use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the CDC Director and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on adult immunization schedule, child/adolescent immunization schedule, Ebola vaccine, hepatitis vaccines, Orthopoxviruses vaccine and COVID vaccines. Recommendation votes on adult immunization schedule, child/adolescent immunization schedule, hepatitis vaccine, Orthopoxviruses vaccine, Ebola vaccine and COVID vaccines are scheduled. No Vaccines for Children votes are scheduled. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: The docket will be opened to receive written comments on October 22, 2021. Written comments must be received on or before November 3, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the November 2–3, 2021 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, October 31, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by November 1, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–23222 Filed 10–20–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–2567, CMS–10790 and CMS–10463]

Agency Information Collection Activities: Proposed Collection; 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 (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 December 21, 2021.

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

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–2567 Statement of Deficiency and Plan of Correction

CMS–10790 Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020 (Pub. L. 116–93)

CMS–10463 Cooperative Agreement to Support Navigators in Federally-facilitated Exchanges

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:* Revision of a currently approved collection; *Title of Information Collection:* Statement of Deficiency and Plan of Correction *Use:* The form CMS–2567 is the means by which State and CMS surveyors document findings of compliance or noncompliance (deficiencies) resulting from inspection of Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) laboratories. The form CMS–2567 is the legal, documentary basis for CMS' certification of a facility's compliance or noncompliance with the Medicare/Medicaid Conditions of Participation or Coverage, and the requirements for Nursing Home participation and CLIA certification.

In December, 2020, Congress passed the Consolidated Appropriations Act, 2021 (CAA, 2021). Section 407 of CAA, 2021, amended Part A of Title XVIII of the Social Security Act (the Act) at section 1822 establishing hospice program survey and enforcement requirements. This amendment, in part, now requires the Accrediting Organizations (AOs) that accredit hospice programs to include the form CMS–2567 to document the findings of their hospice program surveys beginning on October 1, 2021. As of June 2021, there are three AOs with CMS-approved hospice accreditation programs. The AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half. *Form Numbers:* CMS–2567 (OMB control number: 0938–0391); *Frequency:* Yearly and Occasionally; *Affected Public:* Private Sector (Business or for-profits and Not-for-profit institutions); *Number of Respondents:* 65,948; *Total Annual Responses:* 65,948; *Total Annual Hours:* 1,187,064. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB Control Number); *Title of Information Collection:* Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020 (Pub. L. 116–93); *Use:* The requirements in this rule were announced in CMS–1752–P (FY22 IPPS); however, the PRA package has been under development until now. The plan, approved by OMB and CM, is to have the 60-day publish and then have CMS–1752–F2 serve as the 30-day notice, with the goal of approval in early January 2022.

Section 126 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–93), enacted December 20, 2020, included a key provision affecting Medicare payments for Graduate Medical Education (GME). Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) requiring the distribution of additional residency positions (slots) to qualifying hospitals. Section 1886(h)(9)(A) makes an additional 1,000 Medicare funded residency slots available to be phased in beginning in FY 2023 until the aggregate number of 1,000 full-time equivalent residency positions are distributed.

This approval request is for CMS to receive electronic applications for Medicare-Funded GME Residency Positions submitted in accordance with Section 126 of the Consolidated Appropriations Act, 2021. The electronic applications will be submitted by the applicants in CMS' new Medicare Electronic Application Request Information System™ (MEARIS™). There is no existing, hard copy version of the application. The applications will provide CMS with the critical information necessary for CMS to process and score the applications in accordance with the policies finalized in the upcoming final rule to determine the disbursement of the slots and to announce the awardees by the January 31, 2023 required statutory deadline. *Form Number:* CMS–10790 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions), State, Local, or Tribal Governments; *Number of Respondents:* 1,325; *Total Annual Responses:* 1,325; *Total Annual Hours:* 10,600. (For policy questions regarding this collection contact Noel Manlove at 410–786–5161.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Cooperative Agreement to Support Navigators in Federally-facilitated Exchanges; *Use:* Section 1311(i) of the PPACA requires Exchanges to establish a Navigator grant program under which it awards grants to eligible individuals and entities (as described in Section 1311(i)(2) of the PPACA and 45 CFR 155.210(a) and (c)) applying to serve consumers in States with a FFE. Navigators assist consumers by providing education about and facilitating selection of qualified health plans (QHPs) within the Exchanges, as well as other required duties. Entities and individuals cannot serve as federally certified Navigators and carry out the required duties without receiving federal cooperative agreement funding. On July 1, 2021, HHS published the Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule proposed rule. The proposed regulations would amend federal regulations at 45 CFR 155.210(e)(9) to reinstitute the requirement that FFE Navigators provide consumers with information and assistance on access, affordability and certain post-enrollment topics, such

as the eligibility appeals process, the Exchange-related components of the Premium Tax Credit (PTC) reconciliation process, and the basic concepts and rights of health coverage and how to use it.

Under the Terms and Conditions of the Navigator program cooperative agreements, awardees must provide progress reports on a weekly, monthly, quarterly and annual basis during the cooperative agreement period of performance, and a final report at the end of the period of performance. Awardees will submit their progress reports electronically to CMS staff for evaluation and analysis. The results of this evaluation will provide feedback on the effectiveness of the Navigator program, so that HHS and CMS leadership may evaluate the effectiveness of the program and address any areas that need revisions. CMS will also use the information collected from Navigator grant awardees to inform the public about the availability of application and enrollment assistance services from designated organizations. *Form Number:* CMS–10463 (OMB control number: 0938–1215); *Frequency:* Annually, Monthly, Quarterly, Weekly; *Affected Public:* Private sector; *Number of Respondents:* 100; *Total Annual Responses:* 5,200; *Total Annual Hours:* 529,000. (For questions regarding this collection contact Gian Johnson at 301–492–4323.)

Dated: October 19, 2021.

William N. Parham, III,

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

[FR Doc. 2021–23107 Filed 10–21–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Proposed Collection; Comment Request; Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to this notice. This notice solicits comments on the collection of information contained in the Public Health Service (PHS) guideline entitled ''PHS Guideline on Infectious Disease Issues in Xenotransplantation.''

DATES: Submit either electronic or written comments on the collection of information by December 21, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 21, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2012–N–0559 for ''PHS Guideline on Infectious Disease Issues in Xenotransplantation.'' 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 and/or go to the Dockets Management