

Benefit and Payment Parameters for 2018 (CMS-9934-F), standards for qualified health plan (QHP) issuers (including Small Business Health Options Program (SHOP) issuers and stand-alone dental plans (SADP) issuers) are established for the submission of provider and formulary data in a machine-readable format to the Department of Health and Human Services (HHS) and for posting on issuer websites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. The Centers for Medicare and Medicaid Services (CMS) is continuing an information collection request (ICR) in connection with these standards. *Form Number:* CMS-10558 (OMB control number 0938-1284); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 376; *Number of Responses:* 376; *Total Annual Hours:* 10,495. For questions regarding this collection, contact Joshua Van Drei at 410-786-1659.

2. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Beneficiary and Family Centered Data Collection; *Use:* To ensure the QIOs are effectively meeting their goals, CMS collects information about beneficiary experience receiving support from the QIOs. The information collection uses both qualitative and quantitative strategies to ensure CMS and the QIOs understand beneficiary experiences through all interactions with the QIO including initial contact, interim interactions, and case closure. Information collection instruments are tailored to reflect the steps in each type of process, as well as the average time it takes to complete each process. The information collection will:

- Allow beneficiaries to directly provide feedback about the services they receive under the QIO program;
- Provide quality improvement data for QIOs to improve the quality of service delivered to Medicare beneficiaries; and
- Provide evaluation metrics for CMS to use in assessing performance of QIO contractors.

To achieve the above goals, information collection will include: Experience survey, direct follow-up and general feedback web survey. *Form Number:* CMS-10393 (OMB control number: 0938-1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 9,100; *Number of Responses:* 9,100;

Total Annual Hours: 2,191. (For policy questions regarding this collection, contact David Russo at 617-565-1310.)

August 21, 2020, Dated: July 14, 2020.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3391-FN]

Medicare and Medicaid Programs; Application From the Joint Commission for Continued Approval of its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is effective on July 15, 2020, through July 15, 2022.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786-2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a SA to determine whether it continues to meet these requirements. There is an alternative; however, to surveys by SAs.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements. Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5, and 488.5(e)(2)(i). The regulations at § 488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS.

The Joint Commission's current term of approval for their hospital accreditation program expires July 15, 2020.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On February 18, 2020, we published a proposed notice in the **Federal Register** (85 FR 8874), announcing TJC's request for continued approval of its Medicare hospital accreditation program. In the February 18, 2020

proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of TJC's Medicare hospital accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and (5) survey review and decision-making process for accreditation.

- The comparison of TJC's Medicare hospital accreditation program standards to our current Medicare hospital conditions of participation (CoPs).

- A documentation review of TJC's survey process to do the following:

- ++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

- ++ Compare TJC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against TJC-accredited hospitals.

- ++ Evaluate TJC's procedures for monitoring accredited hospitals it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If non-compliance is identified by a SA through a validation survey, the SA monitors corrections as specified at § 488.9(c)).

- ++ Assess TJC's ability to report deficiencies to the surveyed hospitals and respond to the hospital's plan of correction in a timely manner.

- ++ Establish TJC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of TJC's staff and other resources.

- ++ Confirm TJC's ability to provide adequate funding for performing required surveys.

- ++ Confirm TJC's policies with respect to surveys being unannounced.

- ++ Confirm TJC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

- ++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

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

In accordance with section 1865(a)(3)(A) of the Act, the February 18, 2020 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for hospitals. 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 hospital accreditation requirements and survey process with the Medicare CoPs of parts 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's hospital 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—

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

- ++ Section 482.21(b)(2)(i), to incorporate language related to using patient care data to monitor the effectiveness and safety of services and quality of care.

- ++ Section 482.22(c)(5)(ii), to include comparable language, which requires that the updated examination of the patient including any changes in the patient's condition be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

- ++ Section 482.23(c)(6)(i)(A), to address patients' self-administration of hospital-issued medications that may be allowed by a hospital pursuant to a practitioner's order (specifically to incorporate a comparable standard to ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting such self-administration of medications).

- ++ Section 482.26(d)(2), to address timeframes related to records retention of accredited hospitals.

- ++ Section 482.41(c)(2), to include reference to the Healthcare Facilities

Code (HCFC) NFPA Health Care Facilities Code (NFPA 99) (2012 edition).

- ++ Section 482.57(b)(1), to incorporate language related to written documentation requirements for personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out such procedures.

- ++ Glossary adjustment to incorporate language to include the caregiver or support person within the definition of family member.

In addition to the standards review, 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:

- ++ Providing additional clarity to the how TJC determines the size and composition of the organization's survey teams for hospitals as required under § 488.5(a)(5) including Life Safety Code (LSC) surveyors.

- ++ 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 2012 edition of the (NFPA) Health Care Facilities Code (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 at hospital outpatient surgical departments, regardless of the number of patients served.

- ++ Providing clarification to its Surveyor Activity Guide indicating that surveys must consider all hospital provider-based locations.

- ++ Requiring additional training for TJC's surveyors and adjusting TJC's survey processes as they relate to off-site locations, to include surveying for LSC and other Physical Environment standards.

- ++ Making adjustments to TJC's survey processes as they relate to leading and probing questions during interviews.

- ++ Making adjustments to TJC's survey processes as they relate to providing a setting, which promotes ease of sharing information with surveyors during interviews, in

particular placing restrictions on interviewing staff in front of first line supervisors.

++ Requiring additional training for surveyors and making modifications instructing surveyors regarding the level of detail provided to the facility during TJC's daily briefing, to ensure it does not change the integrity of the survey process.

++ Requiring additional training for TJC's surveyors and adjusting TJC's survey processes as they relate to in-depth review of medical records.

++ Making modifications to TJC's survey processes as they relate to the "Governing Body" Condition of Participation (§ 482.12). Specifically:

— Clarifications to TJC's governing body Tracer and Leadership sessions, as they relate to discussion-based investigation techniques and record reviews.

— Determinations of deficiencies and TJC's preliminary decision making processes, such as determining the severity of deficiencies, and TJC's process for citing the governing body based on the deficiencies found at a facility.

— Citing the governing body for deficiencies within a facility's physical environment based on the severity of deficiencies.

++ Clarifying timeframes for Plans of Corrections to be submitted by the facility to TJC and TJC's performance of Evidence of Standard Compliance (ESC) processes, as well as onsite follow up surveys as part of TJC's ESC survey activities.

++ Modifying TJC's survey process related to providing each patient in the sample a unique identifier in deficiency reports and for TJC surveyors to have appropriate identifiable information on a separate identifier list which can be provided to the facility upon exit.

++ Clarifying and providing additional training to surveyors related to survey processes and procedures for review of credentialing and human resources and or personnel file reviews.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this final notice is effective July 15, 2020 through July 15, 2022 (2 years). In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years. This shorter term of approval is based on our concerns related to the comparability of

TJC's survey processes to those of CMS, as well as what CMS has observed of TJC's performance on the survey observation. Some of these concerns stem from the level of detail TJC provides in the daily briefings it provides to facilities, as well as TJC's processes surrounding its staff interview practices. Additionally, we are concerned about TJC's review of medical records and surveying off-site locations, in particular for the Physical Environment condition of participation. Based on these observations and review of TJC's processes as discussed at section V.A. (Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements), we remain concerned about the thoroughness of review conducted within the facilities. While TJC has taken action based on the findings annotated in section V.A., as authorized under § 488.8, we will continue ongoing review of TJC's survey processes across all their approved accrediting programs to ensure that all our recommended changes have been implemented. In keeping with CMS's initiative to increase AO oversight, and ensure that our requested revisions by TJC are complied with, CMS expects more frequent review of TJC's activities to avoid any continued inconsistencies.

VI. Collection of Information and Regulatory Impact Statement

This document does not impose information collection 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.*). In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

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

Dated: July 15, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10396]

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 17, 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 <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.