- Section 416.50(b), to ensure its standards appropriately reference Part 420.
- Section 488.5(a)(4)(ii), to ensure AOA/HFAP's surveyors review the minimum number of medical records as specified by CMS and AOA/HFAP policy.
- Section 488.5(a)(4)(iv), to ensure each that all observations of non-compliance are documented in the survey report.
- Section 488.5(a)(7) through (9), to ensure AOA/HFAP complies with its policy and criteria for surveyor qualifications, education and evaluation system to monitor the performance of surveyors and teams.
- Section 488.26(b), to ensure AOA/HFAP cites findings of observed non-compliance at the appropriate level (condition versus standard level).

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve AOA/HFAP as a national accreditation organization for ASCs that request participation in the Medicare program, effective September 22, 2017 through September 22, 2023.

V. 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. 3501 *et seq.*).

Dated: September 14, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–20281 Filed 9–21–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–R–185, CMS–718–721, CMS–10123/–10124, CMS–10142, and CMS–R–262]

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 November 21, 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: William 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–R–185 Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption under State Laboratory Programs

CMS–718–721 Business Proposal Forms for Quality Improvement Organizations (QIOs)

CMS–10123/–10124 Fast Track Appeals Notices: NOMNC/DENC

CMS–10142 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)

CMS–R–262 Contract Year 2019 Plan Benefit Package (PBP) Software and Formulary Submission

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 currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it

accredits are ''deemed'' to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: Determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements. *Form No.:* CMS–R–185 (OMB control number: 0938–0686); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 12; *Total Annual Responses:* 96; *Total Annual Hours:* 384. (For policy questions regarding this collection contact Arlene Lopez at 410–786–6782.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Business Proposal Forms for Quality Improvement Organizations (QIOs); *Use:* The submission of proposal information by current quality improvement associations (QIOs) and other bidders, on the appropriate forms, will satisfy our need for meaningful, consistent, and verifiable data with which to evaluate contract proposals. We use the data collected on the forms associated with this information collection request to negotiate QIO contracts. We will be able to compare the costs reported by the QIOs on the cost reports to the proposed costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness. *Form Number:* CMS–718–721 (OMB control number: 0938–0579); *Frequency:* Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 1,000. (For policy questions regarding this collection contact Benjamin Bernstein at 410–786–6570.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Fast Track Appeals Notices: NOMNC/DENC; *Use:* Providers shall deliver a Notice of Medicare (Provider) Non-Coverage (NOMNC) to beneficiaries, enrollees, or both beneficiaries and enrollees no later than two days prior to the end of Medicare-covered services in skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, and hospices. Beneficiaries, enrollees or both beneficiaries and enrollees will use this information to determine whether they want to appeal the service termination to their Quality Improvement Organization (QIO). If the beneficiaries, enrollees or both beneficiaries decide to appeal, the Medicare provider or health plan will send the QIO and appellant a Detailed Explanation of Non-Coverage (DENC) detailing the rationale for the termination decision. *Form Number:* CMS–10123 and CMS–10124 (OMB control number: 0938–0953); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 28,177; *Total Annual Responses:* 6,017,832; *Total Annual Hours:* 1,111,196. (For policy questions regarding this collection contact Janet Miller at 404–562–1799.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We require that Medicare Advantage organizations and Prescription Drug Plans complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (*www.medicare.gov,* the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and enrollment. *Form Number:* CMS–10142 (OMB control number: 0938–0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410–786–3026.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Contract Year 2019 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* We require that Medicare Advantage and Prescription Drug Plan organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to us for review and approval. We publish beneficiary education information using a variety of formats. The specific education initiatives that utilize PBP and formulary data include web application tools on *www.medicare.gov* and the plan benefit insert in the Medicare & You handbook. In addition, organizations utilize the PBP data to generate their Summary of Benefits marketing information. *Form Number:* CMS–R–262 (OMB control number 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 520; *Total Annual Responses:* 5,675; *Total Annual Hours:* 54,550. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209.)

Dated: September 19, 2017.

William N. Parham, III,

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

[FR Doc. 2017–20290 Filed 9–21–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the