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 a currently approved collection; *Title of Information Collection:* Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; *Use:* Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting.

On September 29, 2017, the ''Disaster Tax Relief and Airport and Airway Extension Act of 2017'' was enacted into law. Section 302 of this legislation extends the Medicare IVIG Demonstration through December 31, 2020. While existing beneficiaries enrolled in the demonstration as of September 30, 2017 will be automatically re-enrolled, in order to continue to enroll new beneficiaries into the demonstration, an application is required. The original enrollment and financial limits remain and CMS will continue to monitor both to assure that statutory limitations are not exceeded.

This collection of information is for the application to participate in the demonstration. Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they are would be eligible for in the absence of the demonstration. *Form Number:* CMS–10518 (OMB control number: 0938–1246); *Frequency:* Annually; *Affected Public:* Individuals and households; *Number of Respondents:* 1,220; *Total Annual Responses:* 1,220 *Total Annual Hours:* 305. (For policy questions regarding this collection contact Jody Blatt at 410–786–6921.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Generic Clearance for Questionnaire Testing and Methodological Research for the Medicare Current Beneficiary Survey (MCBS); *Use:* The purpose of this OMB clearance package is to extend the approval of the generic clearance to support an effort to evaluate the operations and content of the Medicare Current Beneficiary Survey (MCBS). 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:* 1,500; Total Annual Responses: 1,500; Total Annual Hours: 1,117. (For policy questions regarding this collection contact William Long at 410–786–7927.)

Dated: October 24, 2017.

William N. Parham, III,

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

[FR Doc. 2017–23451 Filed 10–26–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3336–FN]

Medicare and Medicaid Programs: Approval of an Application From the Joint Commission (TJC) for Continued CMS Approval of Its Critical Access Hospital (CAH) Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, 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 critical access hospitals (CAHs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective November 21, 2017 through November 21, 2023.

FOR FURTHER INFORMATION CONTACT: Monda Shaver, (410) 786–3410, Karena Meushaw, (410) 786–6609 or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program eligible beneficiaries may receive covered services in a critical access hospital (CAH), provided certain requirements are met. Sections 1820(c)(2)(B) and 1861(mm) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. The minimum requirements that a CAH must meet to participate in the Medicare Program are at 42 CFR part 485, subpart F. Conditions for Medicare payment for CAHs are at 42 CFR 413.70. Applicable regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to facility survey and certification are at 42 CFR part 488, subparts A and B.

For a CAH to enter into a provider agreement with the Medicare program, a CAH must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1820 of the Act and our regulations at part 485. Subsequently, the CAH is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is an alternative to State compliance surveys. Certification by a nationally recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that if the Secretary of the Department

of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions; that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide the Centers for Medicare & Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Joint Commission's (TJC's) term of approval as a recognized Medicare accreditation program for CAHs expires November 21, 2017.

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 May 19, 2017, we published a proposed notice in the **Federal Register** (82 FR 23004) announcing TJC's request for continued approval of its Medicare CAH accreditation program. In the 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 CAH 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.
- A comparison of TJC's Medicare accreditation program standards to our current Medicare CAH 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 accredited CAHs.

++ Evaluate TJC's procedures for monitoring CAHs 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 State survey agency through a validation survey, the State survey agency 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.

++ 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.

In accordance with section 1865(a)(3)(A) of the Act, the May 19, 2017 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoP for CAHs. There were two comments submitted, neither of which related to the content of the proposed notice.

IV. 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 CAH accreditation requirements and survey process with the Medicare CoPs at part 485, and the survey and certification process requirements of parts 488 and 489. TJC's standards and crosswalk were also examined to ensure that the appropriate CMS regulations would be included in citations as appropriate. We reviewed and evaluated TJC's CAH application, which was conducted as described in section III of this final notice. As a result TJC has revised the following standards and certification processes:

- Section 482.21(d)(2): Updated its standards and crosswalk to include a comparable standard to allow facilities to develop and implement an information technology system explicitly designed to improve patient safety and quality of care as part of its quality improvement program.
- Section 482.21(d)(4): Updated its standards and crosswalk to include a comparable standard that requires facilities that do not participate in a cooperative project to implement projects that are of comparable effort.
- Sections 482. 22(b)(4)(iii) through (b)(4)(iv): Updated its standards and crosswalk to ensure that CAHs are not permitted to have a ''unified and integrated medical staff.''
- Section 482.28(b)(2): Updated its standards and crosswalk to include a comparable standard to require that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutritional professionals.
- Section 482.53(b): Updated its standards and crosswalk to include the ''preparation'' of radioactive materials.
- Section 485.618(d)(4): Updated its standards and crosswalk to address the withdrawal of a request for using Registered Nurses on a temporary basis as part of their State Rural Healthcare Plan with the State Boards of Medicine and Nursing.
- Sections 485.627(b)(1) through (b)(3): Updated its standards and

crosswalk to include comparable standards to require disclosure of the names and addresses of the facility's owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest.

- Section 485.645(a)(2): Updated its crosswalk to include the correct regulatory language to require that the facility limits inpatient beds to no more than 25 and is verified on all surveys.
- Section 488.5(a)(4)(vii): Updated its policies and review process to ensure that approved plans of correction fully address all non-compliant practices identified during the survey; that appropriate policy changes have been made to ensure compliance; and that plans of correction identify the responsible party for ensuring corrective actions are implemented within the CAH and contain a description of how the CAH will monitor and evaluate the effectiveness of the corrective actions, analyze the data, and report findings to the senior leadership and governing body to ensure continued regulatory compliance.
- Section 488.5(a)(12): Provided CMS with assurance that its procedures for responding to, and investigating complaints against accredited facilities are fully implemented and followed.
- Section 488.26(b): Revised surveyor documentation to include appropriately detailed deficiency statements that clearly support the determination of noncompliance and appropriate level of deficiency.

TJC revised its survey policy and procedure to clearly delineate that a survey will not occur until after the applicable Regional Office has made a determination of the CAH's compliance with location and distance requirements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that TJC's CAH program requirements meet or exceed our requirements, and its survey processes are comparable to ours. Therefore, we approve TJC as a national accreditation organization for critical access hospitals that request participation in the Medicare program, effective November 21, 2017 through November 21, 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: *October 16, 2017.*

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–23449 Filed 10–26–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9105–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2017

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2017, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

BILLING CODE 4120–01–P

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786-8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

BILLING CODE 4120–01–C

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other