parties related to the interest(s) the person proposed to represent.

(4) The reasons that the proposed members of the committee identified in this notice do not represent the interests of the person submitting the application or nomination.

(5) Your name, address, telephone number, and the name of the tribe or tribal organization with which you are affiliated.

To be considered, comments and nominations must be received by the close of business on March 13, 1999, at the location indicated in the ''Addresses'' section.

Dated: February 4, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 99–3301 Filed 2–10–99; 8:45 am]

BILLING CODE 4310–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 164–0112b; FRL–6227–3]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, San Joaquin Valley Unified Air Pollution Control District, Sacramento Metropolitan Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the California State Implementation Plan (SIP) which concern the control of oxides of nitrogen (NO_X) emissions from solid fuel fired boilers, steam generators and process heaters within the San Joaquin Valley Unified Air Pollution Control District and from stationary gas turbine operations within the Sacramento Metropolitan Air Quality Management District.

The intended effect of proposing approval of these rules is to regulate emissions of NO_X in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In the Final Rules Section of this **Federal Register**, the EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for this approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated in relation to this rule. If EPA receives adverse comments, the direct final rule will not take effect and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received by March 15, 1999.

ADDRESSES: Written comments should be addressed to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rules are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95814.

San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Suite 200, Fresno, CA 93721.

Sacramento Metropolitan Air Quality Management District, 8411 Jackson Road, Sacramento, CA 95826

FOR FURTHER INFORMATION CONTACT: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1185.

SUPPLEMENTARY INFORMATION: This document concerns San Joaquin Valley Unified Air Pollution Control District's (SJVUAPCD) Rule 4352, Solid Fuel Fired Boilers, Steam Generators and Process Heaters, and Sacramento Metropolitan Air Quality Management District's (SMAQMD) Rule 413, Stationary Gas Turbines. The SJVUAPCD rule was submitted by the California Air Resources Board (CARB) to EPA on March 26, 1996 and the SMAQMD rule was submitted on May 18, 1998. For further information, please see the information provided in the direct final action which is located in the Rules Section of this **Federal Register**.

Authority: 42 U.S.C. 7401–7671q.

Dated: January 14, 1999.

Felicia Marcus,

Regional Administrator, Region 9.

[FR Doc. 99–3144 Filed 2–10–99; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 410, 414, 424, 476, and 498

[HCFA–3002–P]

RIN 0938–AI96

Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would provide for uniform coverage of outpatient diabetes self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity deemed to meet certain quality standards proposed in this rule. The physician or qualified nonphysician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. It sets forth proposed payment amounts that have been established in consultation with appropriate diabetes organizations. It would implement section 4105 of the Balanced Budget Act of 1997.

COMMENT DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 12, 1999.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3002–P, PO Box 31850, Baltimore, MD 21207–8850.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3002–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue,

SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Claude Mone, (410) 786–5666, (Conditions for Coverage and Quality Standards); Angela Mason, (410) 786–7452, (Physician Fee Schedule Payments); Joan Brooks, (410) 786–5526 (Accreditation and Deeming).

SUPPLEMENTARY INFORMATION:

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/nara/index.html, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call 202–512–1661; type swais, then login as guest (no password required).

I. Background

A. Diabetes—Background

1. Prevalence and Costs of Diabetes

In 1997, as reported by the Department of Health and Human Services' Centers for Disease Control and Prevention, (CDC), 15.7 million people in the United States had diabetes, nearly six percent of the United States population (Morbidity and Mortality Weekly Report 4643, 1014–1018, 1997 Center for Disease Control and Prevention). Diabetes is the seventh leading cause of death in the United States, and more than 187,000 persons died from the disease and its related complications in 1995. The American Diabetes Association estimates that $98.2 billion was spent in 1997 on diabetes care ($44.1 billion in costs directly attributable to diabetes and $54.1 billion for indirect medical costs, such as work loss, disability, and premature death.)

Among Americans aged 65 and older, 4 million persons (9.3 percent of this group) are estimated to have diabetes. According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations, and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No. 95–1468–1995: 553–570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. Ten percent of these hospitalizations are a direct result of uncontrolled diabetes, and more than half of these admissions occur in beneficiaries 65 and older (National Hospital Discharge Survey, U.S. National Center for Health Statistics, U.S. Department of Health and Human Services, 1990). In expanding the Medicare program to include outpatient diabetes self-management training services, the Congress intended to empower Medicare beneficiaries with diabetes to better manage and control their conditions. The Conference Report indicates that the conferees believed that ''this provision will provide significant Medicare savings over time due to reduced hospitalizations and complications arising from diabetes.'' (H.R. Conf. Rep. No. 105–217, at 701 (1997)).

2. Classification of Diabetes

Diabetes mellitus is a disease of metabolism presenting as a complex group of syndromes that have in common elevated blood glucose levels. It occurs because the insulin produced by the beta cells of the pancreas is either absent, insufficient, or not used properly by target tissues. As a result, the body is unable to metabolize macronutrients in food in the normal way. Since the body cannot convert glucose into energy, high levels of glucose remain in the blood and spill into the urine, eventually resulting in micro-vascular complications (for example, kidney disease and eye disease) and macro-vascular complications (for example, stroke and ischemic heart disease).

There are two major types of diabetes that affect the Medicare population, Type 1 diabetes, previously called insulin dependent diabetes mellitus, and Type 2 diabetes, previously called non-insulin dependent diabetes mellitus.

B. Medicare Coverage and Payment Before July 1, 1998

1. Medicare Coverage

Before July 1, 1998, Medicare covered diabetes self-management training furnished through outpatient hospital-based programs (Coverage Issues Manual (CIM), HCFA Pub. 6, Section 80–2). Specifically, the CIM provided coverage of diabetes education if the services were furnished under a physician's order by the provider's personnel; and under medical staff supervision to beneficiaries who are registered patients of that provider. We required that the services be closely linked to the care and treatment of the individual beneficiary and provided the beneficiary with essential knowledge that aided in the beneficiary's active participation in his or her own treatment and the skills that enabled self-management.

Finally, all services covered by Medicare had to be reasonable and necessary to treat the beneficiary's diabetes and the referring physician was responsible for maintaining documentation of the necessity of the training program. Section 1862(a)(1)(A) of the Act provides, in pertinent part, that Medicare may pay only for services that are reasonable and necessary for the diagnosis or treatment of illness or injury. In developing the Medicare policy on diabetes self-management, we determined that certain educational services are consistent with the provisions of section 1862(a)(1)(A) of the Act.

2. Medicare Payment

Since 1994, Medicare payment for diabetes education as a separate service has been limited to services furnished in

the hospital outpatient department to the hospital's registered outpatients. These services have been paid under Medicare Part B on a reasonable cost basis. In all other Medicare settings, beneficiary education related to diabetes is treated as an integral part of a direct service if furnished by a physician or nonphysician practitioner or furnished as incident to their services and no separate charge was allowed.

Payment has been made for hospital outpatient diabetes education programs that, at a minimum, teach the beneficiary diet and exercise and blood glucose self-monitoring; establish treatment plans for insulin-dependent beneficiaries; and motivate the beneficiaries to use skills learned to enable them to manage their diabetes. Payment has been made for facility costs associated with the provision of both individual and group education sessions.

C. Recent Legislation

Section 4105(a) of the Balanced Budget Act of 1997 (BBA '97) (Pub. L. 105–33, enacted on August 5, 1997), provides coverage for outpatient diabetes self-management training. Under this coverage, training would include educational and training services furnished in an outpatient setting (according to frequency standards established by the Secretary) to a beneficiary with diabetes by a ''certified provider'' that meets certain quality standards. These services would be covered only if the physician managing the beneficiary's diabetic condition certifies that the services are needed under a comprehensive plan of care in order to provide the beneficiary with the skills and knowledge necessary to help manage his or her diabetes (including skills related to the self-administration of injectable drugs). Services would be paid under the physician fee schedule in amounts established by the Secretary after consultation with appropriate organizations.

The statute states that a ''certified provider'' is a physician, or other individual or entity designated by the Secretary, that, in addition to providing outpatient diabetes self-management training services, provides other items or services for which payment may be made under Medicare. Moreover, the statute requires that a physician or other individual or entity, must meet the quality standards that are established by the Secretary or meet alternative quality standards under the statute. A physician or other individual or entity may be deemed to have met those quality standards by meeting the applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by the Board. Finally, the Secretary may recognize as a certified provider a physician, individual, or entity that is recognized by an organization that represents individuals with diabetes (including Medicare beneficiaries) as meeting standards for furnishing these services.

The legislation also requires that Medicare payment for outpatient diabetes self-management training be made to a certified provider under the physician fee schedule effective July 1, 1998. In addition, it requires the Secretary to consult with appropriate organizations, including organizations representing individuals or Medicare beneficiaries with diabetes in determining a payment amount for diabetes education and training services under the fee schedule. Section 1848 of the Act requires that payments under the physician fee schedule be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense.

In addition, the law provides expanded coverage for blood glucose monitors and testing strips for all beneficiaries with diabetes. (Medicare previously covered these devices and supplies for only insulin-treated diabetics.) In June of 1998, we announced a national coverage decision concerning blood glucose monitors and testing strips in Program Memorandum B98–26–60. This proposed rule addresses only the coverage of, and payment for, outpatient diabetes self-management training services, and the quality standards that we would require an entity approved to furnish training services to meet.

D. Program Instructions

In June of 1998, we issued a program instruction that partially implemented the outpatient diabetes self-management training benefit beginning July 1, 1998 (PM AB–98–36). In this program memorandum, we indicated that outpatient diabetes self-management training services may be covered under Medicare only if the physician who is managing the beneficiary's diabetic condition certifies that the services are needed under a comprehensive plan of care related to the beneficiary's diabetic condition to ensure therapy compliance or to provide the beneficiary with necessary skills and knowledge in the management of his or her disease.

We stated that for initial implementation of this benefit that we were designating physicians, individuals, or entities that are paid under the physician fee schedule and meet the National Diabetes Advisory Board Standards, now called the National Standards for Diabetes Self-Management Education Programs, recognized by the American Diabetes Association (ADA) as approved entities. In addition, under our existing authority, we would continue to pay hospitals that were paid for diabetes self-management training services before July 1, 1998 under CIM 80–2 until we publish a final rule. Once the final rule is published, we will cover only outpatient diabetes self-management training services to those entities that meet the requirements for coverage as explained in the final rule.

In September of 1998, we issued a program memorandum (PM AB–98–51) that clarified a number of issues that occurred as a result of our June, 1998 memorandum. In this program memorandum, we provided additional information for contractors to facilitate implementation of this provision. We explained that the two new Physician's Current Procedural Terminology codes that must be used for billing outpatient diabetes self-management training.

We also amended the contractor instructions concerning the Education Recognition Program Certificate necessary in order to pay claims. This September 1998 memorandum also advised the contractors to publish a notice to the provider community that these certificates must be sent in before the approved entity submits the first claim rather than with the first claim.

We advised that individual training sessions can be provided for a beneficiary if the beneficiary's physician decides that it is medically necessary (for example, as indicated by language or physical challenges, such as severely impaired hearing or sight). Diabetes training sessions should be billed in 1 hour increments only (that is, 1 hour, 2 hours etc.).

In addition, we restated that a hospital outpatient diabetes self-management training program that does not have an Education Recognition Program Certificate that had been paid by Medicare for these services before July 1, 1998, may continue to be paid on a reasonable cost basis, without obtaining recognition until the final rule is published. An approved entity must forward information to its contractor that it has been paid by the Medicare program for outpatient diabetes self-management training before July 1, 1998. Upon receipt of this information,

the contractor would continue to pay claims for these services. Any new hospital outpatient diabetes self-management training program must have an Education Recognition Certificate showing that it meets the required educational standards.

