DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0165]

Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to solicit public comment on a potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that mail-back envelopes be dispensed and education on safe disposal provided with opioid analgesics dispensed in an outpatient setting. Such a requirement could reduce the amount of unused opioid analgesics in patients' homes, thereby reducing opportunities for nonmedical use, accidental exposure, and overdose, and possibly reducing the development of new opioid addiction.

DATES: Submit either electronic or written comments by June 21, 2022.

ADDRESSES: FDA is establishing a docket for public comment on this notice. The docket number is FDA–2022–N–0165. The docket will close on June 21, 2022. Submit either electronic or written comments by June 21, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 21, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–0165 for ''Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6260, Silver Spring, MD 20993, 301–796–3522, *Patrick.Raulerson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Nonmedical use,[1] accidental exposure, and overdose associated with prescription opioid analgesics remain a serious problem in the United States. In 2019, prescription pain relievers, such as opioid analgesics, remained the most common class of prescription drugs used nonmedically in the United States, with approximately 9.7 million people aged 12 and older reporting past-year nonmedical use (Ref. 1). Many people who use opioids nonmedically start with prescription opioid analgesics and transition to illicit substances (Refs. 2 to 5). Also, from 2010 to 2018 there were over 48,000 accidental prescription opioid exposures in young children (Ref. 6).

While the volume of prescription opioid analgesics dispensed has been

[1] We use the term ''nonmedical'' in this document to refer to misuse of a drug, abuse of a drug, or both. ''Misuse'' is the intentional use, for therapeutic purposes, of a drug in a manner other than prescribed. ''Abuse'' is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects.

trending downward following a peak in 2012, there were still an estimated 140.6 million prescriptions, resulting in an estimated 8.7 billion units (*e.g.,* tablets or capsules) dispensed in 2021 from U.S. outpatient retail and mail order pharmacies (Ref. 7). As of 2020, despite the decrease in opioid dispensing, prescription opioids were involved in more than 16,000 fatal overdoses per year (Ref. 8), higher than the number seen at the peak of opioid analgesic dispensing in 2012 (Ref. 9). The lethality of co-involved substances, such as heroin, illicitly manufactured fentanyl, and illicitly manufactured fentanyl analogues has also changed since 2012 and may partly explain why overdose deaths involving opioid analgesics persist, despite the reductions in prescribing.

Patients commonly report having unused opioid analgesics after treatment of acute pain, such as pain following surgical procedures (Refs. 10 and 11). Opioid analgesics prescribed to treat chronic pain conditions can also result in unused drugs. When not properly disposed, these opioid analgesics provide opportunities for nonmedical use, accidental exposure, and overdose. Most people who reported past-year nonmedical use of prescription pain relievers obtained them through friends, relatives, or their own prescription (Ref. 1). Accordingly, FDA's efforts to address the opioid crisis include a focus on encouraging appropriate disposal of unused opioid analgesics.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271), signed into law on October 24, 2018, provides FDA several new authorities to address the opioid crisis. The SUPPORT Act authorized FDA to require through a Risk Evaluation and Mitigation Strategy (REMS) that a safe disposal packaging or safe disposal system for the purposes of rendering the drug nonretrievable be dispensed to certain patients with opioids or other drugs that pose a serious risk of abuse or overdose if, among other things, FDA determines that such safe disposal packaging or system may mitigate such risks and is sufficiently available (21 U.S.C. 355–1(e)(4)).

The purpose of this notice is to seek public comment on the potential application of this authority to require, under the Opioid Analgesic (OA) REMS, that mail-back envelopes and education on safe disposal be provided with opioid analgesics dispensed in outpatient settings. We recognize that this is just one possible application of FDA's new authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 505–1(e)(4) (21 U.S.C. 355–1(e)(4)) related to packaging and disposal. We are considering, and invite comment on, other possible applications of these authorities, including novel packaging or other safe disposal options that would meet the SUPPORT Act standards. Furthermore, we actively encourage drug manufacturers and others to innovate in this space. We believe that the potential disposal requirement outlined below would provide patients and caregivers with a convenient additional option that would complement existing disposal options (*e.g.,* take-back days, kiosks, flushing, and in-home disposal products). This potential requirement could be a significant and readily achievable step toward improving the safe use of opioid analgesics.

FDA is establishing this docket to solicit input from stakeholders on all aspects of this potential requirement under the OA REMS, including comments on specific questions posed in section III of this notice.

II. Mail-Back Envelopes Dispensed With Opioid Analgesics in an Outpatient Setting

In this section, we identify available data showing that many patients do not use all of their prescribed opioid analgesics. This well-documented outcome results in unused opioid analgesics that, if not securely stored, may be easily accessible and subject to nonmedical use, accidental exposure, and overdose. We summarize published literature regarding the potential impacts of in-home disposal options and whether they could increase disposal of unused opioid analgesics, especially when coupled with patient education on the importance of disposal. We then describe existing disposal options and programs, including take-back days, collection kiosks in pharmacies and other locations, flushing, in-home disposal, and mail-back envelopes. We also describe a potential requirement, as part of the OA REMS, that mail-back envelopes and education on safe disposal be provided with opioid analgesics dispensed in an outpatient setting.

A. Unused, Improperly Stored Opioids Provide an Easily Accessible Supply of Opioids for Nonmedical Use, Accidental Exposure, and Overdose

Many patients report having excess opioid analgesic tablets from prescriptions they received after surgical procedures. A systematic review from 2017 reported that after seven common surgical procedures, 67 to 92 percent of patients had excess opioid analgesics (Ref. 11). A more recent systematic review that included articles published up to 2019 determined that, in studies of patient-reported use of opioid analgesics after surgical procedures that reported on unused tablets, most studies reported that 50 to 70 percent of tablets went unused (Ref. 10). Articles published since the last systematic review continue to report excess tablets after treatment of acute pain from surgical procedures or from treatment in emergency departments (Refs. 12 to 21).

Patients who are prescribed opioid analgesics to treat chronic pain may also have unused opioids requiring disposal, for example, when changing opioid therapy (new opioid ingredient or tablet strength), upon discontinuation of opioid therapy, or upon death. Removing unused opioids from a home is an important public health intervention as many studies report that patients frequently store opioid analgesic tablets in unsecure locations (Ref. 10), making them easily accessible for nonmedical use, accidental exposure, and overdose.

B. Provision of Education and In-Home Disposal Options May Increase Disposal of Unused Opioid Analgesics

Educating patients about opioid analgesic disposal options may increase the disposal rate [2] for unused opioids (Ref. 20). In a recent review of the literature examining opioid disposal options and practices, most studies found that fewer than 50 percent of patients disposed of their opioids (Ref. 20). The majority of studies that examined the effect of providing patient education on the rate of disposing of unused postoperative opioids found that patient education increased the disposal rate by 15 to 30 percent compared to patients who did not receive any additional education. Two investigations found that text message reminders also increased the disposal rate by approximately 30 percent in the text message reminder group compared to patients who did not receive reminders (Refs. 21 and 22).

There is also limited evidence that providing a disposal option along with education increased the probability of disposal over that of providing education alone. For example, one study assessed the difference in postoperative disposal rates when patients were

[2] The percent of patients who dispose of unused medications. This document specifically discusses disposal of opioid analgesic medications.

provided a take-home disposal method, patient education, or both (Ref. 23). Compared to usual care, either patient education or providing a take-home disposal method increased the disposal rate approximately 12 percent; for the group of patients who received both education and a take-home disposal method, the disposal rate increased by 19.5 percent. The four studies where a disposal kit was provided uniformly reported an increase in actual or planned disposal rates, and in three of four studies, the rates increased to over 50 percent of the study population (Refs. 23 to 26).

While disposal products provided to patients in these studies were often not specified, and the study populations usually received them after hospital encounters for surgical procedures, it is reasonable to assume that similar increases in disposal rates may also occur with mail-back envelopes and for other situations outside of post-surgical pain. What is less clear is whether education provided in a retail pharmacy setting will be as successful as the patient education provided in a post-surgical setting. We are interested in descriptions of programs that provide mail-back envelopes specifically, as well as those in which patient counseling on disposal is provided at retail pharmacies. In addition to program descriptions, we are interested in data on the effectiveness of mail-back envelope provision and counseling on disposal provided at retail pharmacies in increasing opioid analgesic disposal rates.

C. New REMS Authority Over Drug Disposal and Packaging

Section 3032 of the SUPPORT Act amended FDA's REMS authority. Specifically, as a part of a REMS, FDA may require that a drug for which there is a serious risk of an adverse event occurring from abuse or overdose be dispensed to certain patients with safe disposal packaging or a safe disposal system for purposes of rendering the drug ''nonretrievable'' (as that term is defined in a regulation adopted by the Drug Enforcement Administration (DEA)), if FDA determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available (see section 505–1(e)(4) of the FD&C Act). Under DEA regulations (21 CFR 1317.90(a)), the requirement to render controlled substances ''non-retrievable'' applies only to DEA registrants and does not apply to ultimate users or patients.[3] However, in the SUPPORT Act, Congress made the ''nonretrievable'' standard applicable to any safe disposal packaging or system FDA may require under a REMS (see 21 U.S.C. 355–1(e)(4)). FDA may also require that a drug for which there is such serious risk be made available for dispensing to certain patients in unit-dose packaging, packaging that provides a set duration, or another packaging system that FDA determines may mitigate that risk (21 U.S.C. 355–1(e)(4)).

A packaging or disposal requirement under this provision can be imposed for prescription drugs that are the subject of applications approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) or section 351 of the Public Health Service Act, as well as drugs that are the subject of abbreviated new drug applications (ANDAs) approved under section 505(j) of the FD&C Act if a packaging or disposal requirement is required for the applicable reference listed drug (see section 505–1(i)(1)(B) of the FD&C Act). FDA can permit packaging systems and safe disposal packaging or safe disposal systems for drugs that are the subject of ANDAs that are different from those required for the applicable reference listed drugs (see section 505–1(i)(2)(B) of the FD&C Act). FDA must take into consideration the burden on patients' access to the drug and the burden on the healthcare delivery system that would be associated with any such packaging or disposal requirement, and must consult with other relevant Federal Agencies with authorities over drug disposal packaging in certain circumstances (see section 505–1(e)(4) of the FD&C Act).

The DEA has defined ''non-retrievable'' through regulation (21 CFR 1300.05(b)). It means, in part, ''the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes.'' The regulation further provides that ''a controlled substance is considered non-retrievable when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue,'' and that ''the purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes'' (21 CFR 1300.05(b)).

Under DEA regulations, an entity registered with the DEA [4] may collect controlled substances from ultimate users, to include collection by mail-back packages or envelopes, for the purpose of destruction.[5] To be considered ''destroyed,'' a mail-back package must be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and must be rendered non-retrievable.[6] Mail-back envelopes dispensed with opioid analgesics pursuant to a mail-back program that operates in compliance with DEA regulations and all other applicable laws would be ''for the purposes of rendering the drug nonretrievable,'' as required by section 505–1(e)(4) of the FD&C Act. There are multiple companies that operate DEA-registered mail-back programs and have mail-back envelopes commercially available, which could be utilized by drug manufacturers who would be subject to the potential REMS requirement described in this notice.

D. Mail-Back Envelopes in the Current Landscape of Opioid Disposal Options

There are various options for safely disposing of opioid analgesics available to patients, all of which can achieve the goal of removing the risks associated with having unused and unsecured opioids stored in the home. There are both in-home disposal options (*e.g.,* flushing, commercially available in-home disposal products) and disposal options outside of the home (*i.e.,* collection kiosks, take-back events). FDA currently recommends disposing of opioids in permanent collection sites (*e.g.,* kiosks in pharmacies) or at take-back events (Ref. 27). If these disposal options are not readily available, FDA recommends either flushing (for opioids on FDA's ''Flush List'' (Ref. 28) or mixing with an unpalatable substance and disposing in household trash (Ref. 27).

However, each option has its own challenges, which can result in individuals being unable, unwilling, or reluctant to use them. For example, collection sites (*e.g.,* kiosks) require

[3] 79 FR 53520 at 53541, September 9, 2014.

[4] Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector (21 CFR 1317.40(a); 1301.51). A collector would need to submit a letter of request for modification of their registration to the Registration Unit at the DEA and include the registrant's name, address, registration number, and the type of collection (*e.g.,* a mail-back program and/or a collection receptacle) that the collector intends to conduct.

[5] DEA regulations address take-back events, mail-back programs, and collection receptacles (21 CFR 1317.65, 1317.70, and 1317.75, respectively).

[6] 21 CFR 1317.90(a).

individuals to bring opioid analgesics out of the home to a public place, either a pharmacy or law enforcement facility. This requires planning, access to transportation, and follow-through. Some individuals are unable to readily or easily travel to a collection site. In addition, some individuals may be reluctant to bring opioid analgesics to a public location due to social stigma, or may fear entering law enforcement locations, especially while carrying opioid analgesics.

