

(Compliance Progress) of the report format and include clarifications to Questions 4a, 5b, 5e and 5f. Additionally, three new questions (5c, 5d and 5g) have been added and two items have been added to Question 7b. Information on these additions appears below:

Question 5c: Level of Enforcement—This question, which asks the State to select whether enforcement is conducted only at those outlets randomly selected for the Synar survey, only at a subset of outlets not randomly selected for the Synar survey, or a combination of the two, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5d: Frequency of Enforcement—This question, which

asks the State to select whether every tobacco outlet in the State did or did not receive at least one enforcement compliance check in the last year, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5g. Relationship of State Synar Program to FDA-Funded Enforcement Program—This question, which asks the State to describe the relationship between the State's Synar program and the Food and Drug Administration (FDA)-funded enforcement program, has been added to the ASR format. The Family Smoking Prevention and Tobacco Control Act, recently signed into law by President Obama, requires the FDA to reissue the 1996 regulation aimed at reducing

young people's access to tobacco products and curbing the appeal of tobacco to the young. This regulation must be reissued by April 2010. As part of the implementation of this regulation, FDA will be contracting with States to enforce new Federal youth access provisions. This question asks the State to describe the relationship and coordination between its Synar program and the enforcement program funded by FDA.

Question 7b. Synar Survey Results for States that Do Not Use the Synar Survey Estimation System (SSES)—Two items have been added to this question (accuracy rate and completion rate). These items were added to ensure that the same statistical parameters are asked of both States that do and do not use the SSES to analyze their Synar survey results.

ANNUAL REPORTING BURDEN

45 CFR Citation	Number of respondents ¹	Responses per respondents	Hours per response	Total hour burden
Annual Report (Section I—States and Territories) 96.130(e)(1–3)	59	1	15	885
State Plan (Section II—States and Territories) 96.130(e)(4,5), 96.130(g)	59	1	3	177
Total	59			1,062

¹ Red Lake Indian Tribe is not subject to tobacco requirements.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 15, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–25528 Filed 10–22–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2900–FN]

Medicare and Medicaid Programs; Conditional Approval of the Community Health Accreditation Program for Continued Deeming Authority for Hospices

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

ACTION: Final notice.

SUMMARY: This notice announces our decision to conditionally approve, with

a 180-day probationary period, the Community Health Accreditation Program's (CHAP's) request for continued recognition as a national accreditation program for hospices seeking to participate in the Medicare or Medicaid programs.

DATES: Effective Date: This final notice is effective November 20, 2009 through November 20, 2012, with a 180-day probationary period beginning November 20, 2009 through May 19, 2010.

FOR FURTHER INFORMATION CONTACT:

Aviva Walker-Sicard, (410) 786–8648. Alexis Prete, (410) 786–0375. Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided certain requirements are met. Section 1861(dd)(1) of the Social Security Act (the Act) establishes distinct criteria for entities seeking designation as a hospice program. Under this authority, the regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare

program, the scope of covered services, and the conditions for Medicare payment for hospice care. Provider agreement regulations are located in 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located in 42 CFR part 488.

Generally, in order to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with conditions or requirements set forth in part 418 of our regulations. Then, the hospice 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 accreditation organization that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by 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 conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A, must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning reapproval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accreditation organizations to reapply for continued approval of deeming authority every 6 years, or sooner as determined by CMS. CHAP's term of approval as a recognized accreditation program for hospices expires November 20, 2009.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed 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** of our approval or denial of the application.

III. Provisions of the Proposed Notice

On May 22, 2009, we published a proposed notice (74 FR 24015) announcing CHAP's request for reapproval as a deeming organization for hospices. In this notice, we specified in detail our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 (application and reapplication procedures for accreditation organizations), we conducted a review of the CHAP application in accordance with the criteria specified in our regulation, which include, but are not limited to the following:

- An onsite administrative review of CHAP'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 CHAP's hospice accreditation standards to our current Medicare conditions for participation (CoPs).

- A documentation review of CHAP's survey processes to—

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

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

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

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

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

- ++ Determine the adequacy of staff and other resources.

- ++ Review CHAP's ability to provide adequate funding for performing required surveys.

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

- ++ Obtain CHAP's agreement to provide us 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 22, 2009 proposed notice also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare CoPs for hospices. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

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

We compared the standards contained in CHAP's accreditation requirements and survey process with the Medicare

hospice CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of CHAP's deeming application, which were conducted as described in section III of this final notice, yielded the following:

- CHAP modified its policies related to the accreditation effective date in accordance with the requirements at § 489.13.

- CHAP amended its policies to include required timeframes for investigation of complaints in accordance with the requirements at section 5075.9 of the SOM.

- CHAP developed a policy to ensure facilities with condition level non-compliance on a recertification survey submit an acceptable plan of correction (PoC), and receive a follow-up focused survey, in order to meet the requirements at § 488.20(a) and § 488.28(a).

- CHAP modified its policies surrounding timeframes for sending and receiving PoCs, and to ensure that approved PoCs contain all required elements to meet Medicare requirements at section 2728 of the SOM.

- CHAP developed and incorporated measures to improve the accuracy and consistency of data submissions to CMS, in order to meet the requirements at § 488.4(b).

- CHAP developed an action plan to ensure that deemed status survey files are complete, accurate, and consistent with the requirements at § 488.6(a).

- CHAP developed an action plan to ensure recertification surveys are conducted no later than 36 months after the date of the previous standard survey, in order to meet the requirements at § 488.20(a).

- CHAP amended its policies by eliminating recommendations from the written survey findings, in order to meet the requirements at § 488.28(a) and section 2726 of the SOM.

- CHAP revised its standards to include the definitions used in the revised Medicare hospice CoPs set out at § 418.3.

- CHAP revised its standard to address the requirement that investigations and/or documentation of alleged violations must be conducted in accordance with established procedures, in order to meet the requirements at § 418.52(b)(4)(ii).

- CHAP revised its standards to include the requirement that the hospice document the patient's need for psychosocial, emotional and spiritual care as part of the comprehensive assessment, in order to meet the requirements at § 418.54.

- CHAP revised its standard to include the word “individualized”, to meet the requirements at § 418.56(b).
- CHAP revised its standards to address the requirement that the Quality Assessment and Performance Improvement (QAPI) program be capable of showing improvement in hospice services, in order to meet the requirements at § 418.58(a)(1).
- CHAP revised its standards to address the requirement that patient care quality data be included in the QAPI program, in order to meet the requirements at § 418.58(b)(1).
- CHAP revised its standards to address the requirement that the hospice’s performance improvement activities must affect palliative outcomes, patient safety, and quality of care, in order to meet the requirements at § 418.58(c)(1)(iii).
- CHAP revised its standards to include the requirement that the number of performance improvement projects must reflect the scope, complexity and past performance of the hospices services and operations, in order to meet the requirements at § 418.58(d)(1).
- CHAP revised its standards to include the requirement that the hospice’s infection control program protect patients, families, visitors and hospice personnel by preventing and controlling infections and communicable diseases, in order to meet the requirements at § 418.60.
- CHAP revised its standards to address the requirement that the infection control program is an integral part of the QAPI program, in order to meet the requirements at § 418.60(b)(1).
- CHAP revised its standards to address the requirement that the hospice’s infection control program include a method for identifying infectious and communicable disease problems, in order to meet the requirements at § 418.60(b)(2)(i).
- CHAP revised its standards to address the requirement that the hospice’s infection control program include a plan for implementing the appropriate actions that are expected to result in improvement and disease prevention, in order to meet the requirements at § 418.60(b)(2)(ii).
- CHAP revised its standards to include language to address the CMS waiver requirements for physical therapy, occupational therapy, speech-language pathology and dietary counseling in non-urbanized areas, in order to meet the requirements at § 418.74.
- CHAP revised its standards to ensure that the hospice aide training program addressed the requirements of

reading, writing and verbally reporting clinical information to patients, caregivers, and other hospice staff, in order to meet the requirements at § 418.76(b)(3)(i).

