DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10316]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are require; to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *May 24, 2016.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10316 Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey

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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a Prescription Drug Plan. The data collected in this survey can be used to improve the operation of Medicare Advantage (MA) (both MA and MA–PD) contracts and standalone prescription drug plans (PDPs) through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. The data can also be used by beneficiaries who need to choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level they can be used for contract oversight. *Form Number:* CMS–10316 (OMB control number: 0938–1113); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 56,972; *Total Annual Responses:* 56,972; *Total Annual Hours:* 15,032. (For policy questions regarding this collection contact Beth Simon at 415–744–3780.)

Dated: March 22, 2016.

William N. Parham, III,

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

[FR Doc. 2016–06829 Filed 3–24–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–855O, CMS–10438, CMS–10439 and CMS–10440]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *April 25, 2016.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806, or Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Registration Application; *Use:* The primary function of the CMS–855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to be enrolled in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services and/or prescribing Medicare Part D drugs for Medicare beneficiaries. The application allows a physician or other eligible professional to enroll in Medicare without being approved for billing privileges. The required information is submitted when the applicant requests enrollment in Medicare for the sole purpose of ordering and certifying certain Medicare items and services or for prescribing Medicare Part D drugs. The application is used by Medicare contractors to collect data to help ensure that the applicant has the necessary credentials to order and certify certain Medicare items and services or to prescribe Medicare Part D drugs. This includes ensuring that the physician is not excluded debarred from the Medicare program. *Form Number:* CMS–855O (OMB control number: 0938–1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 448,000; *Number of Responses:* 24,000; *Total Annual Hours:* 243,600. (For questions regarding this collection contact Kimberly McPhillips (410) 786–8438.)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program; *Use:* Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act directs HHS to establish criteria for certification of health plans as QHPs and plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) directs HHS to develop a Web site that assists employers in determining if they are eligible to participate in SHOP.

This proposed information collection was previously published in the **Federal Register** on December 11, 2015 (80 FR 76994) and allowed 60 days for public comment. No comments were received. *Form Number:* CMS–10439 (OMB control number 0938–1194); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 6,000; *Number of Responses:* 6,000; *Total Annual Hours:* 12,000. (For questions regarding this collection contact Christelle Jang at (410) 786–8438.)

3. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations and Enrollment for Employers in the Small Business Health Options Program; *Use:* Section 1311(b)(1)(B) of the Affordable Care Act directs that the SHOP assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Section 1311(c)(1)(F) of the Affordable Care Act directs HHS to establish criteria for certification of health plans as QHPs and plans to utilize a uniform enrollment form for qualified employers. Further, section 1311(c)(5)(B) directs HHS to develop a Web site that assists employers in determining if they are eligible to participate in SHOP.

This proposed information collection was previously published in the **Federal Register** on December 11, 2015 (80 FR 76994) and allowed 60 days for public comment. No comments were received. *Form Number:* CMS–10439 (OMB control number 0938–1194); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 6,000; *Number of Responses:* 6,000; *Total Annual Hours:* 12,000. (For questions regarding this collection contact Christelle Jang at (410) 786–8438.)

4. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and Children's Health Insurance Program Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each State a single, streamlined form that may be used to apply for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program, as applicable. The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if

approved by the Secretary in accordance with section 1413 and if it meets the standards established by the Secretary.

Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that must be used by the Exchange to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single streamlined application. CMS is designing the single streamlined application to be a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions. The paper version of the application will not be able to be tailored in the same way but is being designed to collect only the data required to determine eligibility. Individuals will be able to submit an application electronically, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. The application may be submitted to an Exchange, Medicaid or CHIP agency. The electronic application process will vary depending on each applicant's circumstances, their experience with health insurance applications and online capabilities. The goal is to solicit sufficient information so that in most cases no further inquiry will be needed. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 7,200,000; *Total Annual Responses:* 7,200,000; *Total Annual Hours:* 2,410,767. (For policy questions regarding this collection contact Beth Liu at 301–492–4135.)

Dated: March 22, 2016.

William N. Parham, III,

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

[FR Doc. 2016–06830 Filed 3–24–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0785]

General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drugs Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products.'' This draft guidance recommends studies, including comparative in vitro studies, which should be conducted to demonstrate that a proposed generic solid oral opioid drug product is no less abuse-deterrent than its reference listed drug.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 24, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2016–D–0785 for ''General Principles for Evaluating the Abuse-Deterrence of Generic Solid Oral Opioid Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*