IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the May 26, 2020 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CfCs for ASCs. No comments were received in response to our proposed notice.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's ASC accreditation requirements and survey process with the Medicare CfCs of parts 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's ASC application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes in order to do all of the following:

- Meet the standard's requirements of all of the following regulations:

++ Section 416.2, to include the regulatory definition of an ASC as a comparable TJC standard instead of a glossary definition.

++ Section 416.43(c)(2), to address the broad requirement under the quality improvement program to track adverse patient events.

++ Section 416.44(c), to include reference to the Health Care Facilities Code (HCFC) of the National Fire Protection Association (NFPA) 99 (2012 edition).

++ Section 416.45(a), to include adequate review of credential and personnel files during survey activity.

++ Section 416.48(a), to include policies regarding the administration of drugs be in accordance with acceptable standards of practice.

++ Section 416.50(a), to provide the correct regulatory citation reference to the CMS standard, ''Condition for Coverage—Patient Rights; Notice of Rights.''

++ Section 488.5(a)(4)(iv), to include the requirement that all comparable Medicare CfC citations be included in the findings sections of TJC's survey reports.

CMS also reviewed TJC's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Modifying TJC's accreditation award letter to facilities to remove the term ''lengthen'' to eliminate potential conflict as it relates to survey cycle length not to exceed 36 months, as survey cycles for deeming purposes do not exceed this timeframe.

++ Adding references to the HCFC of the NFPA 99 (2012 edition). (NFPA 99) within its Accreditation Process and Surveyor Activity Guide.

++ Providing clarification to its Surveyor Activity Guide indicating that the 2012 edition of the NFPA Life Safety Code and NFPA 99 applies to ASCs, regardless of the number of patients served.

++ Clarifying the process for TJC's performance of on-site Evidence of Standard Compliance (ESC) processes, including what it means to provide coaching and guidance as part of TJC's ESC survey activities.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective December 20, 2020 through December 20, 2024. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. Due to travel restrictions and the reprioritization of survey activities brought on by the 2019 Novel Coronavirus Disease (COVID–19) Public Health Emergency (PHE), CMS was unable to observe an ASC survey completed by TJC surveyors as part of the application review process, which is one component of the comparability evaluation. Therefore, we are providing TJC with a shorter period of approval. Based on our discussions with TJC and the information provided in its application, we are confident that TJC will continue to ensure that its accredited ASCs will continue to meet or exceed Medicare standards. While TJC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under § 488.8, we will continue ongoing review of TJC's ASC survey processes and will conduct a survey observation once the COVID–19 PHE has expired. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by TJC are completed, CMS expects more frequent review of TJC's activities in the future.

VI. Collection of Information and Regulatory Impact Statement

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.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 8, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–23230 Filed 10–20–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10752, CMS–10137, CMS–R–262 and CMS–10549]

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, 2020.

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 *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–10752 Submissions of 1135 Waiver Request Automated Process

CMS–10137 Solicitation for Applications for Medicare Prescription Drug Plan 2022 Contracts

CMS–R–262 CMS Plan Benefit Package (PBP) and Formulary CY 2022

CMS–10549 Generic Clearance: Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS)

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:* Submissions of 1135 Waiver Request Automated Process; *Use:* Waivers under Section 1135 of the Social Security Act (the Act) and certain flexibilities allow the CMS to relax certain requirements, known as the Conditions of Participation (CoPs) or Conditions of Coverage to promote the health and safety of beneficiaries. Under Section 1135 of the Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. These waivers ensure that providers who provide such services in good faith can be reimbursed and exempted from sanctions.

During emergencies, such as the current COVID–19 public health emergency (PHE), CMS must be able to apply program waivers and flexibilities under section 1135 of the Social Security Act, in a timely manner to respond quickly to unfolding events. In a disaster or emergency, waivers and flexibilities assist health care providers/suppliers in providing timely healthcare and services to people who have been affected and enables states, Federal districts, and U.S. territories to ensure Medicare and/or Medicaid beneficiaries have continued access to care. During disasters and emergencies, it is not uncommon to evacuate Medicare-participating facilities and relocate patients/residents to other provider settings or across state lines, especially, during hurricane and tornado events. CMS must collect relevant information for which a provider is requesting a waiver or flexibility to make proper decisions about approving or denying such requests. Collection of this data aids in the prevention of gaps in access to care and services before, during, and after an emergency. CMS must also respond to inquiries related to a PHE from providers and beneficiaries. CMS is not collecting information from these inquiries; we are merely responding to them.

Prior to this request, CMS did not have a standard process or OMB approval for providers/suppliers impacted to submit 1135 waiver/flexibility requests or inquiries, as these were generally seen on a smaller scale (natural disasters) prior to the COVID–19 public health emergency. CMS has provided general guidance to Medicare-participating facilities which can be viewed at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.* The requests and inquiries would be sent directly, via email, to the Survey Operations Group in each CMS Location (previously known as CMS Regional Offices) and the entity would provide a brief summary to CMS for a waiver/flexibility request or an answer to an inquiry. We are now developing a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during COVID–19 PHE, primarily based on the volume of requests to ensure timely response to facility needs. The waiver request form was approved under an Emergency information collection request on October 15, 2020.

Furthermore, the normal operations of a healthcare provider are disrupted by emergencies or disasters occasionally. When this occurs, State Survey Agencies (SA) deliver a provider/beneficiary tracking report regarding the current status of all affected healthcare providers and their beneficiaries. This report includes demographic information about the provider, their operational status, beneficiary status, and planned resumption of normal operations. This information is provided whether or not a PHE has been declared. We are now developing a streamlined, automated process to standardize submission of this information directly by the provider during emergencies and eliminating the need for SA to provide it. It will consist of a public facing web form.

This information will be used by CMS to receive, triage, respond to and report on requests and/or inquiries for Medicare, Medicaid, and CHIP beneficiaries. This information will be

used to make decisions about approving or denying waiver and flexibility requests and may be used to identify trends that inform CMS Conditions for Coverage or Conditions for Participation policies during public health emergencies, when declared by the President and the HHS Secretary.

Subsequent to the Emergency information collection request, we are revising the package to include a second form, Healthcare Facility Status Workflow, which is for operational status information which will be used to assist providers in delivering critical care to beneficiaries during emergencies. *Form Number:* CMS–10752 (OMB control number: 0938–1384); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 3,730; *Total Annual Responses:* 3,730; *Total Annual Hours:* 3,730. (For policy questions regarding this collection, contact Adriane Saunders at 404–562–7484.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2022 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 658; *Total Annual Responses:* 331; *Total Annual Hours:* 1,550. (For policy questions regarding this collection, contact Arianne Spaccarelli at 410–786–5715.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CMS Plan Benefit Package (PBP) and Formulary CY 2022; *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits.

CMS requires that MA and PDP 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 CMS for review and approval. CMS uses this data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans. *Form Number:* CMS–R–262 (OMB control number: 0938–0763); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 753; *Total Annual Responses:* 8,090; *Total Annual Hours:* 74,038. (For policy questions regarding this collection, contact Kristy Holtje at 410–786–2209.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Generic Clearance: Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use:* The current generic clearance for MCBS Questionnaire Testing and Methodological Research encompasses development and testing of MCBS questionnaires, instrumentation, and data collection protocols, as well as a mechanism for conducting methodological experiments. The current clearance includes conducting field tests and experiments, including split ballot experiments, within the MCBS production environment, and conducting usability tests. The purpose of this OMB clearance package is to revise the current clearance to expand the methods to allow for field tests outside of MCBS production Field tests conducted within production do not incur any additional burden on respondents whereas tests conducted outside production must account for additional respondent burden. The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS, which is sponsored by the Centers for Medicare & Medicaid Services (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. The core of the MCBS is a series of interviews with a stratified random sample of the Medicare population, including aged and disabled enrollees, residing in the community or in institutions. Questions are asked about enrollees' patterns of health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic characteristics, their health and work history, and their family living circumstances. In addition to collecting information through the core questionnaire, the MCBS collects information on special topics. *Form Number:* CMS–10549 (OMB control number: 0938–1275); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 11,655; *Total Annual Responses:* 11,655; *Total Annual Hours:*

3,947. (For policy questions regarding this collection, contact William Long at 410–786–7927.)

Dated: October 16, 2020.

William N. Parham, III,

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

[FR Doc. 2020–23335 Filed 10–20–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–116 and CMS–317]

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 November 20, 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:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations; *Use:* Section 353 (b) of the Public Health Service Act specifies that the laboratory must submit an application in such form and manner as the Secretary shall prescribe that describes the characteristics of the laboratory and examinations and procedures performed by the laboratory. The application must be completed by entities performing laboratory's testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. In this revision, the majority of changes were minor changes to the form and accompanying instructions to facilitate the completion and data entry of the form. We anticipate that the changes will not increase the time to complete the form. *Form Number:* CMS–116 (OMB control number: 0938–0581); *Frequency:* Biennially and Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 52,140; *Total Annual Responses:* 52,140; *Total Annual Hours:* 52,140. (For policy questions regarding this collection contact Kathleen Todd at 410–786–3385.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection of information; *Title of Information Collection:* State Medicaid Eligibility Quality Control Sampling Plan; *Use:* The Medicaid Eligibility Quality Control (MEQC) program provides states and the District of Columbia a unique opportunity to improve the quality and accuracy of their Medicaid and Children's Health Insurance Program (CHIP) eligibility determinations. The MEQC program is intended to complement the Payment Error Rate Measurement (PERM) program by ensuring state operations make accurate and timely eligibility determinations so that Medicaid and CHIP services are appropriately provided to eligible individuals. Current regulations require that states review equal numbers of active cases and negative case actions (*i.e.,* denials and terminations) through random sampling. Active case reviews are conducted to determine whether or not the sampled cases meet all current criteria and requirements for Medicaid or CHIP eligibility. Negative case reviews are conducted to determine if Medicaid and CHIP denials and terminations were appropriate and undertaken in accordance with due process. *Form Number:* CMS–317 (OMB control number: 0938–0146); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 20; *Total Annual Hours:* 520. (For policy questions regarding this collection contact Camiel Rowe at 410–786–0069.)

Dated: October 15, 2020.

William N. Parham, III,

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

[FR Doc. 2020–23219 Filed 10–20–20; 8:45 am]

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