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

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

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

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–10292 State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act

CMS–R–65 Final Peer Review Organizations Sanction Regulations

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:* State Medicaid HIT Plan, Planning Advance Planning Document, and Implementation Advance Planning Document for Section 4201 of the Recovery Act; *Use:* To assess the appropriateness of state requests for the administrative Federal financial participation for expenditures under their Medicaid Electronic Health Record Incentive Program related to health information exchange, our staff will review the submitted information and documentation to make an approval determination of the state advance planning document. *Form Number:* CMS–10292 (OMB control number: 0938–1088); *Frequency:* Once and occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 896. (For policy questions regarding this collection contact Edward Dolly at 410–786–8554.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Final Peer Review Organizations Sanction Regulations; *Use:* The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act (the Act), creating the Utilization and Quality Control Peer Review Organization Program. Section 1156 of the Act imposes obligations on health care practitioners and others who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. The QIOs may allow practitioners or other entities, opportunities to submit relevant information before determining that a violation has occurred. The information collection requirements contained in this information collection request are used by the QIOs to collect the information necessary to make their decision. *Form Number:* CMS–R–65 (OMB control number: 0938–0444); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 4,716. (For policy questions regarding this collection contact Kimberly Harris at 401–837–1118.)

Dated: November 23, 2020.

William N. Parham, III,

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

[FR Doc. 2020–26223 Filed 11–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10443, CMS–10558 and CMS–287–21]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 December 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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*

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 of a previously approved collection: *Title of Information Collection:* Transcatheter Valve Therapy (TVT) Registry; *Use:* The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Aortic Valve Replacement (TAVR)''. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OMB control number: 0938–1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 37,221; *Total Annual Responses:* 148,884; *Total Annual Hours:* 47,765. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; *Use:* Under 45 CFR 156.122(d)(1)(2), 156.230(b), and 156.230(c), and in the final rule, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018 (CMS–9934–F), standards for qualified health plan (QHP) issuers (including Small Business Health Options Program (SHOP) issuers and stand-alone dental plans (SADP) issuers) are established for the submission of provider and formulary data in a machine- readable format to the Department of Health and Human Services (HHS) and for posting on issuer websites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. The Centers for Medicare and Medicaid Services (CMS) is continuing an information collection request (ICR) in connection with these standards. *Form Number:* CMS–10558 (OMB control number 0938–1284); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 376; *Number of Responses:* 376; *Total Annual Hours:* 10,495. (For questions regarding this collection, contact Joshua Van Drei at 410–786–1659).

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Home Office Cost Statement; *Use:* The primary function of the home office cost statement is to provide the documentary support required for a Medicare provider to claim reimbursement for HO/CO costs in their Medicare cost report. A HO/CO must submit an acceptable home office cost statement directly to the servicing contractors for its providers that received a home office cost allocation for reimbursement determinations. Section 1874A of the Act describes the functions of the contractor.

The home office cost statement schedules collect the cost data required to support home office costs claimed in a provider's Medicare cost report. The Schedule S includes the certification statement where the HO/CO attests to the accuracy of the information and allows the HO/CO the opportunity to electronically sign and electronically submit the home office cost statement. The Schedule S–1 collects identifying data about the home office and key officers/employees of the home office. The Schedule S–2 collects identifying information for healthcare provider components, non-healthcare components, and region/division components of the HO/CO, and provides the structure for reporting

costs for those components throughout the cost statement. The A series of schedules collects the HO/CO trial balance of expenses, reclassifications, and adjustments, for allocation of the HO/CO costs to its components. On the B series of schedules, the home office directly allocates costs directly attributable to specific components. On the C and D series of schedules, the HO/CO functionally allocates costs to components in a manner that reasonably relates to the services provided to the components. On the E series of schedules, the HO/CO allocates pooled costs (costs not directly assigned or functionally allocated) to the components. On the F series of schedule, the HO/CO summarizes the cost allocations by component. On the G series of schedules, the HO/CO reports financial data from their balance sheet and income statement. *Form Number:* CMS–287–21 (OMB control number 0938–0202); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 1,626; *Number of Responses:* 1,626; *Total Annual Hours:* 757,716. (For questions regarding this collection, contact Gail Duncan at 410–786–7278.)

Dated: November 20, 2020.

William N. Parham, III,

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

[FR Doc. 2020–26156 Filed 11–25–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1736]

Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a public meeting and requesting comments that appeared in the **Federal Register** of October 13, 2020. In that notice, FDA announced a public meeting, held on November 16, 2020, and requested public input on a potential revised approach for considering the human medical importance of antimicrobial new animal drugs when assessing and managing the antimicrobial resistance risks associated with the use of antimicrobial drugs in animals. Specifically, the Agency requested comments on the potential revised process for ranking antimicrobials according to their relative importance in human medicine, on the potential criteria for their ranking, and on the resulting ranked list of antimicrobial drugs. FDA is taking this action in response to several requests for extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period announced in the notice of public meeting and request for comments published October 13, 2020 (85 FR 64481). Submit either electronic or written comments by March 16, 2021, to ensure that the Agency considers your comments regarding this public meeting and request for comments.

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):* 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–1736 for ''Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs.'' 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