

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2018)
There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

[FR Doc. 2019-02672 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3364-FN]

Application From the Joint Commission (TJC) for Continued Approval of Its Psychiatric 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 for continued recognition as a national accrediting organization for psychiatric hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective February 25, 2019 through February 25, 2023.

FOR FURTHER INFORMATION CONTACT: Mary Ellen Palowitch (410) 786-4496, Monda Shaver (410) 786-3410, Tara Lemons (410) 786-3030.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a psychiatric hospital provided certain requirements are met. Section 1861(f) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a psychiatric 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 subparts A, B, C and E specify the minimum conditions that a psychiatric hospital must meet to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for psychiatric hospitals.

Generally, to enter into an agreement, a psychiatric hospital must first be certified by a State Survey Agency as complying with the conditions or requirements set forth in part 482 subpart A, B, C and E of our regulations. Thereafter, the psychiatric hospital is subject to regular surveys by a State Survey Agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all

applicable Medicare conditions are met or exceeded, we may treat the provider entity as having met those conditions, that is, we may “deem” the provider entity as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare & Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires the 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 accrediting organizations 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 psychiatric hospital accreditation program expires February 25, 2019.

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 August 15, 2018, we published a proposed notice in the **Federal Register** (83 FR 40514), announcing the Joint Commission’s (TJC’s) request for continued approval of its Medicare psychiatric hospital 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 psychiatric hospital accreditation renewal 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 psychiatric hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited psychiatric hospitals; and, (5) survey review and decision-making process for accreditation.

- A comparison of TJC's Medicare hospital accreditation program standards to our current Medicare hospital Conditions of Participation (CoPs) and psychiatric hospital special conditions.

- A documentation review of TJC's psychiatric hospital's survey process to:
 - ++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

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

- ++ Evaluate TJC's procedures for monitoring psychiatric 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 noncompliance 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 hospital and respond to the psychiatric 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 August 15, 2018 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received no comments in response to our 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 psychiatric hospital accreditation program requirements and survey process with the Medicare CoPs at part 482 and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's psychiatric 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 revised its standards and certification processes in order to meet the requirements at:

- Section 482.12(a)(10), to address that consultation will occur directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his/her designee and the timeframe for which direct consultation must occur.

- Section 482.41(b)(3), to provide information related to our rule stating that Life Safety Code provisions do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

- Section 482.41(b)(5), to address cooperation with local firefighting authorities.

- Section 482.41(b)(7), to address installing alcohol-based hand rub dispensers in a manner that adequately protects against inappropriate access.

- Section 482.41(e), to address the omission of a standard to correspond to references and documents in this CMS requirement.

- Section 482.42(b)(1), to address and clarify that "make certain" is defined as "must."

- Section 482.42(b)(2), to address and clarify that "make certain" is defined as "must."

- Section 482.43(b)(2), to address who may develop or supervise the development of the discharge evaluation.

- Section 482.43(c)(1), to address who must develop or supervise the

development of a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

- Section 482.51(a)(3), to address that a qualified registered nurse is immediately available to respond to emergencies.

- Section 482.51(b)(3), to address and include the required equipment that must be available to the operating room suites.

- Section § 488.5(a)(4)(i), to ensure that all surveys are unannounced.

- Section § 488.5(a)(4)(ii), to ensure that its surveyors are provided clear instruction for assessing only the applicable CoPs for the psychiatric hospital accreditation program.

- Section 488.5(a)(4)(iv), to ensure that TJC psychiatric hospital surveyors document findings of noncompliance with accreditation standards at the comparable Medicare CoP; and to ensure that all findings of observed noncompliance noted on surveyor worksheets are clearly and accurately reflected in the final survey deficiency report.

- Section 488.5(a)(4)(v), to ensure that a minimum sample of patient records are reviewed for all elements required by the regulations.

- Sections 488.5(a)(11)(ii), to ensure that data submitted to CMS is timely, complete and accurate.

- Section 488.5(a)(12), to ensure that TJC has a clearly defined complaint investigation process that is comparable to CMS; to ensure that the process for protecting complainant anonymity does not impede the required complaint investigation; to ensure that complaints are investigated, based on the submitted allegations, irrespective of receiving a "waiver of anonymity" from the complainant; to ensure that complaints are reviewed and investigated within the comparable timelines established by CMS; and to ensure that all complaints that would result in condition-level non-compliance, based on allegations described therein, are required to be investigated through an onsite survey.

- Section 488.5(a)(19)(ii), to ensure that TJC proposed survey process and crosswalked standards will not be implemented without prior written notice of approval from CMS.

- Section 488.26, to ensure TJC's survey process meets or exceeds the Medicare program requirements; and to ensure that surveyors assess all required facility locations and services during the survey process.

- Section 489.13, to ensure that the granting of accreditation and recommendations to CMS for Medicare participation occurs only after the

facility has demonstrated full compliance with all requirements.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for psychiatric hospitals that request participation in the Medicare program, effective February 25, 2019 through February 25, 2023.

To verify TJC’s continued compliance with the provisions of this final notice, CMS expects to conduct a follow-up corporate on-site visit and survey observation within 18 months of the publication date of this notice.

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: February 7, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-02673 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; ACF’s Generic Clearance for Grant Reviewer Recruitment Forms (OMB #0970-0477)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office of Planning, Research, and Evaluation (OPRE) is proposing an extension of a currently approved generic clearance (OMB no. 0970-0477) for Grant Reviewer Recruitment (GRR) forms. The GRR forms will be used to select reviewers who will participate in the grant review process for the purpose of selecting successful applications.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be

forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Under this generic approval, ACF conducts and proposes to continue to conduct more than one information collection that is very similar, voluntary, low-burden and uncontroversial. The purpose is to select qualified reviewers for the grant peer review process based on professional qualifications using data entered by candidates and the uploaded writing sample and/or curriculum vitae and/or resume. The grant review process is in accordance with the U.S. Department of Health and Human Services’ (DHHS) Grants Policy Directive (GPD) 2.04 “Awarding Grants”, the DHHS Awarding Agency Grants Administration Manual (AAGAM), Chapter 2.04.104C “Objective Review of Grant Applications”, and the Public Health Service (PHS) Act, Sections 799(f) and 806(e).

Respondents: Individuals who may apply to review ACF grant applications.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Grant Reviewer Recruitment Form	3,000	1	.5	1,500

Estimated Total Annual Burden Hours: 1,500.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given

to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-02624 Filed 2-15-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation (OMB#0970-0481)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Family Assistance (OFA) within the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services has issued grants to organizations to provide healthy marriage and relationship education (HMRE) services. Under a previously approved data collection activity (OMB#0970-0481), the Office of Planning, Research, and Evaluation (OPRE) within ACF is conducting the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation with five HMRE grantees. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. This data collection request is for an extension of