II. Industry Consultations and Rationale for Policy Changes

As required by statute, we have met individually with representatives of various groups or organizations active in the field of diabetes education and training. These organizations or groups include the ADA, the American Medical Association (AMA), the American Academy of Family Physicians, the Endocrine Society, the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Dietetic Association, the Health Industry Manufacturers Association, Merck-Medco, the Diabetes Treatment Centers of America, American Pharmaceutical Association, the National Association of Chain Drug Stores, and the National Community Pharmacy Associations. We have also worked extensively with diabetes experts from the CDC and the Department of Veterans Affairs. In addition, we visited a number of diverse hospital-based training programs to obtain an understanding of the current training programs that are available to Medicare beneficiaries. In some cases, multiple meetings were held. Each group was asked to address specific questions that covered all aspects of this regulation and to provide scientific evidence to support each of their responses to these questions. These meetings and the information obtained from them were extremely useful to us. There was a general sense among the industry that there was not conclusive evidence and data on several issues involved in this proposed rule. As a result, the responses of these groups were very diverse and often conflicting. Thus, writing this proposed rule required sifting through available evidence and balancing diverse interests and opinions, with the benefit to the beneficiary, on both an individual and population level, being the major concern.

Despite the importance of the need for diabetes self-management education and abundant scientific literature on how to provide diabetes self-management training, there is no clear consensus on several issues. These issues include critical questions concerning who should provide the training (and the specific qualifications necessary, that is, the proposed requirements for Certified Diabetic Educators), who should receive this training, and how, when, and where this training should be provided. We solicit comments on all these issues and explicitly request any available empirical data describing the impacts of these or alternative requirements on beneficiary health outcomes.

We believe that all of the consulted parties agree that diabetes self-management training is an interactive, collaborative process involving beneficiaries with diabetes, their physician, and their educators. The educational process should provide the beneficiary with the knowledge and skills needed to perform self-care, manage crisis, and make lifestyle changes required to successfully manage the disease. The goal is to enable the beneficiary to become an active participant in his or her diabetes care. It involves a four-step process that includes the following:

(1) Assessment of the beneficiary's educational needs;

(2) Development of an educational plan, based on the individual goals and needs of the beneficiary;

(3) Educational interventions; and

(4) Evaluation of the beneficiary's success in achieving the beneficiary's self-management goals.

Effective diabetes self-management training recognizes that the person with diabetes must be responsible for self-management of his or her disease, and is based on established principles of learning, especially the need for interactive skill-based learning as opposed to only didactic education.

A 1997 GAO report concluded that Medicare beneficiaries with diabetes are not receiving the quality of care needed to manage their diabetes (Most Beneficiaries with Diabetes Do Not Receive Recommended Monitoring Services, GAO/HHS07–48). Following the issuance of the GAO report, and receiving testimony from clinicians, diabetes experts, and other studies, the Congress expanded Medicare coverage to include coverage of monitors and blood glucose test strips, as well as outpatient self-management education and training for beneficiaries with diabetes.

While it is important to increase access to diabetes training for Medicare beneficiaries with diabetes, it is equally important to maintain a level of quality that is at least equal to the programs currently reimbursed by Medicare and to be able to evaluate the effect of these programs. It is through the establishment and maintenance of quality standards for diabetes training that we would promote desired outcomes that result in improved health status for beneficiaries with diabetes.

III. Provisions of the Proposed Rule

A. Diabetes Self-Management Training Services

We are proposing to add a new statutory authority, section 1865(b) of the Act, to paragraph (a) of § 410.1, ''Basis and scope.'' Section 1865(b) permits us to approve and recognize a national accreditation organization and its accreditation program for accrediting an entity to furnish outpatient diabetes self-management training services.

We are proposing a new subpart H in part 410, ''Outpatient Diabetes Self-Management Training Services.'' In § 410.140, we are proposing the following definitions for purposes of this new subpart:

Approved entity means an individual physician or entity accredited by an approved organization to furnish training services and approved by HCFA to furnish and receive Medicare payment for the training services.

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by HCFA to furnish and receive Medicare payment for the training. Upon being approved by HCFA to receive Medicare payment for training, HCFA refers to this entity as an ''approved entity.''

Organization means a national accreditation organization.

Training means outpatient diabetes self-management training.

We are proposing in § 410.141(a) that admission into an outpatient diabetes self-management training program would be on the order of the physician (or qualified nonphysician practitioner) treating the beneficiary's diabetes. To ensure access to these services in rural areas we would recognize training services ordered by certain nonphysician practitioners who treat a beneficiary's diabetes and whose services would be covered under Medicare as physician services if furnished by a physician. We would require these nonphysician practitioners to be operating within the scope of the statutory benefit and their authority under State law, or regulations. Nonphysician practitioners who generally meet this definition are physician assistants (section 1861(s)(2)(K)(i) of the Act), nurse practitioners (section 1861(s)(2)(K)(ii) of the Act), clinical nurse specialists (section 1861(s)(2)(K)(iii) of the Act), nurse-midwives (section 1861(s)(2)(L) and 1861(gg) of the Act), qualified psychologists (section 1861(s)(2)(M) of

the Act), and clinical social workers (section 1861(s)(2)(N) of the Act). Patient self-referral would not be covered.

B. Conditions for Coverage

We are proposing that outpatient diabetes self-management training must meet the following conditions (§ 410.141(b)).

1. Physician's Order

Following an evaluation of the beneficiary's need for the training, we would require the physician or qualified nonphysician practitioner who is treating the beneficiary's diabetes to order the training.

2. Plan of Care

We would require the physician or qualified nonphysician practitioner to prepare a comprehensive plan of care that describes the content, number, frequency, and duration of the diabetes self-management training services. The plan would contain a statement, as specified by us, and signed by the physician or qualified nonphysician practitioner who is managing the beneficiary's diabetic condition, that the services described in the plan of care are needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary's diabetes. This statement would identify the beneficiary's specific medical conditions (described in § 410.141(d)(1)) that the training program should address. We are proposing that any changes to the plan of care be signed by the physician or nonphysician practitioner treating the beneficiary. In addition, the plan of care would be incorporated into the approved entity's permanent medical record for the beneficiary and be available to us upon request.

3. Reasonable and Necessary Services

We propose that the outpatient diabetes self-management training services be reasonable and necessary for the treatment of the beneficiary's diabetes. Section 1862(a)(1)(A) of the Social Security Act (the Act) provides that Medicare cover only services that are reasonable and necessary for the diagnosis or treatment of a beneficiary's illness or injury. Based on consultation with the industry, we believe that certain outpatient diabetes self-management and training programs are consistent with the reasonable and necessary provisions of section 1862(a)(1)(A) of the Act.

4. Group vs Individual Training Sessions

Except under certain circumstances, we are proposing group training sessions for all beneficiaries consisting of 2 to 20 individuals (all of whom need not be Medicare beneficiaries (§ 410.141(b)(4)). We would cover individual training sessions if no group session is available within 2 months of the physician's order, or if the beneficiary's physician or qualified nonphysician practitioner certifies that he or she has special needs resulting from conditions that would hinder effective participation in a group training session (for example, severe language or physical challenges, such as impaired hearing or sight) (§ 410.70(c)(3)). Within 2 months of a physician's order for outpatient diabetes self-management training services, we would expect that most patients, including those in rural areas, would be able to attend a group session. However, in situations, for example, when there is a geographic barrier that hinders a patient from attending a group session, the regulation would allow for an individual to have an individual training session.

C. Types and Frequency of Training

1. Initial Training

In § 410.141(c)(1), we propose that Medicare cover up to 10 hours of initial outpatient diabetes self-management training within a continuous 12-month period for each beneficiary that meets the conditions described below. In addition, we are proposing that payment would be only for those sessions attended (not for packages of sessions unless there is documentation that the beneficiary attended all sessions (§ 414.62(c)).

2. Additional Training

We propose that a beneficiary who receives the initial training program be eligible for a single follow-up training session of up to one hour each year. (A group session, unless an individual session is needed, is based on the same criteria listed above.) The need for the annual session would be documented by the physician or qualified nonphysician practitioner ordering the services and identify the specific medical conditions (described in § 410.141(d)(1)) that the program must address. The services must be reasonable and necessary. Documentation of any of the criteria that resulted in the initial eligibility would make a beneficiary eligible for the follow-up session. There may be other situations that would qualify a beneficiary for an annual session, for example, a change in physical functional status. We would require that these situations also be documented by the physician or qualified nonphysician practitioner and identified as the situations that make the session reasonable and necessary.

A physician or qualified nonphysician practitioner certifying and monitoring the need for diabetes self-management training would bill for a single evaluation and management code, such as CPT code 99201 (for a new beneficiary when that beneficiary requires a problem focused history, focused examination, and medical decision making) or CPT code 99212 (for an established beneficiary, due to the complexity of monitoring and oversight of care furnished by another provider/site in an offsite setting).

D. Beneficiaries Who May be Covered

1. Medical Conditions

As previously mentioned, the Congress has specifically delegated authority to the Secretary to determine the times and frequency when outpatient diabetes self-management training is appropriate. Since many beneficiaries have longstanding stable diabetes and some beneficiaries have already attended hospital-based outpatient diabetes self-management training, we do not believe that it would be medically reasonable and necessary for all beneficiaries with diabetes to automatically attend self-management training. Therefore, we are proposing in § 410.141(d)(1) that any beneficiary who has any one of the following medical conditions occurring within the 12-month period before the physician's order for the training would be eligible for Medicare coverage for training services from an approved entity:

- New onset diabetes.
- Poor glycemic control as evidenced by a glycosylated hemoglobin (HbA1C) of 9.5 or more in the 90 days before attending the training.
- A change in treatment regimen from no diabetes medications to any diabetes medication, or from oral diabetes medication to insulin.
- High risk for complications based on poor glycemic control; documented acute episodes of severe hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed third party assistance for either emergency room visits or hospitalization.
- High risk based on at least one of the following documented complications:

+ Lack of feeling in the foot or other foot complications such as foot ulcer or amputation.

+ Pre-proliferative or proliferative retinopathy or prior laser treatment of the eye.

+ Kidney complications related to diabetes, such as macroalbuminuria or elevated creatinine.

We are concerned that all beneficiaries with diabetes have access to outpatient diabetes self-management training services while recognizing that certain beneficiaries because of their medical conditions have caregivers. The Medicare statute, however, provides benefits only for services related to the beneficiary. Therefore, we would encourage caregivers to attend the training with the beneficiary or attend separate training, but Medicare payment would be limited to the diabetes self-management training for the beneficiary.

2. Other Conditions

Beneficiaries who are inpatients in a hospital, skilled nursing facility, hospice, or nursing home would not simultaneously be eligible for services under this benefit. It is the responsibility of the facility staff at these facilities to provide effective disease management instruction as part of the basic care and treatment furnished to the beneficiary while the beneficiary is an inpatient of that facility.

If outpatient diabetes self-management training services are furnished in a Federally qualified health center (FQHC) or a rural health center (RHC) setting by a nonphysician practitioner, the services would be bundled into the facility rate. Separate payment for the professional services of nurse practitioners, physician assistants, and clinical nurse specialists furnished in an RHC or FQHC setting is not permitted. The professional services of these nonphysician practitioners are bundled with other facility services when furnished to patients under the RHC and FQHC benefits. The payment made to the RHC or the FQHC under the all-inclusive rate specifically accounts for the services of these nonphysician practitioners furnished in the RHC or FQHC setting because the facility payment rate reflects the costs of these services.

E. Approved Entities

The statute requires that physicians, individuals, or entities who meet certain quality standards may provide outpatient diabetes self-management services and may be designated by the Secretary as ''certified providers.'' Section 400.202 defines a Medicare ''provider'' as including ''a hospital, a (critical access hospital) CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency or a public health agency * * *'' Medicare also covers services by suppliers. Suppliers are defined in § 400.202 and include a physician, or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare. The new outpatient diabetes self-management training benefit could be furnished by a provider or supplier that meets certain quality standards. For consistency throughout this proposed rule, we use the term ''approved entity'' to mean those entities that we may approve to furnish outpatient diabetes self-management training services.

In § 410.141(e), we identify the conditions we would require an approved entity to meet. In order to be an ''approved entity,'' we would require the physician, individual, or entity to furnish other services for which direct Medicare payment may be made. In addition, the approved entity must comply with the Medicare regulations on the prohibition on reassignment of Medicare benefits in §§ 424.73 and 424.80. In summary, these regulations prohibit payment for services to entities other than the physician, provider, or supplier who furnished the services unless there is a specific exception that authorizes reassignment. In some cases, in order for Medicare payment to be appropriate, there must be specific contractual language. We propose that in order to be an ''approved entity'' an individual, physician, or entity must be able to be paid properly under these regulations so that payment would be consistent with the statutory prohibitions on reassignment of benefits.

Also, we would require an approved entity to provide us with any documentation that we may request, including information that is necessary to pay a claim or to perform a focused post-payment medical review study. Finally, we would approve an entity to furnish outpatient diabetes training services if it meets the quality standards prescribed by us; the National Standards for Diabetes Self-Management Education Program, previously the NDAB standard; or standards developed by a national organization that we have approved. In order to show that these quality standards are met, an approved entity must show proof that it has been accredited by an approved accreditation organization.

Entities that may meet the quality standards for furnishing outpatient diabetes training services are hospitals, critical access hospitals, End Stage Renal Disease facilities, and clinics. Individuals that may be properly paid for outpatient diabetes education training services are physicians, clinical nurse specialists, nurse practitioners, clinical social workers, psychologists, and nurse midwives. Moreover, a licensed pharmacist that is a Medicare supplier of durable medical equipment under § 424.57 could qualify as an ''approved entity'' if the individual or entity meets the payment and quality standards.

Currently, physician assistants (PAs) cannot bill Part B of the Medicare program directly for their professional services. The PA's physician supervisor (or a physician designated by the supervising physician or employer as provided under State law or regulation) is primarily responsible for the overall direction and management of the PA's professional activities and for assuring that the services furnished are medically appropriate for the beneficiary. Medicare payment for PA services is made only to the PA's employer regardless of whether the PA is employed as a W–2 employee or whether the PA is an independent contractor (section 4512 of the BBA '97). We would apply these same payment rules to outpatient diabetes training services furnished by PAS.

Dietitians and certified diabetic educators who are in independent practice would not qualify as an approved entity for the purpose of receiving payment for outpatient diabetes training services. We believe, however, that the law and the Conference Report are clear that only those physicians, individuals, and entities that furnish other services for which Medicare payment may be made can be an approved entity. The Conference Agreement specifically states that the Secretary may designate entities ''who currently are reimbursed by Medicare.'' (H.R. Conf. 105–217, at 701.)

F. HCFA's Process for Approving National Accreditation Organizations

In the past, under section 1865 of the Act, HCFA approved national accreditation organizations if HCFA found, taken as a whole, the accreditation of a provider or supplier entity by the national accreditation organization provided reasonable assurance that the Medicare health and safety conditions or requirements for that Medicare provider or supplier type were met. Therefore, in reviewing a

national accreditation organization's request for approval and recognition, HCFA looked at the accreditation organization's program as a whole and determined whether to approve the organization and deem the provider or supplier entities it accredited to meet the applicable HCFA conditions or requirements. In 1996, section 1865 of the Act was amended. HCFA must now determine whether the accreditation of a provider or supplier entity by the national accreditation organization provides assurances that the applicable Medicare health and safety conditions or requirements are met or exceeded. In 1997, Congress passed deeming requirements for Medicare + Choice organizations that require the accreditation organization to apply and enforce standards that are at least as stringent as the HCFA requirements. We believe that the deeming requirements for Medicare + Choice are a reflection of Congress' current thinking about the degree to which HCFA holds accreditation organizations accountable. In reviewing a national accreditation organization's request for approval and recognition, HCFA now looks standard-by-standard at the crosswalk between the accreditation organization's standards and the applicable HCFA conditions or requirements. HCFA expects to see that each Medicare condition or requirement, for the provider or supplier that the accreditation organization accredits, is covered by the accreditation organization's standards. The accreditation organization's standards do not have to adopt the exact language of the HCFA requirements. In fact, the accreditation organization may have requirements that are more stringent than HCFA's conditions or requirements. After evaluating the accreditation organization's standards, HCFA looks at the accreditation organization's processes for assuring that entities meet the accreditation standards.

The process that we would use to deem compliance for outpatient diabetes self-management training programs accredited by national accreditation organizations would be similar to the process used for deeming compliance with individual provider or supplier requirements under Part 488, as well as the process for deeming compliance with the Medicare + Choice quality requirements in part 422, subpart D. The accreditation organization would apply and enforce either HCFA's standards, the standards of the NDAB, or a set of standards established by an organization representing individuals with diabetes and approved by HCFA as standards that are substantially equivalent to the HCFA standards.

In determining whether to approve and recognize a national accreditation organization, we would determine whether the accreditation organization applies and enforces quality standards that have been determined by HCFA to be substantially equivalent to the quality standards in § 410.144 based on a comparison of the accreditation organization's standards and its crosswalk. We would also consider whether the accreditation organization meets the requirements for approved accreditation organizations in § 410.143. We would make these determinations on the basis of the materials submitted by an accreditation organization seeking our approval in accordance with § 410.142. We would, through submittal of appropriate documentation by the national organization requesting accreditation approval from us, determine whether the accreditation organization's requirements concerning the frequency of accreditation, accreditation forms, guidelines and instructions to evaluators are as rigorous as our requirements with a similar emphasis on outcomes.

In § 410.142, we propose the conditions a national accreditation organization would have to meet to be an approved accreditation organization. We may approve an accreditation organization if the organization applies and enforces quality standards that have been determined by HCFA to be substantially equivalent to the quality standards in § 410.144; is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes; and is neither owned or controlled by any entity it accredits, nor owns or controls an entity that could be accredited, as defined at 42 CFR 413.17. Control exists if the accredited entities have power, directly or indirectly, to significantly influence or direct the activities or policies of the accreditation organization. We have included this requirement to preclude any conflict of interest that could compromise the integrity of the accreditation process. In addition, we would require the organization to comply with the application and reapplication procedures set forth in § 410.142(h)(1), ''Procedures for approval of accreditation as a basis for deeming compliance.''

1. Required Information and Materials

We are proposing that a national accreditation organization requesting our approval and recognition of its accreditation program must furnish to us the information and materials discussed below.

We are proposing the organization may not use more than one set of quality standards for its outpatient diabetes self-management training program. In addition, the accreditation organization must inform us of the quality standards it would use. These standards must include a detailed comparison (including a crosswalk if the accreditation organization does not use standards described in § 410.144(a) in their entirety) between the organization's accreditation requirements and quality standards and our quality standards.

We are proposing that the organization provide us with detailed information about its accreditation process, including the frequency of accreditation, and copies of its accreditation forms, guidelines, and instructions to evaluators.

We are proposing that the organization also provide: descriptions of the accreditation review process, the accreditation status decision making process, procedures used to notify an entity of deficiencies in its outpatient diabetes self-management training program, procedures to monitor the correction of those deficiencies, and procedures used to enforce compliance with accreditation requirements. We are also proposing the organization provide us with detailed information about the individuals who perform evaluations for the accreditation organization, including:

- The education and experience requirements for the individuals who perform evaluations.
- The content and frequency of the continuing education furnished to the individuals who perform evaluations.
- The process used to monitor the performance of individuals who perform evaluations.
- The organization's policies and practices with respect to the participation, in the accreditation process, by an individual who is professionally or financially affiliated with the entity being evaluated.

We are proposing that the organization provide us with a description of the organization's data management and analysis system with respect to its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system. The organization must also provide a description of the organization's procedures for responding to and investigating complaints against a

deemed entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and us.

We are proposing that the organization must provide us with a description of its policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's quality standards or requirements, and other actions the organization takes in response to noncompliance with its quality standards and requirements. This description must identify all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organizations, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if we approve the accreditation organization. We are also proposing that the organization provide us with a list of all entities that it has currently accredited to furnish outpatient diabetes self-management training and the type, category, and expiration date of the accreditation held by each of them. In addition, we are proposing that the organization provide us with the name and address of each person with an ownership or control interest in the accreditation organization; documentation that demonstrates its ability to furnish us with electronic data in a format compatible to ours; and a resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities. The organization must acknowledge that, as a condition for approval and recognition by HCFA, it agrees to comply with the requirements set forth in §§ 410.142 through 410.144.

Finally, we are proposing that the national accreditation organization agrees to provide us with any additional information that we may request in order to respond to its request for our approval and recognition of its accreditation program to accredit entities to furnish outpatient diabetes self-management training services.

2. Onsite Visits

We are proposing that we or our agent may visit the prospective accreditation organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

3. Notice and Comment

Because the approval of a national accreditation organization could have broad impact upon large numbers of organizations, providers, and beneficiaries, we are providing notice and comment opportunities. We would publish a proposed notice in the **Federal Register** if we consider approving a national accreditation organization's application for approval. The proposed notice would specify the basis for granting approval, a description of how the organization's accreditation program applies and enforces standards that have been determined by HCFA to be substantially equivalent to the quality standards for outpatient diabetes self-management training services set forth at § 410.144. We would also allow an opportunity for public comment.

We would publish a final notice in the **Federal Register** if we approve a national accreditation organization's request. Publication of the final notice would occur after we have reviewed the public comments received in response to the proposed notice. The final notice would specify the effective date of the approval, and the term of approval, which may not exceed 6 years.

4. Criteria We Would Use to Approve National Accreditation Organizations

Section 410.142(e) proposes that in deciding to approve and recognize an organization's accreditation program to accredit entities to furnish outpatient diabetes self-management training services, we would consider the following criteria: (1) The organization applies and enforces quality standards that have been determined by HCFA to be substantially equivalent to the quality standards set forth at § 410.144, (2) The organization meets the requirements for approved organizations in § 410.143, (3) The organization is not owned or controlled by the entities it accredits, as defined in § 413.17(b)(2) or (b)(3), respectively, of this chapter and (4) The accreditation organization does not accredit any entity it owns or controls.

5. Notice of Our Decision

In § 410.142(f), we propose that we would notify the prospective accreditation organization in writing of our decision. We would include the following information in our notice to the affected organization: (1) We would state whether we have approved or denied the organization's request, (2) If we deny the request we would provide our rationale for denial, and (3) We would communicate the procedures the organization must use for reconsideration and reapplication.

6. Reconsideration of Adverse Decisions

Section 410.142(g) proposes that an accreditation organization that has received our notice of denial of its request for our approval and recognition of its accreditation program to accredit entities to furnish outpatient diabetes self-management training services may request reconsideration of our decision in accordance with part 488 subpart D.

7. Request for Approval Following Denial

Section 410.142(h) proposes that an accreditation organization that has received our notice of denial of its request for approval and recognition of its accreditation program to accredit entities to furnish outpatient diabetes self-management training services may submit a new request to us under the following conditions: (1) The organization has revised its accreditation program to correct the deficiencies we noted in our denial notice; (2) The organization must demonstrate through documentation that the quality standards used by the deemed entities have been determined by HCFA to be substantially equivalent to the quality standards for outpatient diabetes self-management training services set forth at § 410.144; and (3) After compiling this information, the organization must resubmit the application in its entirety. We are proposing that an accreditation organization that has requested reconsideration of our denial of its request for approval and recognition of its accreditation program to accredit entities to furnish outpatient diabetes self-management training services may not submit a new request until all administrative proceedings have been completed.

8. Withdrawal

We are proposing that an organization requesting our approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

9. Reapplying for Accreditation

We are proposing that an accreditation organization must request continued approval and recognition at least 6 months before the expiration of our approval and recognition of the accreditation organization's program.

G. Requirements for Approved Accreditation Organizations

1. Ongoing Responsibilities of an Approved Accreditation Organization

Section 410.143 proposes the ongoing accreditation organization responsibilities. These responsibilities parallel those currently imposed on accreditors by other accreditation and deeming processes under Medicare. An accreditation organization approved and recognized by us must undertake the following activities on an ongoing basis. They must provide to us in writing and on a monthly basis all of the following information: (1) Copies of all accreditation decisions and any accreditation-related information that we may require (including corrective action plans and summaries of our quality standards that are unmet), (2) A notice of all complaints related to accredited entities, (3) If the organization takes any remedial action or adverse actions, within 30 days of taking those actions, (including revocation, withdrawal, or revision of an entity's accreditation status) against a deemed entity, information describing the remedial or adverse action and the circumstances that led to taking the action, (4) A notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without our approval, we may withdraw our approval and recognition of the organization's accreditation program.

We are proposing that within 30 days of notification of a change in our quality standards, the organization submit to us its organization's plan to alter its quality standards to conform to our revised standards (including a crosswalk between our revised standards and the organization's revised standards) within or by the effective date specified in HCFA's notification of a change in the quality standards.

2. Oversight of Approved National Accreditation Organizations

Section 410.143(b) proposes the specific criteria and procedures for continuing oversight. We perform oversight activities to ensure that an approved national accreditation organization and the entities the national accreditation organization accredits continue to meet our quality standards. We may contract with an entity to perform these oversight activities. Oversight consists of equivalency review, validation review, and onsite observation.

3. Equivalency Review

We compare the national accreditation organization's standards and its application and enforcement of those standards to our comparable standards and processes when we impose new requirements or change our process for approving and recognizing accreditation organizations, an accreditation organization proposes to adopt new standards or changes in its accreditation process, or an accreditation organization reapplies to us for continuation of its approval and recognition by us of its program to accredit entities to furnish outpatient diabetes self-management training services.

4. Validation Reviews

We or our agent may conduct an evaluation of an accreditation organization's own evaluation process, by conducting evaluations of deemed entities approved by the accreditation organization and comparing its results to the results of the accreditation organization's evaluation of the deemed entities. At the conclusion of the review, we identify any accreditation programs for which validation evaluation results indicate (1) a 20-percent rate of disparity between the accreditation organization's evaluation of the deemed entities and HCFA's (or its agent's) evaluation on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or (2) any disparity at all on standards that constitutes immediate jeopardy to patient health and safety if unmet. Our beneficiary-centered approach to diabetes self-management training oversight dictates zero tolerance of accreditation organization failures to identify noncompliance that expose beneficiaries to such serious risk. At the conclusion of a validation review, we also identify any accreditation programs for which validation evaluation results indicate, irrespective of the rate of disparity, that there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the quality standards described in § 410.144 are met. Accreditation programs identified as noncompliant through validation review may be subject to withdrawal of our approval.

5. Onsite Inspections

We may conduct an onsite inspection of the accreditation organization's operations and offices to verify information and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

6. Withdrawal of Our Approval and Recognition

If an equivalency review, validation review, onsite observation, or our daily experience with the accreditation organization suggest that an accreditation organization is not meeting the requirements of this subpart, we give the accreditation organization written notice of its intent to withdraw approval and recognition of the organization's accreditation program. We may withdraw our approval of an accreditation organization at any time if we determine that accreditation by the organization no longer guarantees that the approved entity meets the quality standards described in § 410.144, and failure to meet those standards could jeopardize the health or safety of Medicare beneficiaries or constitute a significant hazard to the public health; or the accreditation organization has failed to meet its obligations for accreditation in §§ 410.142 through 410.144.

7. Request for Reconsideration

The final provision of this section proposes the process for reconsideration. An accreditation organization may request a reconsideration of our decision to withdraw our approval and recognition of the organization in accordance with subpart D of part 488 of this chapter.

H. Quality Standards for an Approved Entity

A national accreditation organization approved and recognized by us may accredit an entity to meet one of the following sets of standards: The quality standards prescribed by us; the National Standards for Diabetes Self-Management Education Programs, which were originally established by the National Diabetes Advisory Board (NDAB) and subsequently revised by organizations who participated in the establishment of standards by the Board; or a national nonprofit or not-for-profit organization that represents individuals (including individuals under Medicare) with diabetes as meeting standards for furnishing services.

1. Our Standards

The BBA '97 authorized the Secretary to develop her own quality standards.

We believe that our proposed standards offer sufficient assurances that the outpatient diabetes self-management training programs would provide quality care and the standards are flexible enough to apply in any health care setting.

In developing our standards, we have been heavily influenced by the National Standards for Diabetes Self-Management Education Program standards and agree that the structure necessary to provide quality diabetes self-management education consists of the human and material resources and the management systems needed to achieve program and participant goals. This structure includes the support and commitment of the organization sponsoring the program.

We are committed to working with affected parties to implement these proposed standards and to impose a minimum burden to approved entities. Thus, in developing these proposed standards we have solicited suggestions from organizations representing ADA Education recognition programs, other organizations and the States. Many states have begun to write laws for the establishment of diabetes self-management education programs. Conversely, there are States that have not developed laws to incorporate a diabetes self-management program within their current health systems. Based on the literature in the area of Diabetes Self-Management Education (Diabetes Care, Volume 18, Number 1, January 1995) and considering the recommendations of organizations such as the ADA, the American Association of Clinical Endocrinologist, the Diabetes Treatment Centers of American and the American Medical Association, the following are our proposed standards.

Standard (1) *Organizational structure:* (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(2) *Environment.* Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) *Program staff.* (i) Requires a program coordinator who is responsible for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 14 hours of continuing education about diabetes, educational principles, and behavior change strategies every 2 years.

(4) *Team approach.* (i) Except as permitted under paragraph (a)(4)(ii) of this section, furnishes services using a multidisciplinary instructional staff who are qualified to teach the training content areas required in paragraph (a)(5) of this section. The team must include at least a registered dietitian and a Certified Diabetic Educator (CDE) who have recent didactic and experiential preparation in diabetes clinical and educational issues.

(ii) If the team includes a registered nurse, an approved entity may delay implementation of the requirements for a CDE until 3 years after the effective date of the final rule.

We are proposing in § 410.144(a)(4) that outpatient diabetes self-management training services must be furnished by a multidisciplinary team of at least two health care professionals who have didactic training or experience in diabetes clinical and educational issues. The team must include at least a registered dietitian and a CDE. We believe that accessibility to a CDE is important to persons with diabetes because they like to call their health care providers with questions about diabetes and any other health concerns they may have. It is during these kinds of encounters that the most active level of education and support in the behavior change process occurs, and where the CDE can be extremely valuable to the physician in managing patients with diabetes. By addressing the self-management educational needs of patients with diabetes, the CDE is able to alleviate the demand for time and attention that such patients place on their physicians. Recognizing that there may be a shortage of CDEs, we would delay the implementation of the CDE requirement. We believe that the general management of the vast majority of patients with diabetes is being provided by primary care physicians who may not have a CDE on staff but employ a registered nurse to provide the training at this time. Thus, we are allowing 3 years for a registered nurse to substitute for a CDE.

The team members would be employees of an approved entity defined in § 410.141(e) or capable of reassigning Medicare benefits to the approved entity.

(5) *Training content.* Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal-setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) *Training methods.* (i) Offers individual and group instruction for effective diabetes self-management training services.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(7) *Review and plan of care and goals.* (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration with each beneficiary, that includes relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors. Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's permanent medical record.

(8) *Educational intervention.* Offers appropriate and timely educational intervention based on referral from the beneficiary's physician or nonphysician practitioner and based on periodic reassessments of health status,

knowledge, skills, attitudes, goals, and self-care behaviors.

(9) *Performance measurement and quality improvement.* Establishes and maintains a performance measurement and quality improvement program that meets the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetic control, beneficiary understanding, or beneficiary compliance) and provide for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators, such as, monitoring for compliance, lost work or school days, metabolic control, or others.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using these measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(C) If requested, report to us nationally standardized performance measures to the extent that they become available in the future and the Secretary determines they are appropriate.

(D) Meet minimum performance levels on performance measures described in this paragraph (a)(9) established by us, which are based on national or local empirical experience and are prospectively announced to allow sufficient time for compliance.

(10) *Peer Review Organization review.* Has an agreement with a PRO, which has a contract with us to perform quality assurance reviews. At a minimum, the agreement allows the PRO access to beneficiary or group therapy records and binds an approved entity to comply with corrective actions or to participate in quality improvement projects that the PRO determines are necessary.

We understand that there may be certain disincentives to adopt our standards as a result of these last requirements because the approved entity may not have access to all of the quality data requested by us. However, we believe that any responsible outpatient diabetes self-management training program would want to know how effective their program is therefore, we do not think that it is unreasonable to require the approved entity to report certain quality indicators to the PRO. We are soliciting comments on this approach and whether or not it appears to be too burdensome for the approved entities.

2. The National Standards for Diabetes Self-Management Education Programs

The NDAB, in collaboration with other diabetes-related groups, developed standards in 1983 in response to concerns that the quantity and quality of diabetes education varied considerably throughout the United States. It was hoped that the application of uniform standards would increase the quality, availability, and effectiveness of diabetes education, as well as accessibility, through third-party payment. The standards were deliberately designed to be general enough to be implemented in a variety of settings and to deal largely with the process of development and maintenance of quality diabetes education programs. The original standards consisted of 10 components, with each component divided into elements applicable to the sponsoring institution or the educational program. Review criteria were developed as a method to measure a program's achievement of the standards. The review criteria were extensively pilot tested and found to be feasible, practical, and appropriately stringent.

Using these criteria, the ADA implemented a process in 1986 to officially recognize programs that meet the National Standards for Diabetes Self-Management Education Programs (NSDSMEP). To achieve recognition, a program must undertake a voluntary extensive self-evaluation and documentation process for each element of the standards. Programs that meet these standards are awarded a certificate.

In 1993, the NDAB charged a task force of representatives from the ADA and other organizations to review the current standards and make recommendations for retention or revision. The revised National Standards for Diabetes Self-Management Education Programs define quality programs in terms of structure, process, and outcomes. Each of these three program components is subdivided into elements. There are standards for each of these elements. As mentioned previously in this preamble, the statute has deemed the National Standards for Diabetes Self-Management Programs as they appear in Diabetes Care, Volume 21, Supplement 1, January 1998. If the ADA and other organizations votes by majority vote to amend or change one of standards in the future, we reserve the right to approve or disapprove such change as described in § 410.143, ''Requirements on approved accreditation organization.'' We expect that the ADA would apply to HCFA as an accreditation organization and would be quickly approved and recognized because the ADA uses the NSDSMEP. We would require all approved entities that meet these standards to provide us with a copy of their certification from the ADA as proof of meeting these standards. This would include a copy of their proof of renewal at the time they are required to renew their educational programs with the ADA.

Applying for Education Recognition by the ADA requires the submission of an application plus a processing fee. Each application must include demographic data on the participants served, instructor qualifications, annual program review, the program's curriculum and educational materials, education records with follow-up evaluations, and outcomes data. To apply, a program must obtain a copy of the current ''Meeting the Standards'' manual to understand the review criteria and must have furnished training since and collected 12 months of data. At the end of the 12 month data collection period, three separate copies of the completed application are submitted to the ADA Education Recognition Program along with the current processing fee.

The completed application is reviewed by an expert panel of diabetes educators. After official notification of Education Recognition, the program is sent an Education Recognition Certificate from the ADA.

We are proposing in § 410.72 that the program may be one that, at a minimum meets all of the National Standards for Diabetes Self-Management Education Programs established by the NDAB and revised by a task force of representatives of diabetes and other organizations and has a certificate of education recognition awarded by the ADA. The National Standards for Diabetes Self-Management Education Programs and ADA review criteria follows:

Standard 1. The sponsoring organization shall have a written policy that affirms education as an integral component of diabetes care.

Review criterion: 1–1. There is a written statement from the sponsoring organization to reflect that self-management education is an integral component of diabetes care.

Standard 2. The sponsoring organization shall identify and provide the educational resources required to achieve its educational objectives in terms of its target population. These resources include adequate space, personnel, budget, and instructional materials.

Review criterion: 2–1. For both individual and group instruction, resources (including space, staff, budget, and educational materials) are adequate to support the programs offered and the participants served.

Standard 3. The organizational relationships, lines of authority, staffing, job descriptions, and operational policies shall be clearly defined and documented.

Review criterion: 3–1. The relationships among the sponsoring organization and the diabetes program coordinator, staff, and the advisory committee are clearly defined.

3–2. There is a description of the following for the coordinator and each instructional staff member:

- Role in the program.
- Teaching responsibilities.
- Other program responsibilities.
- Amount of time spent in the program.

3–3. There are written policies approved by the advisory committee concerning the operation of the program.

Standard 4. The service area shall be assessed in order to define the target population and determine appropriate allocation of personnel and resources to serve the educational needs of the target population.

Review criterion. 4–1. The target population is defined (specifically the potential number to be served, types of diabetes, age range, language, ethnicity, unique characteristics, and special educational needs).

Standard 5. A standing advisory committee consisting of a physician, a nurse educator, a dietitian, an individual with behavioral science expertise, a consumer, and a community representative, at a minimum, shall be established to oversee the program.

Review Criteria. 5–1. The advisory committee members specified above attend at least two meetings a year.

5–2. The health professional members include at least one physician, one nurse educator, and one registered dietitian, each with expertise in diabetes.

5–3. The individual with behavioral science expertise is any professional with academic preparation in the behavioral sciences; for example, counseling, health behavior, psychology, social work, and sociology.

5–4. The consumer is any individual with diabetes or the caretaker thereof.

5–5. The community representative is any individual not employed by the institution.

5–6. There is a written policy concerning the membership and responsibilities of the advisory committee.

5–7. There is documentation that the advisory committee is fulfilling its responsibilities to approve the program plan, recommend and approve policy, and review the program annually.

Standard 6. The advisory committee shall participate in the annual planning process, including determination of target audience, program objectives, participant access mechanisms, instructional methods, resource requirements (including space, personnel, budget, and materials), participant follow-up mechanisms, and program evaluation.

Review criterion. 6–1. There is documentation that the advisory committee approves a written program plan each year that includes the items specified above.

Standard 7. Professional program staff shall have sufficient time and resources for lesson planning, instruction, documentation, evaluation, and follow-up.

Review criterion. 7–1. The instructor's available hours and resources are adequate to meet the needs of the program and the participants.

Standard 8. Community resources shall be assessed periodically.

Review criterion. 8–1. There is a list (including name, address, and telephone number) of community resources within the service area that serve the target population and their families. This list is reviewed and updated yearly by the advisory committee.

Standard 9. A coordinator shall be designated who is responsible for program planning, implementation, and evaluation.

Review Criteria. 9–1. The job description for the program coordinator includes his/her responsibilities for:

- Acting as a liaison between the program staff, the advisory committee, and the administration of the institution.
- Providing and/or coordinating the orientation and continuing education for the professional program staff.
- Participating in the planning and review of the program each year.
- Participating in the preparation of the program budget.
- Evaluating program effectiveness.
- Serving as the chair or a member of the advisory committee.
- Overseeing the program with on-site supervision.

9–2. The program coordinator is a CDE or has completed at least 24 hours of approved continuing education that includes a combination of diabetes, educational principles, and behavior strategies.

Standard 10. Health care professionals with recent didactic and experiential preparation in diabetes clinical and educational issues shall serve as the program instructors. Certification as a diabetes educator by the National Certification Board for Diabetes Educators (NCBDE) is recommended. Multidisciplinary instructional staff who are collectively qualified to teach the required content areas shall include at least (1) a registered dietitian and (2) either a registered nurse or other health professional who is a CDE.

Review criteria. 10–1. Program instructors are professional staff who routinely teach in the diabetes self-management education program and include at least (1) a registered dietitian and (2) either a registered nurse or other health professional who is a CDE.

10–2. Program instructors are health care professionals with a valid license, registration, or certification and who are CDEs or have completed at least 16 hours of approved continuing education that includes a combination of diabetes, educational principles, and behavioral strategies.

Standard 11. Professional program staff shall obtain education about diabetes, educational principles, and behavioral change strategies on a continuing basis.

Review criterion. 11–1. The program coordinator and all instructors complete at least 6 hours per year of approved continuing education that includes a combination of diabetes, educational principles, and behavioral strategies.

Standard 12. Based on the needs of the target population, the program shall be capable of offering instruction in the following content areas:

a. Diabetes overview.

b. Stress and psychosocial adjustment.

c. Family involvement and social support.

d. Nutrition.

e. Exercise and activity.

f. Medications.

g. Monitoring and use of results.

h. Relationships among nutrition, exercise, medication, and blood glucose levels.

i. Prevention, detection, and treatment of acute complications.

j. Prevention, detection, and treatment of chronic complications.

k. Foot, skin, and dental care.

l. Behavior change strategies, goal setting, risk factor reduction, and problem solving.

m. Benefits, risks, and management options for improving glucose control.

n. Preconception care, pregnancy, and gestational diabetes.

o. Use of health care systems and community resources.

Review criteria. 12–1. There is a written curriculum that includes educational objectives, content outline, instructional methods and materials,

and the means for evaluating achievement of the objectives for each content area or session of the program.

12–2. The curriculum is current and includes all 15 content areas as appropriate for the identified target population.

Standard 13. The program shall use instructional methods and materials that are appropriate for the target population and the participants being served.

Review criterion. 13–1. Instructional methods and materials are appropriate for the target population and participants in terms of cultural relevance, age, language, reading levels, and special educational needs.

Standard 14. A system shall be in place to inform the target population and potential referral sources of the availability and benefits of the program.

Review criterion. 14–1. The program reviews marketing strategies for the target population and potential referral sources annually.

Standard 15. The program shall be conveniently and regularly available.

Review criterion. 15–1. Program utilization, program completion rate, and waiting periods are assessed yearly.

Standard 16. The program shall be responsive to requests for information and referrals from consumers, health care professionals, and health care agencies.

Review criterion. 16–1. There is a procedure for responding to requests for information and referrals.

Standard 17. An individualized assessment shall be developed and updated in collaboration with each participant. The assessment shall include relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.

Review criterion. 17–1. An initial assessment of the items specified above is documented in the education record and updated as needed.

Standard 18. An individualized education plan, based on the assessment, shall be developed in collaboration with each participant.

Review criterion. 18–1. The participant's pre-program knowledge and skill level in relation to the fifteen content areas of the National Standards is assessed. Educational needs are identified with the participant and documented in the education record.

Standard 19. The participant's educational experience, including assessment, intervention, evaluation, and follow-up shall be documented in a permanent medical or education record. There shall be documentation of collaboration and coordination among program staff and other providers.

Review criteria. 19–1. The participant's progress through the program is documented in the educational record and includes:

- The initial assessment and education plan as specified above.
- An indication of the content taught, dates of instruction, and the instructors.
- Post-program assessment of the participant's knowledge and skill level of each of the appropriate content areas of the National Standards.
- Behavioral goals.
- A plan for follow-up.
- Communication of participant's progress and any follow-up recommendations to the primary care provider.
- Follow-up assessment and any resulting interventions.

19–2. Each program instruction documents his/her own interventions with the participants.

19–3. Communication and collaboration among program staff are facilitated by and documented in the education record.

Standard 20. The program shall offer appropriate and timely educational interventions based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.

Review criteria. 20–1. At least one follow-up assessment of the items specified above and any interventions are documented in the education record.

20–2. Participants achievement of behavioral goals is assessed and documented 1–3 months after goal setting.

Standard 21. The advisory committee shall review program performance annually, including all components of the annual program plan and curriculum, and use the information in subsequent planning and program modification.

Review criteria. 21–1. The advisory committee conducts and documents the results of an annual review of the program including:

- Program objectives.
- The curriculum, instructional methods, educational materials, and community resource list.
- Actual audience compared to the target population.
- Participant access and follow-up mechanisms.
- Program resources (space, personnel, and budget).
- Program effectiveness/participant outcomes.
- Marketing strategies to the target population and any potential referral sources.

21–2. The results of the annual review are reflected in the next annual program plan.

Standard 22. The advisory committee shall annually review and evaluate predetermined outcomes for program participants.

Review criteria. 22–1. Participants' outcomes are measured and evaluated, specifically, the degree to which the participants achieve their behavioral goals and one other outcome measure (for example, monitoring for complications, lost work or school days, metabolic control, or others).

22–2. The program's effectiveness at improving outcomes among participants is evaluated by the advisory committee and the results of this evaluation are reflected in the next annual program plan.

3. Standards of an Organization That Represents Individuals With Diabetes.

We propose that an organization may apply to us for approval of its standards so that we can recognize it as an ''organization that represents individuals with diabetes.'' Upon our approval, and recognition, the organization may deem that a physician, individual, or entity has met the quality standards for a deemed entity. We would review and consider applications for approval and recognition only from organizations that represent individuals with diabetes including Medicare beneficiaries. Given the Congress' interest in ensuring the well-being of Medicare beneficiaries with diabetes, we do not believe that Congress intended that anyone with frivolous criteria could apply to us for recognition as an accrediting organization. In fact, we believe that these other organizations would have comprehensive *bona fide* quality standards and be organizations that are either non-profit or not-for-profit with demonstrated experience in representing the interest of individuals with diabetes. This could include, 501(c)(3) organizations, existing accrediting organizations, or professional organizations that do not have a proprietary or financial interest with the entities they would be accrediting. It is our intention to be able to approve organizations as ''organizations that represent individuals with diabetes'' upon the effective date of the final rule. Therefore, we would begin accepting applications from organizations. Applications should be mailed to the following address: Office of Clinical Standards and Quality, Room S3–02–01,

Health Care Financing Administration, 7500 Security Blvd., Baltimore, MD 21244.

I. Requirements for Deemed Entities

Section 1865 gives us the authority to deem that any provider entity meets certain requirements if the entity is accredited and periodically reaccredited by a national organization. The process that must ensure that the entity, as a condition of accreditation, meets standards that are at least as stringent as our applicable standards.

Section 410.145(a) specifies the conditions under which an approved entity may be deemed to meet the quality requirements. The first requirement is that the approved entity have submitted necessary documentation and be fully accredited (and periodically reaccredited) by a national accreditation organization approved by us. Only full accreditation offers us adequate assurance that the approved entity meets the quality standards. Entities that are conditionally or provisionally accredited (or the equivalent thereof) by their accreditation organization do not meet all of their accreditation organization's standards, and for this reason, would not be deemed to meet quality standards in § 410.144.

The second requirement is that the entity may not be accredited by an organization that owns or controls the entity. We believe this requirement is necessary to prevent a conflict of interest.

1. Effective Date for Deemed Entities

Section 410.145(b) establishes when deemed status is effective. Deemed status is effective on the later of the following dates: the date on which the accreditation organization is approved by us, or the date that the accreditation organization deems the entity to meet the HCFA quality standards described in § 410.144. Medicare payment may not be made to an entity before the entity meets all of the requirements to be approved by us under § 410.141(e). Medicare payment would be made only for those services that are furnished after the date we approve the entity to furnish services (§ 424.44(d)).

2. Requirements for Deemed Entities

Section 410.145(c) establishes the obligations of deemed entities. We are proposing that as a requirement for deemed status, an entity must, before submitting a claim for Medicare payment, forward a copy of its certificate or proof of accreditation from its accreditation organization indicating that the entity meets the quality standards described in § 410.144. In addition, an entity deemed to meet Medicare standards must submit to evaluations to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to us a copy of its most current accreditation evaluation, together with any information related to the evaluation that we may require (including corrective action plans.) These two activities are part of our ongoing oversight strategy for ensuring that the accreditation organization applies and enforces its accreditation standards in a manner comparable to ours.

