State MMA Phase Down (SPD) exchange enables CMS to implement the Medicare Prescription Drug, Improvement, and Modernization Act, also called the Medicare Modernization Act (MMA), which was enacted into law in 2003. This data exchange allows the State Medicaid Agency (SMA) to identify Medicare beneficiaries with coverage under the Medicaid program. The SMAs also identify other low-income Medicare beneficiaries who have applied for the Part D Low-Income Subsidy (LIS). As a result of the identification of these two groups of beneficiaries, CMS auto-assigns and/or facilitates enrollment of the appropriate beneficiaries into Part D plans.

Section 1860 D–14 of the Social Security Act sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771 (b) establishes requirements for determining a beneficiary's eligibility for full subsidy under the Part D program. Regulations set forth in 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program. *Form Number:* CMS–10344 (OMB control number: 0938–1127); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 612. (For policy questions regarding this collection contact Roland Horrea at 410–786–0668.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Electronic Funds Transfer Authorization Agreement; *Use:* Section 1815(a) of the Social Security Act provides the authority for the Secretary of Health and Human Services to pay providers/suppliers of Medicare services at such time or times as the Secretary determines appropriate (but no less frequently than monthly). Under Medicare, CMS, acting for the Secretary, contracts with Fiscal Intermediaries and Carriers to pay claims submitted by providers/suppliers who furnish services to Medicare beneficiaries. Under CMS' payment policy, Medicare providers/suppliers have the option of receiving payments electronically. *Form Number:* CMS–588 (OMB control number: 0938–0626); *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 100,000. For questions regarding this collection contact Kim McPhillips at 410–786–5374.

Dated: September 20, 2019.

William N. Parham, III,

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

[FR Doc. 2019–20858 Filed 9–24–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10595]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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 October 25, 2019.

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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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

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

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

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: Extension without change of a currently approved collection; *Title of Information Collection:* QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), collectively referred to as the PPACA, established new competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)— private health

and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with standards regarding Plan or Display Errors SEPs. The title of the package has been changed to better reflect its subject matter. The burden estimate for the ICR included in this package reflects the time and effort for QHP issuers to provide notifications to enrollees on the ICRs regarding Plan or Display Errors SEPs. *Form Number:* CMS–10595 (OMB control number: 0938–1301); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 505; *Total Annual Responses:* 3,400; *Total Annual Hours:* 1,700. (For questions regarding this collection contact Deborah Hunter at 202–309–1098).

Dated: September 20, 2019.

William N. Parham, III,

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

[FR Doc. 2019–20856 Filed 9–24–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3614]

Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue To Be Available Over-the-Counter; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry (GFI) #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance document, when finalized, will provide information to sponsors of medically important antimicrobial new animal drug products who are interested in changing the approved marketing status of these products from over-the-counter (OTC) to by veterinary prescription (Rx) consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight to mitigate development of antimicrobial resistance. It also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2019–D–3614 for ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' 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 Dockets Management Staff 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 Dockets Management Staff. If you do not wish your name and