II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at 42 CFR 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAHHS–HFAP's request for continued CMS approval of its CAH accreditation program. This notice also solicits public comment on whether AAHHS–HFAP's requirements meet or exceed the Medicare conditions of participation for CAHs.

III. Evaluation of Deeming Authority Request

AAHHS–HFAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its CAH accreditation program. This application was determined to be complete on May 31, 2019. Under Section 1865(a)(2) of the Act and our regulations at 42 CFR 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of AAHHS–HFAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAHHS–HFAP's standards for CAHs as compared with CMS' CAH conditions of participation.
- AAHHS–HFAP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of AAHHS–HFAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AAHHS–HFAP's processes and procedures for monitoring a CAH found out of compliance with AAHHS–HFAP's program requirements. These monitoring procedures are used only when AAHHS–HFAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys conducted by the State survey agency, the State survey agency monitors corrections as specified at 42 CFR 488.9.

++ AAHHS–HFAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ AAHHS–HFAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAHHS–HFAP's staff and other resources, and its financial viability.

++ AAHHS–HFAP's capacity to adequately fund required surveys.

++ AAHHS–HFAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAHHS–HFAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: July 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–16371 Filed 7–30–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–643 and CMS–10052]

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 August 30, 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:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* We use the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS–643 (OMB control number: 0938–0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,801; *Total Annual Responses:* 1,600; *Total Annual Hours:* 1,600. (For policy questions regarding this collection contact Thomas Pryor at 410–786–1132.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Recognition of pass-through payment for additional (new) categories of devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* Section 402 of the Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000, made changes in the provision for transitional pass-through payment for devices under the hospital OPPS. Section 402 of BIPA amended section 1833(t)(6) of the Act to require that we abandon the item-specific approach in determining the eligibility of medical devices for transitional pass-through payments. This provision mandated that we adopt a category approach for making such payments. In accordance with this requirement, we would pay for any device that falls in categories we establish for this purpose. This provision required us to establish the initial set of categories, to include devices previously determined eligible for transitional pass-through payments, effective April 1, 2001.

The law made clear that application and approval processes are no longer required as the basis for determining an individual medical device's eligibility for transitional pass-through payments. However, we must assemble certain crucial information to be able to determine the appropriateness of establishing an additional (new) category. The information that we seek to collect is essential to determine whether additional categories of medical devices are appropriate for transitional pass-through payments. The intent of these provisions is to ensure that timely beneficiary access to new technologies is not jeopardized by inadequate payment levels.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. *Form Number:* CMS–10052 (OMB control number 0938–0857); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 160. (For policy questions regarding this collection contact AuSha Washington at 410–786–3736.)

Dated: July 25, 2019.

William N. Parham, III,

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

[FR Doc. 2019–16224 Filed 7–30–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3505]

Medical Device User Fee Rates for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2020. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2020, which apply from October 1, 2019, through September 30, 2020. To avoid delay in the review of your application, you should pay the application fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee.