

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from our receipt of the request to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of JCAHO's request to become a national accreditation program for CAHs. This notice also solicits public comment on the ability of JCAHO requirements to meet or exceed the Medicare conditions of participation for CAHs.

III. Evaluation of Deeming Authority Request

On February 1, 2002, JCAHO submitted all the necessary materials concerning its request for approval as a deeming organization for CAHs to enable us to make a determination. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of JCAHO will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of JCAHO standards for a critical access hospital as compared with our comparable critical access hospital conditions of participation.
- JCAHO's survey process to determine the following:
 - Survey team composition, surveyor qualifications, and the capacity of the organization to provide continuing surveyor training.
 - The comparability of JCAHO's processes to that of State agencies, including survey frequency and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - JCAHO's processes and procedures for monitoring providers or suppliers found to be out of compliance with JCAHO program requirements. These monitoring procedures are used only when JCAHO identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(b)(3).
 - JCAHO's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - JCAHO's capacity to provide us with electronic data in an ASCII

comparable format as well as the reports necessary for validation and assessment of the organization's survey process.

- The adequacy of JCAHO's staff and other resources, and its financial viability.
- JCAHO's capacity to adequately fund required surveys.
- JCAHO's policies with respect to whether surveys are announced or unannounced.
- JCAHO'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.

IV. Response to Comments and Notice Upon Completion of Evaluation

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a final notice, we will respond to the public comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget did not review this proposed notice.

In accordance with Executive Order 13132, we have determined that this proposed notice would not have a significant affect on the right of States, local or tribal governments.

Authority: Sec. 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

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

Dated: March 18, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3076-FN]

Medicare Program; Approval of the Indian Health Service (IHS) as a National Accreditation Organization for Accrediting American Indian and Alaska Native Entities To Furnish Outpatient Diabetes Self-Management Training

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

ACTION: Final notice.

SUMMARY: This final notice announces the approval of the Indian Health Service (IHS) as a national accreditation organization for outpatient Diabetes Self-Management Training (DSMT) services. This notice also announces the decision of the IHS to adopt the National Standards for Diabetes Self-Management Education Programs (NSDSMEP), for purposes of determining that American Indian and Alaska Native (AI/AN) entities meet the necessary quality standards to furnish outpatient diabetes self-management and training services under Part B of the Medicare program. Therefore, diabetes self-management training (DSMT) programs accredited by the IHS will receive "deemed" status under the Medicare program.

EFFECTIVE DATE: This accreditation is effective on March 22, 2002, for a term of 6 years.

FOR FURTHER INFORMATION CONTACT: Eva Fung, (410) 786-7539.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1861(qq) of the Social Security Act (the Act) provides us with the statutory authority to regulate Medicare outpatient coverage of diabetes self-management training (DSMT) services. The section also permits DSMT programs to be deemed to have met our regulatory standards if they are accredited by an organization that represents individuals with diabetes as having met standards for furnishing DSMT services. Section 1865 (b) of the Act specifies a process whereby we approve and recognize national accrediting organizations for the purpose of recognizing health care entities accredited by the organization to have met such program requirements. The regulations published in accordance with section 1865(b) have served as the model for our approval of accreditation programs.

The final rule on DSMT, published on December 29, 2000 in the **Federal Register** (65 FR 251) explicitly modeled its accreditation organization approval process after the section 1865 approval process specified in 42 CFR part 488, subpart A. The final rule states that DSMT programs interested in participating in the Medicare program must meet conditions for coverage specified in our regulations at 42 CFR part 410, subpart H. One requirement is that entities must satisfy required quality standards. Currently, one way that an entity must satisfy the quality standards under § 410.145 is to be accredited by a CMS-approved accrediting body. The regulations pertaining to the application process for national accreditation organizations for DSMT at § 410.142(a) specify that we may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training. After we approve and recognize the accreditation organization, it may accredit an entity to meet one of the sets of quality standards described in § 410.144, and we will deem these entities to have met these standards.

II. Review Process and Findings

A. Review Process

In evaluating an application from an accrediting organization, we consider the following factors under section 1865(b)(2) of the Act and specified for DSMT purposes at § 410.142(e):

- The organization uses and enforces quality standards that CMS has determined meet or exceed the CMS quality standards described in § 410.144(a), or uses the National Standards for Diabetes Self-Management Education Programs (NSDSMEP) quality standards described in § 410.144(b);
- The organization meets the requirements for approved organizations in § 410.143;
- The organization is not owned or controlled by the entities it accredits, as defined in § 413.17(b)(2) or (b)(3); and
- The organization does not accredit any entity it owns or controls.

We are required by § 410.142(d) to publish a proposed notice in the **Federal Register** after the receipt of a written request for approval from a national accreditation organization. After review of the national accreditation organization's application, the regulations require that we publish a notice of our approval or disapproval after we receive a complete package of information and the organization's deeming application.

B. Review Findings

We received a complete application from the Indian Health Service (IHS) on September 5, 2001. On October 26, 2001, we published a proposed notice in the **Federal Register** (66 FR 54262) announcing the application of the IHS for approval as an accreditation organization for American Indian/Alaska Natives (AI/AN) diabetes self-management training programs. We reviewed the application, and our findings indicated that the IHS meets the CMS criteria as "a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes" to accredit entities to furnish training in § 410.142(a).

We recognize that the IHS has a solid record of well-balanced experience in representing the interest of individuals with diabetes in the past decades. The AI/AN population has the highest rate of diabetes in the world and the prevalence of diabetes is 350 percent higher than in the general U.S. population. Recognizing the size of the AI/AN population affected by diabetes, the Congress, since 1979, has funded the IHS-administered National Diabetes Program to promote collaborative strategies to combat diabetes, develop standards-of-care policies for diabetes, disseminate comprehensive information about diabetes, and advocate for the AI/AN population in the health field. The IHS has played a leadership role in the development of diabetic care surveillance and data collection in the AI/AN diabetes program. The IHS monitors the quality of the AI/AN diabetic education service through the established system and network of the IHS National Diabetes Program, the IHS Area Consultants, the IHS Model Diabetes Program, the Special Diabetes Grant Programs and the IHS Integrated Diabetes Education and Clinical Standards Recognition Program for AI/AN Communities. Additionally, the IHS works in partnership with the IHS Model Diabetes Programs to tailor educational materials, treatment programs, nutrition counseling and physical activities to accommodate cultural, physical and geographical needs.

We recognize that the traditional definition of "nonprofit organization" used by HHS in other contexts generally does not cover governmental entities. However, we have determined that the IHS possesses the indicia of nonprofit status because among other things, it is not formed for commercial or profit-making purposes; it does not have shares or shareholders, and it serves

charitable purposes. All the health care services, including DSMT services, are furnished to the AI/AN population free of charge, and The Indian Health Care Improvement Act requires Medicare and Medicaid reimbursements be allocated back to the facilities to make improvements in the programs and maintain compliance with the applicable conditions and requirements.

We do not anticipate a conflict of interest in the deeming of AI/AN DSMT entities by IHS. The Indian Self-Determination and Education Assistance Act (ISDEAA) (25 U.S.C. 450f) authorizes the IHS to contract or compact with tribes for independent administration and operation of health services and programs in their communities. Under ISDEAA and the Public Health Service Act (42 U.S.C. section 254c-3(c)), the tribes may administer the diabetes programs funds independently from the IHS, and the agency serves in a consultative role regarding best practices. The IHS provides technical assistance to tribes on an as needed basis and has limited authority to sanction or assume a tribal health program. We therefore believe that IHS's deeming authority will be exercised in compliance with § 410.142(e) (regarding relationships with owned or controlled entities).

In the best interests of the AI/AN population, which has been affected by diabetes in alarming proportions, we have exercised our flexibility and discretion to approve the IHS application to accredit AI/AN DSMT programs. Our decision is based on the consideration of the unique relationship between the IHS National Diabetes Program, the Tribal Diabetes Program and the Special Diabetes Grant Program, as well as the distinct IHS funding structure that does not exist in other types of health care systems.

During the term of approval as an accrediting organization, IHS will: (1) Enforce the NSDSMEP for its deemed entities; (2) comply with the requirements for approved accreditation organizations under § 410.143; (3) continue to refrain from exercising administrative authority over the IHS Model Diabetes Programs, Tribal Model Diabetes Programs and the 1997 BBA Diabetes Grant Programs; and (4) continue to retain its consultative role regarding best diabetes practices.

