

(1) Identify, obtain, and organize sales information, prepare response:	30–70 hours
(2) Identify, obtain, and organize information on advertising and marketing expenditures, prepare response:	50–130 hours
(3) Identify, obtain, and organize placement information, prepare response:	240–560 hours
(4) Identify, obtain, and organize information regarding compliance review, prepare response:	20–40 hours
(5) Identify, obtain, and organize information regarding data collection, prepare response:	20–40 hours

The staff anticipates that the cumulative hours burden to respond to the information requests will be between 360 and 840 hours per company. Nonetheless, in order to be conservative, the staff estimates that the burden per company for each of up to fourteen intended recipients will be 840 hours. Accordingly, the staff estimates a total burden for these companies of approximately 11,760 hours (14 companies × 840 average burden hours per company). These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent company that has received the information request.

Estimated Cost Burden: \$252,000.

It is difficult to calculate with precision the labor costs associated with the information requests, as the costs entail varying compensation levels of management and/or support staff among companies of different sizes. Financial, legal, marketing, and clerical personnel may be involved in the information collection process. The staff has assumed that professional personnel and outside legal counsel will handle most of the tasks involved in gathering and producing responsive information, and has applied an average hourly wage of \$300/hour for their labor. Thus, the staff estimates that the total labor costs per company will range between \$108,000 (\$300 × 360 hours) and \$252,000 (\$300 × 840 hours).

The staff estimates that the capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may necessitate that industry members maintain the requested information provided to the Commission, they should already have in place the means to compile and maintain business records.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011-4196 Filed 2-24-11; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Recommendations Received From the HIT Policy Committee

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Section 3002(e) of the Public Health Service Act, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, requires the National Coordinator for Health Information Technology to publish in the **Federal Register** and post on the internet all policy recommendations made by the HIT Policy Committee.

Policy recommendations presented at the February 2, 2011 HIT Policy Committee meeting have been transmitted from the HIT Policy Committee to the National Coordinator and are available on the ONC Web site: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_policy_recommendations/1815.

Dated: February 14, 2011.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2011-4290 Filed 2-24-11; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2326-FN]

Medicare and Medicaid Programs; Approval of the Joint Commission for Deeming Authority for Psychiatric Hospitals

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Joint

Commission for recognition as a national accreditation program for psychiatric hospitals seeking to participate in the Medicare or Medicaid programs. This initial 4-year approval is effective February 25, 2011, through February 25, 2015.

DATES: *Effective Date:* This final notice is effective February 25, 2011.

FOR FURTHER INFORMATION CONTACT: L. Tyler Whitaker, (410) 786-5236; Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in 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. The regulations at 42 CFR part 482, subpart E specify, among other things, the conditions that a psychiatric hospital must meet to participate in the Medicare program. Regulations concerning provider agreements are located at 42 CFR part 489 and those pertaining to survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into a provider agreement, a psychiatric hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1861(f) of the Act, and 42 CFR part 482, including the special provisions applying to psychiatric hospitals in subpart E of our regulations. Thereafter, the psychiatric hospital 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. Accreditation by a nationally-recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization (AO) that all applicable Medicare conditions are met or exceeded, we may “deem” that provider entity as having met the requirements. Accreditation by an AO is

voluntary and is not required for Medicare participation. A national AO applying for deeming authority under 42 CFR 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 conditions.

II. Deeming Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for deeming authority is conducted in a timely manner. The statute provides 210 calendar days after the date of receipt of a complete application, with any documentation necessary to make a 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 accreditation 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 and Response to Comments

In the October 22, 2010 **Federal Register** (75 FR 65360), we published a proposed notice announcing the Joint Commission's request for approval as a deeming organization for psychiatric hospitals. In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission's application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

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

- A comparison of the Joint Commission's psychiatric hospital accreditation standards to our current Medicare psychiatric hospital conditions of participation (CoPs).

- A documentation review of the Joint Commission's survey processes to:

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

- + Compare the Joint Commission's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- + Evaluate the Joint Commission's procedures for monitoring psychiatric hospitals determined to be out of compliance with the Joint Commission's program requirements. The monitoring procedures are used only when the Joint Commission identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

- + Assess the Joint Commission's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- + Establish the Joint Commission's ability to provide us with electronic data and reports necessary for effective validation and assessment of the Joint Commission's survey process.

- + Determine the adequacy of staff and other resources.

- + Review the Joint Commission's ability to provide adequate funding for performing required surveys.

- + Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced.

- + Obtain the Joint Commission'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 October 22, 2010 proposed notice also solicited public comments regarding whether the Joint Commission's requirements met or exceeded the Medicare CoPs for psychiatric hospitals. We received 4 comments in response to our proposed notice.

All of the commenters expressed strong support for the Joint Commission's application for psychiatric hospital deeming authority. The commenters stated that the Joint Commission's standards are clearly written and closely align with the Medicare CoPs, and that the Joint Commission's accreditation program provides psychiatric hospitals with a viable alternative to other healthcare accreditation organizations.