In-home disposal options also have challenges. Many patients are reluctant to flush opioids (or other medications) due to environmental concerns (Ref. 28). FDA's recommendation to mix some opioids (*i.e.,* those not on the ''flush list'') with an unpalatable substance and dispose in household trash is a multistep process some patients may be unwilling or reluctant to undertake. In addition, disposal of opioids in household trash may not prevent all accidental exposures.

Commercially available in-home disposal products (*e.g.,* DisposeRx packets or Deterra kits) commonly dispensed by some pharmacies are another option, but they also require multiple steps (*e.g.,* emptying pills from one container into another container, adding water, shaking to mix contents, disposing in household trash) (Refs. 29 to 31), and some individuals may be reluctant to use them due to environmental concerns. Further, FDA's understanding is that these products may not render drugs ''nonretrievable'' within the meaning of the DEA regulation referenced in section 505–1(e)(4)(B). Mail-back envelopes require individuals to put the mail-back envelopes in a mailbox, which, for some individuals, may be physically distanced from their home (*e.g.,* apartments, P.O. boxes, Native American reservations). Additionally, patients may be reluctant to put opioids in the mail for fear of diversion (Ref. 32). Some individuals may be more inclined to use one option; others a different option. Accordingly, FDA believes it is important to provide patients with a range of reasonable options, and to provide appropriate education on each of these options.

FDA is aware that many organizations, both public and private, have ongoing efforts to increase safe disposal of unused opioids. For example, large retail pharmacy chains and many independent pharmacies operate drug disposal programs that include making drug disposal kiosks available in pharmacies, sponsoring drug ''take-back'' days and providing in-home disposal products (Refs. 33 to 37). It is our understanding that pharmacists often are instructed to counsel patients and include educational materials about safe disposal in conjunction with providing in-home disposal products. Some States and municipalities have passed legislation requiring manufacturers who sell drugs in their jurisdictions to fund drug disposal programs that can include subsidizing kiosks in pharmacies and/or the provision of in-home disposal products, including, occasionally, mail-back envelopes (Refs. 38 to 40).

The Agency believes it is important for patients to have multiple options for disposing of unused opioids, including kiosks, take-back events, and in-home disposal options. Mail-back envelopes are one option that has multiple favorable characteristics. They do not require patients to mix medications with water, chemicals, or other substances. Mail-back envelopes are also required to be postage paid,[7] thereby providing patients with a free disposal option. Further, most patients can mail these envelopes from their home. Additionally, the DEA and the U.S. Postal Service (USPS) have regulations and policies to ensure that mail-back envelopes are fit for purpose.[8] The USPS has longstanding policies in place to safely and securely transport mail-back envelopes to the location where they will be destroyed.[9] Finally, unlike other alternatives described here, the DEA requires mail-back envelopes to be disposed of in a manner that renders them non-retrievable,[10] which is typically accomplished through incineration. As a result, mail-back envelopes (along with collection kiosks) result in less opioids in the water supply and landfills than is associated with other disposal options.

FDA recognizes that, notwithstanding these benefits, mail-back envelopes are, at present, relatively underutilized. Large retail pharmacy chains have focused on take-back days, kiosks, and a provision of commercially available in-home disposal products (Refs. 33 to 37), while it appears manufacturers subject to State-mandated disposal requirements have primarily focused on collection kiosks. FDA anticipates that a REMS-mandated disposal program for opioid analgesics focused on provision of mail-back envelopes, together with education on multiple safe disposal options, could complement these existing opioid disposal programs.

E. Approach Under Consideration: Mail-Back Envelopes and Education on Proper Disposal Must Be Provided to Patients With Opioid Analgesics Dispensed in Outpatient Pharmacies

FDA is considering adding a mail-back envelope requirement to the OA REMS to require that all opioid analgesics, including immediate-release (IR), extended-release (ER), and long-acting (LA) formulations, used in the outpatient setting that are subject to the OA REMS be dispensed with mail-back envelopes.

Although most studies reported excess opioid analgesics after a surgical procedure (Refs. 10 and 11), suggesting the need to target disposal options for patients with acute pain, the pharmacist at the time of dispensing may find it difficult to differentiate whether a patient is being treated for acute or chronic pain. For example, using specific formulations of opioid analgesics as a proxy for distinguishing between acute or chronic pain would not be appropriate because patients with chronic pain may take both IR and ER or LA formulations. In fact, most patients receiving an opioid analgesic, regardless for how long, use IR formulations (Ref. 41). Further, as mentioned above, opioid analgesics prescribed for chronic pain can also become unneeded. Therefore, FDA is considering having any mail-back envelope requirement apply to all opioid analgesics, including IR, ER, and LA formulations, used in the outpatient setting for acute or chronic pain that are subject to the OA REMS.

That said, requiring that a mail-back envelope be dispensed with every opioid analgesic prescription could be inefficient and lead to an excess of dispensed mail-back envelopes. The use of algorithms to target mail-back envelope distribution in a thoughtful, tailored manner would be expected to positively impact program fidelity and outcomes and decrease waste. Some existing retail pharmacy programs that provide disposal options to patients use algorithms to target disposal options to certain patients or certain circumstances, such as only providing disposal options every 6 months to patients who continue to fill multiple opioid analgesic prescriptions (Refs. 33 and 34). Other potential algorithms

[7] 21 CFR 1317.70(c)(4). DEA added this requirement because it believed that ''pre-paid postage will ensure that the package is not returned to sender, which will help reduce its handling and therefore, the diversion risks'' (79 FR 53520 at 53536, September 9, 2014).

[8] See 21 CFR 1317.70; USPS Publication 52, Mail-back programs.

[9] Mail-back collectors are required to provide mail recipients with readymade packaging and labels that comply with USPS regulations for mailing controlled substances, including unique Intelligent Mail package barcodes. See USPS Publication 52, Mail-back programs.

[10] See 21 CFR 1317.70(a); 1317.90(a).

could target the provision of mail-back envelopes to patients filling a prescription for an amount of opioids generally consistent with acute pain treatment, or to patients with a change in dose of a recurring opioid analgesic prescription who may then have unused opioids. FDA recognizes that the upfront effort to implement algorithms could be complicated but expects that the use of algorithms would be more efficient and would reduce the long-term burden on the healthcare delivery system by targeting the distribution of mail-back envelopes to patients most likely to have unused opioids. FDA would appreciate input on appropriate optimal algorithm design for a potential targeted mail-back envelope provision. We would also expect, regardless of the algorithm used, that mail-back envelopes would be provided to any patient or caregiver who requests one. Additionally, we would expect that if a given patient does not want the mail-back envelope, they could decline the offer.

Multiple studies we reviewed indicated that unused opioids are often stored in unsecure locations (Ref. 10) and that patients were reluctant to dispose of unused opioid analgesics for various reasons, including the patient's belief that they might need the unused opioids in the future (Refs. 32, 42, and 43). In the studies that we reviewed, patient and caregiver education about disposal was often provided with an at-home disposal option during counseling about care after a procedure, and patients were reminded about disposal during followup contacts. For example, one study found that combining an in-home disposal option with patient education focused on the importance of disposal increased the disposal rate versus simply providing an in-home disposal option or patient education (Ref. 23). Accordingly, we believe that patient and caregiver education that explains the importance of safe storage and proper disposal and addresses patients' reluctance to dispose of opioids would be an integral component of any mail-back envelope REMS requirement. We also believe that take-home educational materials on proper disposal, as well as followup reminders (*e.g.,* automated text messages), are likely to have a positive reinforcing effect on patient counseling provided by the pharmacist at the time of dispensing.

There are multiple ways a mail-back envelope REMS requirement could be designed and operationalized. We describe two possibilities here, and welcome input on others. One option would be to require that drug manufacturers subject to the OA REMS make mail-back envelopes available to outpatient pharmacies at no cost and allow pharmacies to provide mail-back envelopes and counseling on disposal according to their own policies and procedures. Additionally, to encourage patient education, FDA may also require manufacturers to create educational materials to assist pharmacists in counseling patients on safe storage and proper disposal. However, this option would not require that pharmacies actually provide mail-back envelopes, counseling on disposal, or take-home educational materials. As such, this option would ultimately rely on pharmacy policies and procedures to drive the use of mail-back envelopes and counseling on safe disposal.

Alternatively, FDA could require manufacturers to only distribute opioids to outpatient pharmacies certified in the REMS. Certification could require that mail-back envelopes, patient counseling, take-home materials, and followup reminders (*e.g.,* text messages) be provided according to the terms of the REMS, and that all of these activities be conducted and appropriately documented. Again, manufacturers would supply mail-back envelopes to pharmacies at no cost. Certification of pharmacies could include requiring pharmacy staff to complete specified training on how to counsel patients on safe storage and proper disposal. As with the first option, FDA may also require manufacturers to create educational materials to assist pharmacies with patient counseling.

For any mail-back envelope REMS requirement, FDA would intend for the program to increase the quantity of unused opioids properly disposed of, and, therefore, to decrease the quantity of unused opioids available for nonmedical use, accidental exposure, and overdose. FDA anticipates the potential for greater impact with the second option than the first but acknowledges that the second option would impose greater burdens on the healthcare system.

The potential burdens associated with a mail-back envelope REMS requirement on pharmacies and pharmacists would include, depending on the program design: (1) Completion of any REMS-mandated training and certification; (2) implementation of REMS-compliant processes in pharmacies; and (3) documentation of compliance with REMS requirements by pharmacies. These efforts are in addition to existing State and Federal pharmacy requirements associated with dispensing opioids (*e.g.,* checking prescription drug monitoring programs). A mail-back envelope REMS requirement is likely to be more effective under the second scenario described above. However, the more requirements the REMS imposes, the more likely that relevant stakeholders, particularly pharmacies, will have challenges complying with the requirements. Ensuring the requirements are met may necessitate remediation steps, such as reeducation, or even decertification, if a pharmacy fails to comply. Declining to certify or decertifying a pharmacy could affect patients' access to appropriately prescribed opioid analgesics.

Accordingly, the ability of potential OA REMS disposal requirements to be integrated into healthcare providers' existing workflow is an important consideration in FDA's decision making. The Agency is seeking input on the design of a potential mail-back envelope REMS requirement that strikes the right balance between positive impact on unused opioid analgesic disposal and burden on pharmacies and other stakeholders.

F. Other Considerations for Requiring Provision of Mail-Back Envelopes With Opioid Analgesics

Current DEA and USPS regulations and policies require mail-back envelopes to be nondescript, *i.e.,* they must not include any markings or other information that might indicate that the package contains controlled substances.[11] These specifications help alleviate concerns that mail-back envelopes can easily be identified for diversion while in transit. However, if a potential mail-back envelope REMS requirement were implemented, it could be expected to greatly increase the number of mail-back envelopes in circulation. The USPS has informed the Agency that the existing regulatory scheme, as well as USPS' rigorous monitoring and policing mechanisms, should be adequate to accommodate an increase in mail-back envelope utilization. We welcome other stakeholder views on this issue, including how any potential adverse consequences could be mitigated.

FDA expects that a mail-back envelope OA REMS requirement would provide patients with an additional disposal option that complements disposal options already available through ongoing public and private efforts. The Agency understands mail-back envelopes will not be the preferred disposal option for all patients. FDA's expectation is that existing disposal

[11] 21 CFR 1317.70(c)(1); USPS Publication 52, Mail-back programs.

programs (*e.g.,* provision of in-home disposal options by many pharmacies, including most major chain pharmacies) will continue, such that a mail-back envelope mandate would provide patients with an additional disposal option without affecting other existing disposal options. We are seeking input on how a mail-back envelope OA REMS requirement could be designed and operationalized to complement existing disposal efforts and programs.

G. Other Actions That Could Complement a Mail-Back Envelope REMS Mandate

FDA is considering additional actions that may be necessary or appropriate if we were to impose a mail-back envelope disposal requirement under the OA REMS. For example, FDA would need to amend recommendations in the ''Remove the Risk'' campaign on safe disposal of opioids to include information on the availability and use of mail-back envelopes (Ref. 44). Likewise, FDA would need to amend the information on disposal in FDA-approved prescriber and patient labeling for opioids that would be subject to the mail-back envelope REMS requirement, as this labeling currently does not mention mail-back envelopes. FDA is also considering whether it might be appropriate to have a large media campaign aimed at increasing public awareness of the importance of promptly disposing unused opioids and how to safely dispose of them. FDA welcomes input on these and any other potential actions that could increase the effectiveness of a mail-back envelope disposal requirement under the OA REMS.

III. Additional Request for Comments And Information

FDA is soliciting comments from stakeholders regarding all aspects of the potential mail-back envelope REMS mandate described in this document. The Agency is particularly interested in comments on the following topics:

1. The potential safety advantages and public health impacts of providing mail-back envelopes with opioid analgesics dispensed in an outpatient setting.