III. Analysis of and Responses to Public Comments and Provisions of the Final Notice

During the 30-day comment period, we received one comment in support of the IHS application. We reviewed the application and determined that IHS has

demonstrated experience in representing the interests of individuals with diabetes and is therefore qualified to accredit entities to furnish training. The IHS is adopting the NSDSMEP quality standards as permitted by the statute. Therefore, we have approved the IHS' application as an accreditation organization for diabetes self-management training programs under § 410.142(d) for a term of 6 years. The IHS is the second accreditation organization that we have approved for accrediting diabetes self-management training programs.

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

Authority: Sections 1861(qq), 1871 of the Social Security Act (42 U.S.C. 1395(qq), 1395bb).

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

Dated: February 3, 2002.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3089-N]

Medicare Program; Annual Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

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

ACTION: Notice.

SUMMARY: This notice is soliciting interested parties to submit requests for review of the appropriateness of the payment amount for a particular intraocular lens furnished by an ambulatory surgical center.

DATES: Requests for review must be received at the address provided no later than 5 p.m. E.S.T. on April 22, 2002.

ADDRESSES: Mail requests for review (one original and three copies) to the Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: Betty Shaw,

Mailstop C1-09-06, 7500 Security Blvd., Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Betty Shaw, (410) 786-6100; or Mary Stojak, (410) 786-6939.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103-432) were enacted. Section 141(b) of SSAA 1994 requires us to develop and implement a process under which interested parties may request, for a class of new technology intraocular lens (NTIOLs), a review of the appropriateness of the payment amount for IOLs furnished by ambulatory surgical centers (ASCs) under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act).

On June 16, 1999, we published a final rule in the **Federal Register** titled "Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers" (64 FR 32198), which added subpart F to 42 CFR part 416. That rule set forth the process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of \$50 for intraocular lenses (IOLs) that we determine are NTIOLs. This payment adjustment is good for a 5-year period that begins when we recognize a payment adjustment for the first intraocular lens in a new subset of an existing class of intraocular lens or a new class of technology, as explained below. Any subsequent IOL with the same characteristics as the first IOL recognized for a payment adjustment will receive the adjustment for the remainder of the 5-year period established by the first recognized IOL. After July 16, 2002, we may change the \$50 adjustment amount through a notice with comment period.

Review Process for Establishing Classes of New Technology Intraocular Lenses

We evaluate requests for the designation of an IOL as an NTIOL by doing the following:

(1) Publishing a notice in the **Federal Register** announcing the deadline and requirements for submitting a request for us to review payment for an IOL.

(2) Receiving requests to review the appropriateness of the payment amount for an IOL.

(3) Compiling a list of the requests we receive and identify the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested

party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(4) Publishing a notice in the **Federal Register** listing the requests, and giving the public 30 days to comment on the IOLs for which a review was requested.

(5) Reviewing the information submitted with the request to review, and requesting confirmation from the Food and Drug Administration (FDA) about labeling applications that have been approved on the model lens under review. We also request a recommendation from the FDA about whether or not the lens model represents a new class of technology that sets it apart from other IOLs.

Using a baseline of the date of the last determinations of new classes of intraocular lenses, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses that are classified by a predominant characteristic as reducing the risk of intraoperative or postoperative complication or trauma, or demonstrating accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

(6) Determining which lenses meet the criteria to qualify for the payment adjustment based on clinical data and evidence submitted for review, the FDA's analysis, public comments on the lenses, and other available information.

(7) Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class.

(8) Publishing a notice in the **Federal Register** (within 120 days after we publish the notice identified in paragraph (4) of this section) announcing the IOLs that we have determined are "new technology" IOLs. These NTIOLs qualify for the following payment adjustment:

(a) Determinations made before July 16, 2002—\$50.

(b) Determinations made after July 16, 2002—\$50 or the amount announced through proposed and final rules in connection with ambulatory surgical center services.

(9) Adjusting payments effective 30 days after the publication of the notice announcing our determinations described in paragraph (8) of this section.

Who May Request a Review?

Any party who is able to furnish the information required in § 416.195 (A