3. Removal of deemed status.

Section 410.145(d) addresses removal of deemed status. We would remove an entity's deemed status if: (1) We determine, on the basis of our own evaluation or the results of the accreditation evaluation, that the entity does not meet the quality standards for outpatient diabetes self-management training; (2) we withdraw our approval of the accreditation organization that deemed the entity to furnish outpatient diabetes self-management training; however, the removal of the entity's deemed status would not occur until 60 days after the accreditation organization is no longer recognized or (3) the entity fails to meet the requirements for deemed entities in § 410.145(c).

If we remove recognition of an accreditation organization because of its failure to meet our requirements, those entities who have deemed status with that accreditation organization would have up to 60 days to become accredited by another accreditation organization approved by us.

The final paragraph in § 410.145(d)(3) states that we can remove deemed status if the entity fails to meet the requirements in § 410.145(c). We retain the authority to initiate enforcement action against any entity that it determines, on the basis of its own evaluation or the results of the accreditation evaluation, no longer meets the Medicare standards for which deemed status was granted. We expect the accreditation organization to have a system in place for enforcing compliance with its standards, perhaps sanctions for motivating correction of deficiencies, but we cannot delegate to the accreditation organization the authority to terminate the entity's approval.

J. Outpatient Diabetes Self-Management Training Payment Methodology

1. Proposed Method of Payment

a. Consultation With Industry

In keeping with the requirements of the BBA '97, we have consulted individually with the same groups and organizations mentioned previously to establish payment amounts for outpatient diabetes self-management training services that would be paid under the physician fee schedule. The consensus among the industry is that cost data on providing diabetes training is inadequate. We consulted with the ADA to provide us with guidance in assessing the types of resource inputs that a typical diabetes training program would use in order for us to price diabetes services.

b. Calculation of proposed RVUs

We do not expect to establish physician work RVUs for diabetes outpatient self-management training services, because we believe diabetes training can appropriately be performed by individuals other than a physician. We would establish, however, practice expense and malpractice expense RVUs for these services. Our plans for the future are to develop the practice expense RVUs for diabetes training in a manner consistent with the resource-based practice expense methodology used for all other services paid under the physician fee schedule. The development of resource-based practice expense RVUs is the subject of a separate proposed rule (HCFA–1006–P) published in the **Federal Register** on June 5, 1998 (63 FR 30818). Malpractice RVUs for diabetes training have been extrapolated based on analogous procedures.

2. Costs Included in Developing Payment

The direct costs attributed to the provision of this service are the costs of an hourly professional salary (for example, registered nurse, registered dietitian, or certified diabetes educator), counseling materials, special equipment, administrative costs of billing, record maintenance, and the scheduling of patients. Indirect costs include the cost of office equipment and supplies, continuing training, accounting, office rent, utilities, and similar costs.

3. Determining Resource Inputs

Section 1848 of the Act requires that payments under the physician fee schedule be based on national uniform RVUs based on the resources used in furnishing a service. The resource

inputs that we would use to determine the practice expense RVUs for this service would be based on the estimated cost for furnishing an hourly training session by the ADA. In order to be consistent with national RVUs under the physician fee schedule, we would adjust the hourly professional salary, change the physician component to a professional salary rate, disallow for appointment cancellations, increase the scheduling secretary's salary, and adjust the allowance for billing costs and telephone calls. We would recognize the legal fees for malpractice insurance as part of the separate malpractice RVU. The following shows the estimated cost determination worksheet provided to us by the ADA along with our adjustments to the cost estimates in order to make the ADA's estimated costs consistent with the national physician fee schedule.

TABLE 1.—DIABETES SELF-MANAGEMENT TRAINING RESOURCE COSTS PROVIDED BY THE AMERICAN DIABETES ASSOCIATION (ADA) AND HCFA'S ADJUSTMENTS USED TO DETERMINE PROPOSED PAYMENT

Services (data provided by ADA)	ADA estimated costs	HCFA adjustments individual/group	HCFA RVUs individual/group	HCFA adjusted costs individual/group	AMA category
DIRECT COSTS					
Professional Salary/Hour (RN or RD)	$24.00				
Benefits/hour (28% salary)	6.72	$25.32=National Professional Rate			
Total	30.72	25.32/2.53*	0.69/0.07	$25.32/2.53*	Clinical.
Physician Component (Oversight)	3/min				
Total	6.00	0.84/0.84	0.02/0.02	0.84/0.84	Clinical.
Counseling Materials:					
Printed Videos, Strips, Medical Supplies.	5.00			5.00/5.00	Medical supplies.
Special Equipment:					
Computer Software ($6,000 over 3 years).	0.96			0.96/0.96	Office supplies.
Calculators, Scales, Gloves	0.25			0.25/0.25	Medical supplies.
Reference Materials (Journals, Books, etc.) ($500/year).	0.25			0.25/0.25	Other.
Costs of Operation:					
Billing Insurance Forms/Follow-Up (8% of cost).	6.40			2.13/2.13**	Clerical.
Record Maintenance (charts, files).	3.00			3.00/3.00	Clerical.
Scheduling Patients (10 min. × $12).	2.00	2.15 is National scheduling secretary rate.	0.06/0.06	2.15/2.15	Clerical.
Reports to Referral Source	4.32			4.32/4.32	Clerical.
No shows	3.00	0.00	Not allowed cost	0.00/0.00	
Phone Calls (one 15-minute call/visit 30/hour.	7.50			3.75/3.75***	Office.
Total	32.68		0.59/0.59	21.81/21.81	
Total Direct Costs	69.40			47.97/25.18	
INDIRECT COSTS					
Rent	2.25			2.25/2.25	Office.
Utilities	1.40			1.40/1.40	Office.
Office Supplies & Equipment	1.73			1.73/1.73	Office.
Telephone ($125/m/173.3 wk. Hrs. Mo.).	0.72			0.72/0.72	Office.
Continuing Education	0.72			0.72/0.72	Other.
Accounting	0.25			0.25/0.25	Other.
Total Indirect Costs	7.07		0.19/0.19	7.07/7.07	
Legal Fees=Total Malpractice RVU.	0.20	0.37	0.01/0.01	0.37/0.37	Malpractice Expense.
Total Individual/Group Costs	76.67		1.51/0.89	55.41/32.62*	

*Based on an average of 10 members in a group, since a group is defined as 2 to 20 individuals.
**Based on the average of three billings during an individual and group session.
***Based on a 50% telephone contact to beneficiaries during individual and group sessions.

4. Payment

We propose to pay this service under the physician fee schedule (§ 414.62). The proposed RVUs are as follows:

Individual sessions	Group sessions per individual	Individual sessions	Group sessions per individual
Physician Work RVUs = 0.	Physician Work RVUs = 0.	Practice Expense RVUs = 1.51.	Practice Expense RVUs = .89.

Individual sessions	Group sessions per individual
Malpractice Expense RVUs = .01.	Malpractice Expense RVUs = .01.

Table 1 explains how we derived the proposed payment rates for providing diabetes training on an individual basis and in a group setting, based on the estimated resource costs provided by the ADA. Since the number of beneficiaries within a group would vary, we have based our methodology on an assumption that there would typically be 10 beneficiaries attending a group session.

The Act requires that payments vary among fee schedule areas according to the extent that resource costs vary as measured by the geographic practice cost indices (GPCIs). Section 1848(e)(1)(C) of the Act requires us to review and, if necessary, adjust the GPCIs at least every 3 years. On October 31, 1997, we published a final rule, Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule, Other Part B Payment Policies, and Establishment of the Clinical Psychologist Fee Schedule for Calendar Year 1998 (62 FR 59256). Addendum E to that rule identifies the 1999 GPCIs for practice expense RVUs and malpractice expense RVUs.

Using the proposed RVUs, we would pay $55.41 for individual sessions and $32.62 per person within a group session. These same payment rates would apply for the 1-hour annual refresher training. Actual payments to an entity approved by us would be adjusted for geographic variation and determined based on the physician fee schedule methodology as described in a separate final rule published in the **Federal Register** on October 31, 1997 (62 FR 59048).

Billing for payment would be submitted in 60-minute increments. The following CPT codes would be used for billing:

G0108—Outpatient diabetes self-management training services, individual session, per 60 minutes of training.

G0109—Outpatient diabetes self-management training services, group session, per individual, per 60 minutes of training.

Based on information received from the diabetes industry, we propose that beneficiaries receive up to 10 hours of diabetes training within the same year, either as an individual or within a group setting. As previously stated in this proposed regulation, we are proposing that all beneficiaries who receive the initial training program be eligible for an annual single training session of up to one hour (a group session, unless an individual session is needed based on the same criteria listed above).

We would refine the diabetes training payment amount in the future by incorporating this service into the refinement process used for other Medicare services payable under the physician fee schedule. Medicare co-payments and deductibles would apply for diabetes outpatient self-management training services.

K. Time Limits for Filing Claims

We are proposing to add a new paragraph (d), ''Outpatient diabetes self-management training,'' to § 424.44, ''Time limits for filing claims.'' New paragraph (d) would state that we would make payment to an entity for the furnishing of outpatient diabetes self-management training after we approve the entity to furnish the services under part 410 subpart H.

L. Photocopying Reimbursement and Mailing Costs for Practitioners

Section 4105(c) of the BBA '97 requires the Secretary to establish outcome measures, including glycosylated hemoglobin (past 90-day average blood sugar levels), for purposes of evaluating the improvement of the health status of Medicare beneficiaries with diabetes mellitus. In order to obtain adequate clinical documentation used in developing these outcome measures, we would direct Peer Review Organizations to collect this information from a physician or qualified nonphysician practitioner treating a beneficiary with diabetes as authorized by § 476.111(a).

We are proposing to pay physicians and nonphysician practitioners for photocopying and mailing cost directly attributable to the physician or nonphysician's responsibility to the PROs to provide photocopies of requested beneficiary medical records (§ 476.111(d)). The proposed payment is $.10 per page for photocopying plus first class postage costs for mailing the records. The proposed photocopying amount includes the cost of labor, supplies, equipment, and overhead. We are proposing the above amount based on the final rule establishing photocopying payment for hospitals published in the **Federal Register** (See 57 FR 47779 through 47787, October 20, 1992).

M. Appeals

We propose that in order to become an approved entity, a physician, individual, or entity must be approved by an accreditation organization and approved by us. If an individual, physician, or entity is found not to meet the conditions in either § 410.141(e), we would disapprove the application. We would provide administrative review of this decision by using the procedures for suppliers in part 498. Similarly, in the event we find an approved entity not to be in compliance with the conditions set forth in § 410.141(e), we may revoke the approved entity's Medicare billing number. In that event, we would also provide administrative appeal rights under the procedures in Part 498. Therefore, we have revised the definition of ''supplier'' that appears in § 498.2 to include an ''approved entity'' for furnishing outpatient diabetes self-management training.

N. Outcome Measures

We are requesting comments on the type of process and outcome measures we should be collecting in the future in order to review the progress of beneficiaries and the success of programs. We also solicit comments on the desirability in the future of replacing these proposed prescriptive training and personnel requirements with reliance on outcome measures.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the information collection requirements (ICRs) as summarized and discussed below.

Section 410.141 Outpatient Diabetes Self-management and Training

Section 410.141(b) states that diabetes self-management training must be included in a comprehensive plan of

care and documented in the patient's medical record by the physician or qualified nonphysician practitioner treating the beneficiary for training services that meet the requirements of this section. In addition, this section requires that HCFA-approved entities submit their plan of care to HCFA upon request. While the documentation and recordkeeping requirement imposed by this section is subject to the PRA, the requirements to disclose information to HCFA upon request are not subject to the PRA in accordance with 5 CFR 1320.4(a)(2), since the disclosure of information to or for a Federal agency during the conduct of an administrative action or audit involving an agency against specific individuals or entities is exempt from the PRA.

Therefore, the burden associated with this section that is subject to the PRA is the time and effort for the physician or qualified nonphysician practitioner to ensure that each patient's plan of care is documented and maintained in his or her medical record. We estimate that it will require 30 minutes to document each plan of care. And, on an annual basis there will be 2,250,000 required plans of care (2,000,000 aged beneficiaries + 250,000 disabled beneficiaries). Therefore, the total annual burden of this requirement is 1,125,000 hours (2,250,000 plans of care * 30 minutes = 1,125,000 hours).

Section 410.141(c)(2) requires the physician or qualified nonphysician practitioner treating the beneficiary document in the beneficiary's medical record the specific medical condition that the additional beneficiary training must address.

While this ICR is subject to the PRA, we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 410.141(c)(3)(ii) states that the beneficiary's physician or qualified nonphysician practitioner must document in the beneficiary's medical record that the beneficiary has special needs, such as severe vision, hearing, or language limitations that would hinder effective participation in a group training session.

While this ICR is subject to the PRA, we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 410.141(e)(3) requires that an entity submit the necessary documentation to, and is accredited by, an accreditation organization approved by HCFA under § 410.142 to meet one of the sets of quality standards described in § 410.144. The burden associated with this requirement is the time and effort necessary for an entity requesting to be deemed to submit the necessary documentation to an accreditation organization. It is estimated that it will take each of the estimated 750 entities 60 hours to complete these requirements every 3 years, for an annual burden of 20 hours. Therefore, the total annual burden imposed by these requirements is estimated to be 15,000 hours.

Section 410.141(e)(4) states that a physician, individual, or entity must provide documentation to HCFA as requested.

Since this requirement will be collected as part of an investigation or audit against specific individuals or entities, we believe that this ICR is exempt in accordance with 5 CFR 1320.4(a)(2). In addition, we believe that since the request for information is addressed to a single person as defined in 5 CFR 1320.3(h)(6), the collection does not meet the definition of an information collection as defined in 5 CFR 1320.3(c).

Section 410.142 HCFA Process for Approving National Accreditation Organizations

Section 410.142(b) states that a national organization requesting accreditation approval by HCFA must furnish to HCFA the information and materials described in this section.

The burden associated with these requirements is the time and effort to furnish to HCFA the information and materials described in this section. It is estimated that during the first year it will take 5 national organizations 96 hours to comply with these requirements. Since organizations will generally be approved for at least 6 years, we have annualized the total burden to be 96 * 5 = 480 hours/6 years = 80 annual hours.

Section 410.142(c) states that HCFA may visit the prospective accreditation organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

The burden imposed by this section is the time and effort necessary to disclose documentation related to the onsite visit. However, we believe that these requirements are exempt from the PRA since they will be imposed under the conditions defined in 5 CFR 1320.4 and meet the exception(s) to the definition of information as set forth in 5 CFR 1320.3(h)(3), (h)(6), and (h)(9) and as such does not meet the definition of an information collection.

Section 410.142(g) states that an accreditation organization that has received HCFA's notice of denial of its request for HCFA approval and recognition of its accreditation program to accredit entities to furnish outpatient diabetes self-management training services may request reconsideration of HCFA's decision in accordance with part 488 subpart D of this chapter.

We believe that this ICR is exempt in accordance with 5 CFR 1320.4(a)(2) since this requirement is the result of an administrative action, investigation, or audit against specific individuals or entities.

Section 410.142(h) states that an organization that has received HCFA's notice of denial of its request for accreditation may submit a new request to HCFA if it meets the conditions in this section.

We anticipate that these requirements will be imposed on less then 10 persons on an annual basis, and, therefore, are not subject to the PRA as defined in 5 CFR 1320.3(c).

Section 410.142(j) states that at least 6 months before the expiration of HCFA's approval and recognition of the accreditation organization's program, an accreditation organization must request from HCFA continued approval and recognition.

The burden associated with this requirement is the time and effort necessary for an organization to submit to HCFA a request for reapproval. The burden associated with this requirement is captured in § 410.142(b).

Section 410.143 Requirements for Approved Accreditation Organizations

Section 410.143(a)(1) states that an accreditation organization approved by HCFA must provide to HCFA in a written form and on a monthly basis all of the ICRs set forth in § 410.143(a)(1)(i) through (a)(1)(iv).

The burden associated with these requirements is the time and effort for an accreditation organization to comply with the requirements of this section. It is estimated that it will take each organization 4 hours to complete these requirements. There are approximately 5 respondents for a total of 20 annual hours.

Section 410.143(a)(2) states that within 30 days of a change in the HCFA standards, submit to HCFA its organization's plan to alter its standards to conform to the revised HCFA

standards (including a crosswalk between the revised HCFA standards and the organization's revised standards) within the timeframes for adopting the revised HCFA standards specified in the notification of change it receives from HCFA.

The burden associated with these requirements are the time and effort for an organization to submit its organization's plan. It is estimated that it will take each organization 10 hours to comply with these requirements. There are approximately 5 respondents for a total of 50 hours.

Section 410.143(b) states that HCFA (or its agent(s)) may perform oversight activities such equivalency reviews, validation reviews, and onsite inspections ensure that an approved accreditation organization and the entities the accreditation organization accredits continue to meet the quality standards described in § 410.144. In addition, an accreditation organization that is dissatisfied with a determination to withdraw HCFA approval and recognition may request a reconsideration of HCFA's decision in accordance with part 488 subpart D of this chapter.

The burden imposed by this section is the time and effort necessary to disclose documentation under the reviews and inspections.

However, we believe that these requirements are exempt from the PRA since they will be imposed under the conditions defined in 5 CFR 1320.4 and meet the exception(s) to the definition of information as set forth in 5 CFR 1320.3(h)(3), (h)(6), and (h)(9) and as such does not meet the definition of an information collection.

Section 410.144 Quality Standards for a Deemed Entity

Section 410.144(a)(1)(ii) and (iii) states that a deemed entity document the organizational relationships, lines of authority, staffing, job descriptions, and operational policies. In addition, it must maintain a written policy that affirms education as an integral component of diabetes care.

The burden associated with this requirement is the time and effort for an entity to document and maintain the information described above. It is estimated these requirements will take each entity 8 hours. There are approximately 750 entities for a total annual burden of 6,000 hours.

Section 410.144(a)(7) states that an entity must review each beneficiary's plan of care, develop, and update an individual assessment in collaboration with each beneficiary, and document the results, including assessment, intervention, evaluation, and follow-up in the beneficiary's permanent medical record.

The burden associated with this requirement is captured in § 410.141(b) above.

Section 410.144(a)(9) states that an entity must establish and maintain a performance measurement and quality improvement program that meets the requirements of this section. In addition, if requested, an entity must report to HCFA nationally standardized performance measures to the extent that they become available in the future and the Secretary determines they are appropriate.

While the requirements to maintain documentation and the reporting of nationally standardized performance measures are subject to the PRA, the requirements to disclose information to HCFA upon request are not subject to the PRA in accordance with 5 CFR 1320.4(a)(2), since the disclosure of information to or for a Federal agency during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is exempt from the PRA.

Therefore, the burden associated with this section, that is subject to the PRA, is the time and effort necessary for an entity to maintain documentation related to the performance measurement and quality improvement program and the reporting of nationally standardized performance measures. It is estimated that the recordkeeping requirements will take each entity 3 hours on an annual basis since there are approximately 750 entities for a total annual burden of 2,250 hours. Since HCFA is not currently requiring entities to report nationally standardized performance measures, we are not assigning any burden to this requirement. When HCFA does mandate the requirement to report these performance measures, the burden associated with this requirement will be adjusted accordingly.

Section 410.144(a)(10) states that each deemed entity must have an agreement with a PRO, which has a contract with HCFA to perform quality assurance reviews. At a minimum, the agreement must allow the PRO access to beneficiary or group therapy records, and binds an approved entity to comply with corrective actions or to participate in quality improvement projects that the PRO determines are necessary.

The burden associated with this requirement is the time and effort necessary to maintain the necessary documentation to demonstrate that the deemed entity has entered into a written agreement with a PRO that meet the requirements of this section.

We estimate that it will take 750 entities 5 minutes on an annual basis to maintain the necessary documentation for an overall annual burden of 63 hours.

Section 410.145 Requirements for Deemed Entities

Section 410.145(a)(10) states that an entity may be deemed to meet the HCFA quality standards described in § 410.144 if the entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by a national accreditation organization approved by HCFA. The burden associated with meeting these requirements is captured in § 410.141(e)(3).

Section 410.145(c) states that an entity may be deemed to meet the HCFA quality standards described in § 410.144(a) if the entity—(1) forwards a copy of its certificate from its accreditation organization indicating that the entity meets the HCFA quality standards described in § 410.144(a) before submitting a claim for Medicare payment; (2) agrees in writing to submit to evaluation (including onsite inspections) by HCFA (or its agent) to validate its accreditation organization's accreditation process; and (3) authorizes in writing for its accreditation organization to release to HCFA a copy of its most recent accreditation evaluation, and any accreditation-related information that HCFA may require.

The burden associated with these requirements is the time and effort for an entity to submit a copy of its certificate, along with its agreement, and authorization.

It is estimated that it will take each entity 5 minutes to comply with these requirements. There are approximately 750 respondents for a total of 63 hours.

Section 414.62 Payment for Outpatient Diabetes Self-Management Training Services

Section 414.62(c) states that beneficiary participation in training sessions must be documented on attendance sheets.

While this ICR is subject to the PRA, we have not accounted for the burden of this ICR because we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We solicit comment on our preliminary conclusion

that this activity would be done in the normal course of business and, thus, would have no burden for providers.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Louis Blank, HCFA–3002–P

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, HCFA Desk Officer.

V. Regulatory Impact Analysis

A. Background

We have examined the impacts of this proposed rule as required by Executive Order 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). The statutory provision that this rule further implements would cause this to be a major rule because we have estimated that the annual costs associated with this rule would be significantly higher than $100 million beginning in 1999.

Section 1102(b) of the Social Security Act (the Act) requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may mandate an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more. We believe that this proposed rule would not mandate such expenditures.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. States and tribal governments are not considered to be small entities. This rule provides additional benefit payments to providers for offering classes on diabetes self-management. Therefore, there are no regulatory burden issues affecting small entities to be considered with respect to these benefit payments. In section C. of the RIA that discusses the accreditation approval process, we acknowledge that some small entities may face a regulatory burden in obtaining accreditation. We discuss proposed measures that we believe will lessen the regulatory burden on these entities.

This proposed rule sets forth an expanded benefit for Medicare beneficiaries with diabetes who meet the criteria for self-management training services. It also identifies who may be an approved entity that may furnish these services, and lists the quality standards that must be met by these approved entities. This regulation would primarily affect beneficiaries with diabetes and certain health care professionals, such as physicians, nurses, physician-directed clinics, and hospital outpatient departments.

We estimate that there are 4.5 million Medicare beneficiaries with diabetes (approximately 4 million aged beneficiaries and .5 million disabled beneficiaries). Of this total, we estimate that about half, or 2.25 million beneficiaries, would receive diabetes self-management training services. This estimate assumes that the remaining 2.25 million Medicare beneficiaries either have already received the training or do not currently meet the conditions of coverage. These beneficiaries may meet the conditions of coverage at a later date, if their medical condition changes.

