DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–65, CMS–1572, CMS–10175, CMS–10220, CMS–10471, and CMS–10495]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 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 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 must be received by April 28, 2017.

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–R–65 Final Peer Review Organizations Sanction Regulations in 42 CFR Sections 1004.40, 1004.50, 1004.60, and 1004.70

CMS–1572 Home Health Agency Survey and Deficiencies Report

CMS–10175 Certification Statement for Electronic File Interchange Organizations

CMS–10220 Security Consent and Surrogate Authorization Form

CMS–10471 Medicare Prior Authorization of Power Mobility Devices (PMDs) Demonstration

CMS–10495 Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments

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:* Final Peer Review Organizations Sanction Regulations in 42 CFR Sections 1004.40, 1004.50, 1004.60, and 1004.70; *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 Tiffany Jackson-Dickey at 410–786–1124.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home Health Agency Survey and Deficiencies Report; *Use:* In order to participate in the Medicare Program as a Home Health Agency (HHA) provider, the HHA must meet federal standards. This form is used to record information and patients' health and provider compliance with requirements and to report the information to the federal government. *Form Number:* CMS–1572 (OMB Control Number: 0938–0355); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 3,830; *Total Annual Responses:* 3,830; *Total Annual Hours:* 958. (For policy questions regarding this collection contact Sarah Fahrendorf at 410–786–3112.)

3. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations; *Use:* Health

care providers can currently obtain a National Provider Identifier (NPI) via a paper application or over the Internet through the National Plan and Provider Enumeration System (NPPES). These applications must be submitted individually, on a per-provider basis. The Electronic File Interchange (EFI) process allows provider-designated organizations (EFIOs) to capture multiple providers' NPI application information on a single electronic file for submission to NPPES. This process is also referred to as bulk enumeration. To ensure that the EFIO has the authority to act on behalf of each provider and complies with other federal requirements, an authorized official of the EFIO must sign a certification statement and mail it to us. *Form Number:* CMS–10175 (OMB Control Number: 0938–0984). *Frequency:* Occasionally. *Affected Public:* Private Sector; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 75. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374.)

4. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Security Consent and Surrogate Authorization Form; *Use:* The primary function of the Medicare enrollment application is to obtain information about the Provider or supplier and whether they meet the Federal and/or State qualifications to participate in the Medicare program. In addition, the Medicare enrollment application gathers information regarding the provider or supplier's practice location, the identity of the owners of the enrolling organization, and information necessary to establish the correct claims payment.

Enrollees have the option of submitting either a CMS–855 form, or submitting information via a Web based process. In establishing a Web based application process, we allow providers and suppliers the ability to enroll in the Medicare program, revalidate their enrollment and make changes to their enrollment information via Internet-based Provider Enrollment, Chain and Ownership System (PECOS). Individual providers/suppliers (hereinafter referred to as ''Individual Providers'') log into Internet-based PECOS using their User IDs and passwords established when they applied online to the National Plan and Provider Enumeration System (NPPES) for their National Provider Identifiers (NPIs). Authorized Officials (AOs) of the provider or supplier organizations (hereinafter referred to as ''Organizational Providers'') must register for a user account and authenticate their identity and connection to the organization they represent before being able to log into Internet-based PECOS. Once authenticated, AOs for Organizational Providers, receive complete access to their enrollment information via Internet-based PECOS. Individuals and AOs of Organizational Providers are not required to submit a Security Consent and Surrogate Authorization Form to enroll, revalidate or make changes to their Medicare enrollment information.