- CHAP revised its standards to require the hospice aide training program include instruction in appropriate and safe techniques in performing personal hygiene and grooming tasks, in order to meet the requirements at § 418.76(b)(3)(ix)(A) through (F), and § 418.76(b)(3)(x) through (xiii).

- CHAP revised its standards to include the requirement that hospice aide in-service training be supervised by a registered nurse, in order to meet the requirements at § 418.76(d)(1).

- CHAP revised its standards to require a registered nurse, who is a member of the interdisciplinary group, assign patients to hospice aides, in order to meet the requirements at § 418.76(g)(1).

- CHAP revised its standards to address the requirement that hospice aide assignment be ordered by the interdisciplinary group, in order to meet the requirements at § 418.76(g)(2)(i).

- CHAP revised its standards to ensure that the supervising registered nurse assesses an aide’s ability to comply with infection control policies and procedures, in order to meet the requirements at § 418.76(h)(3)(iv).

- CHAP revised its standards to ensure the supervising registered nurse assess an aide’s ability to report changes in the patient’s condition, in order to meet the requirements at § 418.76(h)(3)(v).

- CHAP revised its standards to ensure that the hospice continually monitors and manages all services provided at all locations so that each patient and family receives the necessary care and services, in order to meet the requirements at § 418.100(f)(2).

- CHAP developed a surveyor tool that includes the requirement to review three new hires for documentation of training and competency on the use of restraints and seclusions, in order to meet the requirements at § 418.110(n)(4).

- CHAP revised its standards to ensure all entries in the medical record are legible and appropriately authenticated, in order to meet the requirements at § 418.104(b).

- CHAP revised its standards to ensure necessary medical appliances and durable medical equipment are provided by the hospice, in order to meet the requirements at § 418.106.

- CHAP revised its standards to address the hospices’ responsibility to provide adequate staffing to ensure the

plan of care outcomes are achieved and negative outcomes are avoided, in order to meet the requirements at § 418.110(a).

- CHAP added new standards to address CMS’ ability to waive space and occupancy requirements for facilities occupied by Medicare participating hospices on December 2, 2008, in order to meet the requirements at § 418.110(f)(4)(i) through (ii).

- CHAP revised its accreditation decision letters to ensure they are accurate and contain all the required elements necessary for the CMS Regional Office to render a decision regarding deemed status of a hospice.

To verify CHAP’s continued compliance with the provisions of this final notice, we will conduct a follow-up corporate onsite visit within 6 months of the date of publication of this notice.

Our review of CHAP’s renewal application for hospice deeming authority revealed that CHAP has ongoing, serious, widespread areas of noncompliance, specifically CHAP’s inability to provide us with accurate and timely data on deemed providers, lack of complete and accurate deemed facility survey files, and failure to ensure that recertification surveys are conducted on an interval not exceeding 36 months. Due to the significant number of areas of noncompliance identified during the review of CHAP’s renewal application for hospice deeming authority, we have concerns that CHAP’s accreditation program for hospices may no longer provide reasonable assurance that its accredited entities meet the Medicare requirements.

In accordance with § 488.8(d)(3), every 6 years, or sooner as determined by CMS, an approved accreditation organization must reapply for continued approval of deeming authority. CMS notifies the organization of the materials the organization must submit as part of the reapplication procedure. An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish CMS, upon request and at any time, with the reapplication materials CMS requests. CMS will establish a deadline by which the materials are to be submitted.

In accordance with § 488.8(f)(3)(i), if we determine that an accreditation organization has failed to adopt requirements comparable to CMS requirements, we may grant a conditional approval of the accreditation organization’s deeming authority for a period of up to 1 year to adopt comparable requirements; in this

case, we are providing CHAP with a probationary period of 180 days. Within 60 days after the end of CHAP's probationary period, we will make a final determination as to whether or not CHAP's hospice accreditation requirements are comparable to CMS requirements and issue an appropriate notice that includes reasons for our determination, no later than July 18, 2010. If CHAP has not made improvements acceptable to CMS during the 180-day probationary period, we may remove recognition of deemed authority for its hospice program effective 30 days after the date we provide written notice to CHAP that its hospice deeming authority will be removed. In addition, due to the significant number of areas of noncompliance, we will conduct a follow-up corporate onsite visit to validate compliance with the provisions of this final notice.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that CHAP's accreditation program for hospices requires further revision and subsequent review. We believe that with additional time, CHAP will be able to make the necessary revisions to ensure that CHAP's accreditation program for hospices meets or exceeds the Medicare requirements as stated in Part 418. Therefore, we conditionally approve CHAP as a national accreditation organization for hospices that request participation in the Medicare program, effective November 20, 2009 through November 20, 2012, with a 180-day probationary period beginning November 20, 2009 through May 19, 2010. As stated above, we will publish a final determination giving final approval or revoking such approval no later than July 18, 2010.

IV. 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).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 24, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–25072 Filed 10–22–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1505–N]

Medicare Program; Criteria for Medicare Coverage of Inpatient Hospital Rehabilitation Services

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

ACTION: Rescission of Ruling.

SUMMARY: This notice rescinds HCFA Ruling 85–2, “Medicare Criteria for Coverage of Inpatient Hospital Rehabilitation Services,” 50 FR 31040 (July 31, 1985), as corrected at 50 FR 32643 (Aug. 13, 1985) which established the criteria for Medicare coverage of inpatient hospital rehabilitation services.

DATES: *Effective Date:* This notice is effective on January 1, 2010.

FOR FURTHER INFORMATION CONTACT: Julie Stankivic, (410) 786–5725.

SUPPLEMENTARY INFORMATION:

I. Background

The criteria for Medicare coverage of inpatient hospital rehabilitation services set forth in HCFA Ruling 85–2 (HCFAR–85–2) were developed more than 25 years ago, and were designed to provide coverage criteria for a small subset of providers furnishing intensive and complex therapy services in a fee-for-service environment to a small segment of patients whose rehabilitation needs could only be safely furnished at a hospital level of care. In the final rule implementing the Inpatient Rehabilitation Facility Prospective Payment System for Federal FY 2010, published August 7, 2009 in the **Federal Register** (74 FR 39762), we adopted inpatient rehabilitation facility (IRF) coverage requirements and technical revisions to certain other IRF requirements to reflect the changes that have occurred in medical practice during the past 25 years. The new IRF coverage requirements adopted in the final rule are effective for IRF discharges occurring on or after January 1, 2010. As discussed in the final rule (74 FR 39762, at 39797), we anticipate that these new coverage requirements will be further

interpreted by new manual provisions in Chapter 1, Section 110 of the Medicare Benefit Policy Manual that will also go into effect on January 1, 2010. Thus, HCFAR 85–2 (and the current manual provisions, rev. 1, effective October 1, 2003) will continue to apply for all IRF discharges that occur prior to January 1, 2010.

II. Provisions of the Notice

Effective January 1, 2010, this notice rescinds HCFAR 85–2 published in the **Federal Register** on July 31, 1985 (50 FR 31040).

III. 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.

Authority: Sections 1812, 1814, 1861 and 1862 of the Social Security Act (42 U.S.C. 1395d, 1395f, and 1395x, and 1395y). (Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 24, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH–187]

Proposed Enhancements to Occupational Health Surveillance Data Collection Through the Healthcare Personnel Safety (HPS) Component of the National Healthcare Safety Network (NHSN); Correction

A notice of public meeting and availability for public comment was published in the **Federal Register**, September 21, 2009, (74 FR 48081). This notice is corrected as follows:

On page 48081, third column: The heading “Place” the name of the hotel has been changed to the Doubletree Hotel.