CMS–10225 Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; *Use:* This information collection relates to the required third party disclosures by certain Medicare-participating hospitals and Critical Access Hospitals (CAHs) and physicians to their patients. The intent of the disclosure notice is to assist the patient in making an informed decision regarding their care. The disclosure requires hospitals and CAHs to disclose to its patients whether the hospitals/CAHs are physician-owned and, if so, the names of the physician-owners. The second disclosure requires all hospitals and CAHs that do not have a Doctor of Medicine (MD) or a Doctor of Osteopathic Medicine (DO) on the premises at all times to disclose this to patients upon admission or registration for both inpatient and specified outpatient services. *Form Number:* CMS–10225 (OMB Control Number: 0938–1034); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 2,556; *Total Annual Responses:* 162,993; *Total Annual Hours:* 6,435. (For policy questions regarding this collection contact Natalie Clybourn at 410–786–5642).

Dated: May 5, 2017

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2497]

Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft revisions to the ''FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics'' (Blueprint). The Blueprint is part of the FDA-approved risk evaluation and mitigation strategy (REMS) for extended release (ER) and long-acting (LA) opioid analgesic medications (ER/LA Opioid Analgesics REMS).

FDA is seeking comment on the draft revisions to the Blueprint and has added sections of draft revised Blueprint to the background materials for the public workshop scheduled for May 9–10, 2017. Although the draft revisions to the Blueprint will not be a discussion topic at the workshop, FDA expects the draft revisions to provide important context for discussions during the workshop.

DATES: To ensure that FDA considers your comments on the draft revisions to the Blueprint, submit either electronic or written comments by July 10, 2017.

ADDRESSES: 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2017–D–2497 for ''Draft Revisions to FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 Division of Dockets Management. 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.gpo.gov/fdsys/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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft revised Blueprint to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised Blueprint.

FOR FURTHER INFORMATION CONTACT: Janelle Derbis, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration 20 North Michigan Ave., Suite 510, Chicago, IL 60602, 312–596–6516.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of draft revisions to the ''FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics'' (draft revisions to the Blueprint). In addition to seeking comment on the draft revisions to the Blueprint, FDA expects the draft revisions to create important context for discussions at a public workshop on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of opioids) for health care providers. That workshop, which is scheduled for May 9–10, 2017, was previously announced in the **Federal Register** on April 18, 2017 (82 FR 18300).

I. Background

On July 12, 2012, FDA approved an ER/LA Opioid Analgesics REMS, including an FDA-created ''Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioid Analgesics.'' The goal of the REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications.

The ER/LA Opioid Analgesics REMS requires that training in the form of accredited continuing education be made available to health care providers who prescribe ER/LA opioid analgesics. The accredited continuing education must include all elements of the FDA Blueprint, which includes a basic outline and the core messages related to ER/LA opioid analgesics. FDA developed the Blueprint following extensive input from stakeholders and sought input on a draft version on November 7, 2011 (76 FR 68766), before approving it in 2012 as part of the ER/LA Opioid Analgesics REMS.

On May 3–4, 2016, FDA convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss whether this REMS assures safe use of these products; whether or not it is unduly burdensome to patient access to the drugs; and whether it (to the extent practicable) minimizes the burden to the health care delivery system (March 14, 2016, 81 FR 13372). FDA also sought input on possible modifications to the ER/LA Opioid Analgesic REMS, including expansion of the scope and content of prescriber training and expansion of the REMS program to include immediate release (IR) opioid analgesics. Advisory Committee members were in favor of modifying the REMS program to include the IR opioid analgesics as well as broadening the training program to include pain management. The majority of the members were in favor of a requirement for all prescribers to complete training. Many of the members recommended that the required training program be implemented through mechanisms outside the FDA REMS authority. The majority of members also stated that other health care providers involved in the management of pain should be included as a target audience for education, though they did not specify that the training should be mandatory for non-prescribing health care providers.

II. Potential Modifications to the FDA Blueprint

FDA is considering modifications to the existing Blueprint in light of recommendations from the May 2016 Advisory Committee meeting. The draft revisions to the Blueprint being made available pursuant to this notice would broaden the Blueprint to include information on pain management, including the principles of acute and chronic pain management; non-pharmacologic treatments for pain; and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic). FDA intends to consider public input as it considers modifications to the ER/LA Opioid Analgesics REMS.

III. May 2017 Public Workshop

On April 18, 2017, FDA published a notice announcing a public workshop scheduled for May 9–10, 2017, to seek input on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of opioids) for health care providers. Through the public workshop, FDA hopes to obtain additional insight from a variety of stakeholders on how best to ensure that health care providers receive training in pain management and the safe use of opioids. The draft revisions to the Blueprint being made available at *https://www.fda.gov/Drugs/NewsEvents/ucm553931.htm* are intended to provide important context for the public workshop's discussion. However, the Blueprint itself will not be a discussion topic at the workshop. FDA intends to consider any comments submitted to this docket as it considers possible modifications to the ER/LA Opioid Analgesics REMS.

Dated: May 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09442 Filed 5–9–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamate) Countermeasures

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: The Secretary is issuing a declaration pursuant to section 319F–3 of the Public Health Service Act to