Individual and Organizational Providers may complete their Medicare enrollment responsibilities on their own or elect to delegate this task to a Surrogate. A Surrogate is an individual or organization identified by an Individual or Organizational Provider as someone authorized to access CMS computer systems, such as Internet-based PECOS, National Provider Plan and Enumeration System (NPPES) and the Medicare and Medicaid Electronic Health Records (EHR) Incentive Program Registration and Attestation System (HITECH), on their behalf and to modify or view any information contained therein that the Individual or Organizational Provider may have permission or right to access in accordance with Medicare statutes, regulations, policies, and usage guidelines for any CMS system. Surrogates may consist of administrative staff, independent contractors, 3rd party consulting companies or credentialing departments. In order for an Individual or Organizational Provider to delegate the Medicare credentialing process to a Surrogate to access and update their enrollment information in the above mentioned CMS systems on their behalf, it is required that a Security Consent and Surrogate Authorization Form be completed, or Individual and Organizational Providers use an equivalent online process via the PECOS Identity and Access Management (I&A) system. The Security Consent and Surrogate Authorization form replicates business service agreements between Medicare providers, suppliers or both and Surrogates providing enrollment services. The form, once signed, mailed and approved, grants a Surrogate access to all current and future enrollment data for the Individual or Organization Provider. *Form Number:* CMS–10220 (OMB Control Number: 0938–1035); *Frequency:* Occasionally; *Affected Public:* Individuals and Private Sector; *Number of Respondents:* 226,100; *Total Annual Responses:* 226,100; *Total Annual Hours:* 226,100. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374.)

5. *Type of Information Collection Request:* Extension of a currently approved collection of information; *Title of Information Collection:* Medicare Prior Authorization of Power Mobility Devices (PMDs) Demonstration; *Use:* The purpose of the Medicare Prior Authorization of Power Mobility Devices Demonstration (the Demonstration) is to ensure that payments for PMDs are appropriate before the claims are paid, thereby preventing the fraud, waste, and abuse in the seven states participating in the Demonstration: California, Florida, Illinois, Michigan, New York, North Carolina and Texas. Additional benefits of the Demonstration include ensuring that a beneficiary's medical condition warrants their medical equipment under existing coverage guidelines and preserving their ability to receive quality products from accredited suppliers. In order to gather qualitative information for analysis, the evaluation team will use semi-structured interview guides that focus on the direct impact of the Demonstration on stakeholder groups. Stakeholders will be drawn from advocacy organizations, power mobility device supply companies, state and local government, and healthcare practitioners. This information collection request explains the research methodology and data collection strategies designed to minimize the burden placed on research participants, while effectively gathering the data needed for the evaluation of the Demonstration. *Form Number:* CMS–10471 (OMB Control Number: 0938–1235); *Frequency:* Yearly; *Affected Public:* Private sector (business or other for-profit and not-for-profit institutions) and State and Local Governments; *Number of Respondents:* 254; *Total Annual Responses:* 254; *Total Annual Hours:* 288. (For policy questions regarding this collection contact Debbie Skinner at 410–786–7480.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers

of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers. *Form Number:* CMS–10495 (OMB Control Number: 0938–1237); *Frequency:* Once; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 227,157; *Total Annual Responses:* 457,454; *Total Annual Hours:* 3,099,297. (For policy questions regarding this collection contact Veronika Peleshchuk Fradlin at 410–786–3323.)

Dated: February 22, 2017.

William N. Parham, III,

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

[FR Doc. 2017–03809 Filed 2–24–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0696]

Current State and Further Development of Animal Models of Serious Infections Caused by Acinetobacter baumannii and Pseudomonas aeruginosa; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding the current state and further development of animal models for serious infections caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa.* FDA is conducting this workshop in order to facilitate the development of narrow-spectrum antibacterial drugs, such as those that are active against only a single species of bacteria that may not occur frequently.

This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, academic experts, contract research organizations, and industry on various aspects of development efforts pertaining to animal models of serious infections. The input from this public workshop will also help FDA in developing topics for future discussion.

DATES: The public workshop will be held on March 1, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by March 15, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration information. The workshop draft Agenda will be made available at: *http://www.fda.gov/Drugs/NewsEvents/ucm534031.htm* prior to the meeting.

ADDRESSES: The public workshop will be held at the DoubleTree by Hilton Hotel Washington DC-Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's phone number is 301–589–5200.

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–N–0696 for ''Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa.*'' 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