IV. Provisions of the Final Notice

A. Differences Between the Joint Commission's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the Joint Commission's psychiatric hospital accreditation requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of the Joint Commission's deeming application, which were conducted as described in section III. of this final notice, yielded the following:

- To meet the requirements at Appendix AA of the SOM, the Joint Commission revised its policies to ensure surveyors draw a representative number of patients from each distinct program area for observation and interview based on the size of that program.

- To meet the requirements at § 482.13(e), the Joint Commission revised its crosswalk to address the requirement that all patients have the right to be free from physical or mental and corporal punishment.

- To meet the requirements at § 482.24(b)(2), the Joint Commission revised its standards to address the requirement that the medical record system must allow for timely retrieval of patient information by diagnosis and procedure.

- To meet the requirements at § 482.26(b)(1), the Joint Commission revised its crosswalk to ensure the hospital maintains proper safety precautions against radiation hazards.

- To meet the requirements at § 482.41(a), the Joint Commission modified its standards to prevent hospitals from conducting back-to-back emergency preparedness response drills.

- To meet the requirements at § 482.41(a)(1), the Joint Commission revised its standards to include all of the essential electrical system specific requirements, per National Fire Protection Association (NFPA) 99:1999: 12-3.3 and corresponding Chapter 3 requirements.

- To meet the requirements at § 482.41(b)(1)(i), the Joint Commission revised its standards to address the availability of the fire safety plan, and ensure that all required fire safety elements are addressed. In addition, the Joint Commission revised its standards to require quarterly testing of tamper and water flow devices, and ensure no gaps exist around penetrations.

- To meet the requirements at § 482.41(b)(9)(i) through (iii) and § 482.41(b)(9)(v), the Joint Commission

revised its Web site to ensure it includes all of the alcohol-based hand rub dispenser requirements.

- To meet the requirements at § 482.45(b)(3), the Joint Commission revised its standards to address the hospital's responsibility to provide organ transplant data directly to the Department of Health and Human Services when requested by the Secretary.

- To meet the requirements at § 482.56, the Joint Commission revised its crosswalk to ensure that if the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services are organized and staffed to ensure the health and safety of patients.

- To meet the requirements at § 482.61(a)(3), the Joint Commission revised its standards to ensure psychiatric hospitals clearly document the reason for admission as stated by the patient and/or others significantly involved in the patient's care.

- To meet the requirements at § 482.61(a)(5), the Joint Commission revised its standards to address the requirement that, when indicated, a complete neurological examination be recorded at the time of the admission physical examination.

- To meet the requirements at § 482.61(c)(1)(ii), the Joint Commission revised its standards to include both short-term and long-range patient goals.

- To meet the requirements at § 482.61(c)(1)(iv), the Joint Commission revised its standards to ensure the patient's treatment plan includes the responsibilities of each member of the treatment team.

- To meet the requirements at § 482.62, the Joint Commission revised its crosswalk to address the psychiatric hospital's responsibility to formulate written, individualized, comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

- To meet the requirements at § 482.62(f), the Joint Commission revised its standard to ensure that the hospital has a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.

- The Joint Commission revised its psychiatric hospital survey procedures to ensure all applicable hospital CoPs at 42 CFR part 482 are adequately evaluated for compliance.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that the Joint Commission's requirements for

psychiatric hospitals meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for psychiatric hospitals that request participation in the Medicare program effective February 25, 2011 through February 25, 2015.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 18, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-4294 Filed 2-24-11; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1347-N]

Medicare Program; Public Meeting in Calendar Year 2011 for New Clinical Laboratory Tests Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for a specified list of new Clinical Procedural Terminology (CPT) codes for clinical laboratory tests in calendar year (CY)

2012. The meeting provides a forum for interested parties to make presentations and submit written comments on the new codes that will be included in Medicare's Clinical Laboratory Fee Schedule for CY 2012, which will be effective on January 1, 2012. The development of the codes for clinical laboratory tests is largely performed by the CPT Editorial Panel and will not be further discussed at the meeting.

DATES: Meeting Date: The public meeting is scheduled for Monday, July 18, 2011 from 9 a.m. to 2 p.m., Eastern Standard Time (E.S.T.).

Deadline for Registration of Presenters: All presenters for the public meeting must register by July 11, 2011.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5 p.m., E.S.T. on July 11, 2011.

Deadline for Submission of Written Comments: Interested parties may submit written comments on the proposed payment determinations by September 23, 2011, to the address specified in the **ADDRESSES** section of this notice. We note that comments submitted should pertain to the payment basis for a specified list of new Clinical Procedural Terminology (CPT) codes.

ADDRESSES: The public meeting will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Glenn McGuirk, (410) 786-5723.

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) requires the Secretary to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD-9-CM). The procedures and public meeting announced in this notice for new clinical laboratory tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub.