The burden estimate for this information collection has not changed since the last OMB approval.

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1561]

Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: As part of the work by the Federal Government to address the opioid crisis, the Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled ''Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment.'' The purpose of the public workshop is to obtain scientific input on methods to evaluate the Opioid Analgesics Risk Evaluation and Mitigation Strategy (OA REMS) education program. To assist in the workshop discussion, FDA is making available an issues paper that provides a brief overview of the REMS background and challenges with evaluating the REMS education intervention.

DATES: The public workshop will be held virtually and broadcast via webcast only on December 11, 2020, from 9 a.m. to 5 p.m., Eastern Time. Submit either electronic or written comments on this public workshop by February 11, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public workshop via an online teleconferencing platform.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 11, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 11, 2021. 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.

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–2020–N–1561 for ''Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4462, Silver Spring, MD 20993–0002, 301–796–9029, *OAREMS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, FDA approved a REMS for extended-release and long-acting (ER/LA) opioid analgesic medications (ER/LA REMS). The ER/LA REMS required that prescriber training in the form of accredited continuing education (CE) be made available to health care providers who prescribe ER/LA opioid analgesics.

On May 3 and 4, 2016, FDA convened a joint meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and the Anesthetic and Analgesic Drug Products (AADP) Advisory Committee to discuss whether the ER/LA REMS assured safe use of these products, whether it was not unduly burdensome to patient access to the drugs, and whether it (to the extent practicable) minimized the burden to the health care delivery system (see the **Federal Register** of March 14, 2016 (81 FR 13372)). FDA also sought input from the committees on effective short- and long-term approaches for measuring the success of the ER/LA REMS in reducing serious outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics. Committee members suggested that a study to assess specific prescribing behaviors and patient outcomes before and after prescriber completion of a REMS-compliant CE, or a study comparing prescriber behavior and patient outcomes for prescribers who completed an educational activity with prescriber behavior and patient outcomes for those who did not, would be useful to evaluate the effect of the ER/LA REMS. The DSaRM and AADP Advisory Committees, however, struggled with how to define appropriateness of prescribing.

Based on recommendations from the 2016 joint advisory committee public meeting, FDA required a modification to the ER/LA REMS to: (1) Include all opioid analgesics (immediate-release, ER, and LA) intended for outpatient use that were not included in another REMS; (2) expand the educational blueprint to encompass broad pain management concepts; and (3) train other members of the health care delivery team involved in the management of patients with pain. The current REMS, the OA REMS, was approved on September 18, 2018 (*https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17*).

The central component of the OA REMS is a voluntary CE program for all health care providers, including nurses and pharmacists, who are involved in the management of patients with pain (in addition to doctors and others who prescribe these products). Under the OA REMS, the application holders of affected products are meeting this requirement by providing educational grants to accredited CE providers who develop and offer the training. A variety of formats (*e.g.,* didactic, case-based, interactive, multimedia, adaptive) and settings (live, webinar, internet) have been used to provide these educational activities (*https://opioidanalgesicrems.com/RpcUI/home.u*). The OA REMS also includes a patient counseling guide to assist prescribers in properly counseling patients on their responsibilities for using these medicines safely and to provide patients with additional written instructions as needed (see *https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2019_11_14_Patient_Counseling_Guide.pdf*). The labeling for opioid analgesics includes a product-specific one-page Medication Guide to be given to patients each time they are dispensed their opioid analgesic medicine.

The goal of the OA REMS is to educate prescribers and other health care providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS program is based on the FDA Blueprint (*https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2019_11_14_FDA_Blueprint.pdf*). Through better education, the health care team will have an improved understanding of how to manage pain and the role of opioid analgesics, as well as nonpharmacologic and non-opioid analgesics, in pain management. The education will also provide information about the risks of opioids and use of other therapies. This information is intended to assist health care providers in reducing adverse outcomes of addiction; unintentional overdose; and death resulting from inappropriate prescribing, abuse, and misuse. The REMS aims to accomplish this goal by:

1. Ensuring that training based on the FDA Blueprint is effective in educating prescribers and other health care providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and the appropriate use of opioid analgesics.

2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics (see Opioid Analgesic REMS page on the Approved Risk Evaluation and Mitigation Strategies (REMS) website, available at *https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17*).

The REMS-compliant CE content, based on the FDA Blueprint, includes information on the following:

- The fundamental concepts of pain management, including definitions and mechanisms of pain;
- how to assess patients in pain and identify risk factors for abuse and addiction;
- the range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies;
- how to integrate opioid analgesics into a pain treatment plan tailored to the needs of the patient;
- how to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing the use of opioid analgesics;
- how to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal;
- how to counsel patients and caregivers about the use of naloxone for opioid overdose;
- when referral to a pain specialist is appropriate;
- the fundamental elements of addiction medicine; and
- how to identify and manage patients with opioid use disorder.

The workshop will focus primarily on the evaluation of the effect of REMS CE on prescriber behavior and patient outcomes, which is one component of the OA REMS assessment plan. The OA REMS assessment plan also includes:

- Evaluations of the distribution of letters to health care providers, professional societies, and licensing boards;
- the status of grants and descriptions of CE programs awarded;
- the number of CE activity completers;
- audits of activities;
- the overall pain/opioid CE landscape;
- surveillance and monitoring related to opioid analgesic use, misuse, abuse, overdose, addiction, and death;
- an evaluation of drug utilization patterns;
- an evaluation of CE completers' knowledge; and

• an evaluation of patient experiences around pain management and an evaluation of patient knowledge.

The OA REMS assessment plan also includes an evaluation of the effect of REMS-compliant CE on prescriber behavior and patient outcomes. FDA has been in discussion with the application holders on possible study designs and approaches to measure the effect of the OA REMS-compliant CE on prescriber behaviors and patient outcomes, and a number of challenges have been identified, including but not limited to:

• how to define and measure good pain management practices and key patient outcomes related to pain management and opioid safety and

• How to isolate an effect of REMS-compliant CE given all of the other drivers of prescribing behavior and patient outcomes (*e.g.,* widespread availability of other education programs, opioid analgesic prescribing limits, required checks of prescription drug monitoring programs)

II. Topics for Discussion at the Public Workshop

On December 11, 2020, FDA will hold a public scientific workshop entitled ''Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes—Exploring the Path Forward for Assessment.'' The main objective of the workshop is to discuss three major topics. The three major topics are as follows:

1. Specific, measurable outcomes that might demonstrate that the REMS training based on the FDA Blueprint is effective in educating prescribers and other health care providers (including pharmacists and nurses) involved in the treatment and monitoring of patients in pain about recommended pain management practices and the appropriate use of opioid analgesics.

2. The feasibility of conducting a study to specifically evaluate the effect of OA REMS-compliant CE on prescriber behavior and patient outcomes amidst the numerous concomitant strategies to combat the opioid crisis at the Federal, State, and local levels. This discussion will include, for example, what effect size might be reasonable to expect to result from a one-time completion of a CE program and whether there are methods (*e.g.,* study design, data sources, metrics) that could isolate and identify the effect that REMS-compliant CE has on prescriber behavior and patient outcomes. Participants may also be asked to discuss:

• Whether a pilot study would be informative and, if so, what features of the pilot study would be key;

• which types of stakeholders might be well-positioned to conduct such a study;

• how a single study might evaluate the varying formats of CE activity; and

• reasonable timing for outcome evaluation relative to completion of a CE activity.

3. Whether there might be suitable alternative study approaches to better understand the influence of CE, more broadly, on pain management practice and patient outcomes, if a study to directly measure the impact of REMS-compliant CE is thought to be infeasible.

FDA has developed an issues paper entitled ''Methods for Evaluating the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS).'' This issues paper provides a brief overview of the REMS background and challenges with evaluating the REMS education. The issues paper can be found on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/opioid-analgesics-rems-study-workshop-12112020.*

Panelists are expected to include individuals with expertise in dissemination and implementation science, public health, health services research, pharmacoepidemiology, program evaluation, and CE. Public participation and comment are encouraged.

III. Participating in the Public Workshop

Registration: To register for the public workshop, send an email to *OAREMS@fda.hhs.gov* by 11:59 p.m. Eastern Time on November 30, 2020. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by December 2, 2020. All requests to make oral presentations must be received by the close of registration on November 30, 2020. If selected for presentation, any presentation materials must be emailed to Paul Tran (see **FOR FURTHER INFORMATION CONTACT**) no later than December 4, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. Additional information will be made available regarding accessing the webcast 2 days before the public workshop at *https://www.fda.gov/drugs/news-events-human-drugs/opioid-analgesics-rems-study-workshop-12112020.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/opioid-analgesics-rems-study-workshop-12112020.*

Dated: October 30, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1845]

Risk Evaluation and Mitigation Strategy Assessment Summary for Web Posting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the establishment of a docket to solicit public comment on a proposal to publish a summary of FDA's review of Risk Evaluation and Mitigation Strategy (REMS) assessments. The purpose of the docket establishment is to increase Agency transparency and promote exchange of information regarding the assessment of REMS programs.

DATES: Submit either electronic or written comments by January 4, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be