerts, mailings and various other methods to keep licensees informed. She added that the next edition of *The Script* would focus on the new legislation.

The board took a break at 11:30 a.m.

The board reconvened at 11:38 a.m.

13. Update and Discussion on the Forty-Fifth Annual Report of the Research Advisory Panel of California for 2015 Regarding Controlled Drugs Research

Chairperson Law reported that the Research Advisory Panel of California recently submitted its annual report to the Legislature and Governor. A copy of the Forty-Fifth Annual Report of the Research Advisory Panel of California 2015 was included in the meeting materials.

There were no comments from committee members or the public.

14. Board Publications – Review and Recommendations for changes

a. Counterfeit Prescription Drugs: Protect Yourself, Your Family and Your Pets

b. Buying Prescription Medications Online: Are the Drugs You Buy Real or Fake?

Chairperson Law reported that Department of Consumer Affairs requested that the board assess the two board produced publications listed above. He said the committee could determine if the pamphlets should be updated or removed from publication. A copy of both documents was included in the meeting materials.

Chairperson Law said the pamphlets contained good information but perhaps they were not hitting the proper target audience. He suggested asking retailers associations to distribute the pamphlets to customers when they fill their prescriptions. Ms. Herold said staff could ask the California Retailers Association if it is interested in helping out. She added that copies also could be made available at board meetings and speaking engagements.

Chairperson Law asked that the pamphlets also be translated into the top five languages and that pharmacies should be notified that they are available so they can be distributed to customers.

Ms. Sodergren suggested updating the pamphlets to include information about the .pharmacy domain. Ms. Herold agreed.

Lori Hensic of Kaiser Permanente asked if online pharmacies could be required to post this type of information on their websites. Ms. Herold said that was a good idea and that staff could look into that. Ms. Hensic added that perhaps online sites that use the .pharmacy domain also could be required to disseminate this type of information, because their customers are obviously seeking out and using online pharmacy sites.

15. Update on *The Script* Newsletter

Chairperson Law reported that the Summer 2016 edition of *The Script* was being formatted for publishing. He added that board staff was currently working on articles for the Winter 2016/17 edition of *The Script*.

Ms. Herold and Ms. Damoth informed the committee that *The Script* was ready for publication within days.

16. Update on Media Activity

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

- **MPA Media**, July 14, 2016: Kathryn Feather, regulation of acupuncture needle distributors.
- **Capitol Television Network News**, July 27, 2016: Jonathan Underland, drug-take back regulations.
- **KPIX**, Aug. 16, 2016: Molly McCrea, opioid compound U-47700
- **Veterinary Information Network News Service**, Aug. 29, 2016: Edie Lau, unlicensed business selling veterinary prescription drugs online.

There was no comment from committee members or the public.

17. Update on Public Outreach Activities Conducted by the Board

Chairperson Law reported a list of major public outreach activities provided by the board's staff:

- July 18: Supervising Inspector Christine Acosta presented HD compounding for CPhA.
- August 9: Inspector Jennifer Hall provided a review of new laws to the board's competency committee.
- August 18: Supervising Inspector Christine Acosta presented the new compounding regulations to Tenet health.
- August 24: Inspector Trang Song presented at the Vietnamese Pharmacist Association

There was no comment from committee members or the public.

18. Review and Discussion of News or Journal Articles

Chairperson Law reported that several items of potential interest for the committee were included in the meeting materials.

There were no comments from committee members or the public.

19. Review and Discussion of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain*

Chairperson Law reported that a copy of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain* was included in the meeting materials.

Ms. Herold told the committee that the Medical Board's goal is to not have duplicate guidelines out in the community. She noted that the Medical Board put out its guidelines two years before the CDC acted. She added that the good news is the information is out there for prescribers to see what both organizations believe is appropriate pain treatment with opioids, which is the same in most cases and is beneficial information for prescribers.

There were no comments from the public.

20. Future Meeting Dates

a. December 1, 2016

Chairman Law reported that the committee's next meeting date is December 1, 2016.

The meeting adjourned at 11:54 a.m.