2. Whether there are specific opioid analgesic drug products for which requiring mail-back envelopes is more important from a public health perspective and, if so, which products.

3. How pharmacies could identify those patients who are most likely to have unused opioids to optimize provision of mail-back envelopes to these patients and potentially positively impact the share of mail-back envelopes that are utilized to safely dispose of opioid analgesics.

4. How pharmacies could develop and implement algorithms to determine when to provide a mail-back envelope, including how feasible or practical it would be for pharmacies to do so.

5. Whether requiring provision of mail-back envelopes under the OA REMS should also include a requirement for patient counseling and/or provision of take-home materials on safe disposal at the point of dispensing.

6. What key educational messages regarding secure storage and safe disposal should be included in any patient education component of the potential OA REMS requirement described in this notice, including educational messages to increase uptake and use of mail-back envelopes, as well as what form that education should take (*e.g.,* handouts, pharmacist counseling of patients).

7. How a mail-back envelope requirement could be designed and implemented to help ensure that the disposal requirement minimizes burden on pharmacies while still providing the public health benefit. As discussed in the document, there is a tradeoff between the potential effectiveness of a mail-back envelope REMS requirement and the level of burden imposed on those pharmacies involved in implementing the requirement.

8. Possible challenges, including technical and logistical challenges, with the potential REMS mandate described in this notice, and what factors could impact manufacturers' ability to provide mail-back envelopes to pharmacies, or the ability of pharmacies to dispense mail-back envelopes and provide appropriate disposal education to consumers.

9. The impact of a mail-back envelope REMS requirement on other stakeholders, including manufacturers, prescribers, payers, and patients.

10. How a mail-back envelope REMS requirement could be designed and operationalized to provide another option for patients that would complement current pharmacy disposal programs, policies, and procedures, as well as Federal, State, local, and private sector efforts on proper opioid disposal.

11. Possible negative impacts of a potential mail-back envelope REMS mandate, including whether there is a risk that it could diminish the impact of other public and private efforts around safe disposal. For example, could it be the case that for some patients, provision of a mail-back envelope together with another commercially available in-home disposal product, and education on how to use both, could be overwhelming and lead to less comprehension and utilization of either option?

12. How manufacturers and FDA could best assess the effectiveness of a mail-back envelope OA REMS requirement. Assessing the impact of a mail-back envelope requirement in a REMS is likely to be challenging because, among other reasons, current DEA regulations prohibit mail-back envelopes from being opened prior to destruction, preventing a direct inventory of contents; and some of the opioids disposed of in mail-back envelopes would presumably be disposed of using another disposal option if the mail-back envelope were not provided.

13. How patients and others may perceive the environmental impact of a potential mail-back envelope requirement, including the potential for such envelopes to reduce the amount of medications flushed or disposed of in landfills.

14. Any existing programs that provide mail-back envelopes, especially programs that provide patient counseling on disposal and that operate in retail pharmacies, including any data on the effectiveness of these programs.

15. Section 3032 of the SUPPORT Act authorizes the Agency to use its REMS authority to require that a safe disposal packaging or safe disposal system for the purposes of rendering the drug nonretrievable be dispensed to certain patients with drugs that pose a serious risk of abuse or overdose if, among other things, FDA determines that such safe disposal packaging or system may mitigate such risks and is sufficiently available (21 U.S.C. 355–1(e)(4)). We recognize that the approach described in this document is only one potential use of the Agency's REMS authority concerning disposal. Comment on other possible uses of the Agency's REMS authority concerning disposal, including providing any data or information about whether other disposal packaging or disposal systems we might consider mandating, such as commercially available in-home disposal products, would satisfy the statutory requirements at 21 U.S.C. 355–1(e)(4).

16. Discuss other actions FDA could take in addition to, and in support of, a mail-back envelope disposal REMS requirement to increase safe disposal of unused opioid analgesics.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and available for viewing by

interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some references may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the web addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08372 Filed 4–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; Summer Research Education R25 and DSR Member Conflict SEP.

Date: June 17, 2022.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental & Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Aiwu Cheng, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities National Institute of Dental & Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892, *Aiwu.cheng@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 18, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–08522 Filed 4–20–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Health Services Organization, Delivery, Quality and Effectiveness.

Date: May 4, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 15, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–08500 Filed 4–20–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.