B. Diabetes Costs and Benefits

After consultation with the industry, we believe it is reasonable to cover up to 10 hours of initial diabetes self-management training within a continuous 12-month period and up to 1 hour of additional training annually (after the initial training) for each beneficiary that meets the conditions of coverage. We estimate that there would actually be 10 1-hour sessions billed in the first year and possibly one follow-up session (up to 1 hour) billed each year thereafter, if the beneficiary qualifies for the follow-up session. We have assumed that most beneficiaries with diabetes that currently qualify would have the training in the first few years of coverage. This accounts for the large influx of spending in the first few years. The outyear estimates assume that a limited number of beneficiaries with new diabetes diagnoses would receive the full training benefit, and that others would receive refresher courses if ordered by their physician. In addition, we have assumed that there would be newly diagnosed beneficiaries with diabetes each year that would receive up to 10 hours of initial diabetes self-management training, but they represent a smaller number of diabetics.

The following table displays the budgetary cost of the outpatient diabetes self-management training program to the Medicare program.

PROJECTED BUDGET IMPACT OF NEW BENEFIT

[$ in millions]

FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
$40	$390	$320	$180	$80

These costs are considerable, especially in the first few years, but we also expect substantial benefits. When someone has diabetes, his or her body has trouble making or using insulin, a hormone produced by the pancreas.

Insulin enables the body's tissues to use glucose, a sugar that circulates in the bloodstream and that normally provides energy for the body's cells. Because a diabetic beneficiary cannot properly use glucose in the blood, blood sugar levels remain high, unless a person takes appropriate medication (such as insulin) or is able to reduce blood sugar levels through diet and exercise. The consequences of diabetes can be severe. It is the fourth leading cause of death by disease in the United States. Diabetes can also result in many other medical problems, including heart disease, stroke, kidney disease, loss of sensation and circulation in the legs, possibly leading to amputations, and blindness. Proper health care and self-management can help circumvent these problems or slow their onset. There are two critical questions that go to the heart of diabetes self-management training. First, when should the person receive the training? Second, how much training should the person receive? Initial training may bring about short term behavioral changes. Some experts, however, express concern about the difficulty people with diabetes have in maintaining behavior changes unless they get additional education and support as a follow-up to the initial training. To assure that our beneficiaries receive the amount of training and support we believe they need to maintain good health or improve their existing health status, we would provide, when medically necessary, refresher training in a subsequent year following the initial training. We believe that these actions would have a positive result on the Medicare program, and we plan to monitor specific outcome measures to assure that only quality programs are reimbursed by the Medicare program.

There is a possibility of delays in enrolling newly approved entities because of the accreditation process. However, existing outpatient diabetes self-management programs would continue to be paid as they are now. The estimates assume that roughly 70 percent of beneficiaries would be able to receive the self-management training from currently approved entities. Also, the estimates do not reflect payments for beneficiaries who are inpatients in facilities such as hospitals or nursing homes. Finally, we assume that the number of beneficiaries with diabetes grows in the same manner as total Part B enrollment. This results in increasing the number of beneficiaries with diabetes by about 40,000 per year.

C. Accreditation Process

Section 1865 of the Act requires us to determine whether the accreditation of a provider or supplier entity by a national accreditation organization provides assurances that the applicable Medicare health and safety conditions or requirements are met.

The BBA '97 authorized the Secretary to develop her own quality standards. We have condensed the standards originally established by the NDAB and recognized by the ADA, and we believe that our proposed standards offer sufficient assurances that the outpatient diabetes self-management training programs would provide quality care and the standards are flexible enough to apply in any health care setting.

The ADA Education Recognition Program is a national voluntary process that identifies diabetes self-management training programs that meet National Standards for Diabetes Self-Management Education Programs. The ADA currently recognizes outpatient diabetes self-management programs. To date, the ADA has given recognition to approximately 575 education programs. Under the conditions in this proposed rule, the ADA, along with any other national accreditation organization that wishes to be approved and recognized by HCFA, would be required to submit appropriate documentation requesting accreditation approval from us. Once we have determined that the organizations meet the HCFA requirements concerning frequency of accreditation, accreditation forms, and that they use guidelines and instructions to evaluators that are as rigorous as our requirements with a similar emphasis on outcomes, they may then be approved and recognized as national accreditation organizations.

We fully expect that the ADA will apply to HCFA as a national accreditation organization and be quickly approved to accredit entities. Our review of the ADA-recognized programs indicates that there is a minimum of at least one program in each State and the District of Columbia. These programs are located in both small rural hospitals as well as large urban hospitals. While the majority of these programs are hospital-based, there are some that are clinics and one in Arizona that is an insurance plan. Thus, we believe that the geographic distribution of recognized programs is such that Medicare beneficiaries would be able to receive training without a delay of the benefit.

We recognize that some small entities such as rural physicians and qualified nonphysician practitioners may find the 12-month collection of data and the start-up fees required by the ADA to be a burden to their practices. The approximate cost for an entity to get accredited, based on current ADA figures, is $682.50, which includes an $82.50 application fee and a $600 initial accreditation fee. The subsequent triennial fee is $500. Additional items, such as recordkeeping costs and other overhead costs, have not been factored into the cost of becoming an approved entity. We estimate that there will be a total of 750 accredited entities when this rule is implemented and we estimate there are currently 575 entities that are ADA-certified and that already pay accreditation costs. The additional 175 entities would pay the $682.50, so the additional private sector cost would be $119,437.50.

In addition, we acknowledge that some existing programs are currently accredited by their State or local agency and may now find it a burden to become accredited by a national organization. However, we expect that at least four other national accreditation organizations would apply to us for recognition and that these entities may find the quality standards of these organizations to be substantially equivalent to the existing State or local standards. The CDC has a cooperative agreement with the 50 States, all U.S. territories, and the District of Columbia. This agreement provides funding to these geographic entities, which they currently use to perform a variety of diabetes-related activities. Ten of the 50 States use a portion of their funds to administer their State diabetes self-management training accreditation programs. Under this proposed rule, there will be no loss of revenue from this cooperative agreement for any of these geographic entities. Those States that currently use their funds from the cooperative agreement to administer their State diabetes self-management training programs can either choose to become an organization or choose instead to fund other diabetes-related activities, including the development of educational programs for the use of approved entities that desire to obtain national accreditation in order to qualify for Medicare payment under this benefit.

One way we are trying to lessen the burden on rural and small entities is by postponement of the requirement for the CDE to be part of the diabetes self-management team. This proposed rule requires that nonphysician diabetes educators complete 14 hours of approved diabetes-related continuing education every two years. The approximate cost of obtaining these

credits is $300. (This estimate is based on diabetes-related training information that we received from the American Association of Diabetes Educators.) We believe that existing programs would have approximately 3½ years from the publication of this proposed rule to provide outpatient diabetes self-management training while preparing to meet the HCFA standard concerning the CDE.

We estimate that there would be 750 approved entities when this final rule is fully implemented. Each approved entity would need a CDE. The initial certification of a CDE costs $250 and another $250 every 5 years to maintain certification. It would cost approximately $37,500 (750 × $250 ÷ 5) per year for CDE certification at the rate of one CDE per approved entity. The continuing education requirement for a CDE associated with this proposed rule would cost approximately $300 every 2 years. The estimated total cost for continuing education for all CDEs would be $112,500 (750 × $300 ÷ 2) per year at the rate of one CDE per approved entity. The estimated total cost for combined certification and continuing education for all CDEs would be approximately $150,000 per year.

D. Conclusions

We anticipate that this proposed rule would improve health of Medicare beneficiaries with diabetes by providing them with the skills and knowledge necessary to effectively manage their diabetic condition. We recognize that there may be some burden on existing and new entities because of the requirement that they must be accredited by a national accreditation body. However, we must ensure that Medicare pays only for those programs that are of the highest quality. We believe that the overall burden to these entities is worth the benefit that will be gained to both the Medicare beneficiary and the program.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare.

For the reasons set forth in the preamble, 42 CFR Chapter IV would be amended as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. Part 410 would be amended as follows:

1. The authority citation for part 410 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise indicated.

2. Section 410.1, paragraph (a) is revised to read as follows:

§ 410.1 Basis and scope.

(a) *Statutory basis.* This part is based on the indicated provisions of the following sections of the Act:

1832—Scope of benefits furnished under the Medicare Part B supplementary medical insurance (SMI) program.

1833 through 1835 and 1862—Amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage.

1861—Definition of the kinds of services that may be covered.

1865(b)—Permission for HCFA to approve and recognize a national accreditation organization and its accreditation program for accrediting an entity to furnish outpatient diabetes self-management services.

1881—Medicare coverage for end-stage renal disease beneficiaries.

* * * * *

3. New subpart H, consisting of §§ 410.140 through 410.145, is added to read as follows:

Subpart H—Outpatient Diabetes Self-Management Training Services

Sec.

Subpart H—Outpatient Diabetes Self-Management Training Services

§ 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

Approved entity means an individual, physician, or entity accredited by an approved organization to furnish training and approved by HCFA to furnish and receive Medicare payment for the training.

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by HCFA to furnish and receive Medicare payment for the training. Upon being approved by HCFA to receive Medicare payment for training, HCFA refers to this entity as an ''approved entity.''

Organization means a national accreditation organization.

Training means outpatient diabetes self-management training.

§ 410.141 Outpatient diabetes self-management training.

(a) *General rule.* Medicare Part B covers training defined in § 410.140 ordered by a physician or qualified nonphysician practitioner (as these terms are defined in § 410.32) for a beneficiary with a diabetic condition to ensure therapy compliance or to provide the beneficiary with necessary skills and knowledge to manage the beneficiary's condition.

(b) *Conditions for coverage.* The training must meet the following conditions:

(1) Following an evaluation of the beneficiary's need for the training, it is ordered by the physician or qualified nonphysician practitioner treating the beneficiary's diabetes.

(2) It is included in a comprehensive plan of care (established by the physician or qualified nonphysician practitioner treating the beneficiary for diabetes) that meets the following requirements:

(i) Describes the content, number, frequency, and duration of the training as written by the physician or qualified nonphysician practitioner treating the beneficiary.

(ii) Contains a statement specified by HCFA and signed by the physician or qualified nonphysician practitioner managing the beneficiary's diabetic condition. By signing this statement, the physician or qualified nonphysician practitioner certifies that he or she is managing the beneficiary's diabetic condition and the training described in

the plan of care are needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary's diabetes. The physician's or qualified nonphysician practitioner's statement must identify the beneficiary's specific medical conditions (described in paragraph (d)(1) of this section) that the training would address.

(iii) Provides that any changes to the plan of care are signed by the physician or qualified nonphysician practitioner treating the beneficiary.

(iv) Is incorporated into the approved entity's permanent medical record for the beneficiary and is made available, upon request, to HCFA.

(3) It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(4) Except as permitted in paragraph (c)(3) of this section, it is furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(c) *Types and frequency of training*—(1) *Initial training.* Medicare Part B covers up to 10 hours of initial training within a continuous 12-month period for each beneficiary that meets the conditions in paragraph (d) of this section.

(2) *Additional training.* After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers a single follow-up training session lasting no more than 1 hour for a beneficiary each year. The physician or qualified nonphysician practitioner treating the beneficiary must document in the beneficiary's medical record the specific medical condition (described in paragraph (d)(1) of this section) that the additional training must address.

(3) *Exception.* Medicare covers up to 10 hours of training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(i) No group session is available within 2 months of the date the training is ordered.

(ii) The beneficiary's physician or qualified nonphysician practitioner documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that would hinder effective participation in a group training session.

(d) *Beneficiaries who may be covered.* Medicare Part B covers initial training services for a beneficiary who meets the following conditions:

(1) *Medical conditions.* A beneficiary has one of the following medical conditions occurring within the 12-month period before the physician's order for the training:

(i) New onset diabetes.

(ii) Poor glycemic control as evidenced by a glycosylated hemoglobin (HbA1C) level of 9.5 or more in the 90 days before attending the training.

(iii) A change in treatment regimen from no diabetes medications to any diabetes medication, or from oral diabetes medication to insulin.

(iv) High risk for complications based on poor glycemic control (documented acute episodes of severe hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed third party assistance for either emergency room visits or hospitalization).

(v) High risk based on at least one of the following documented complications:

(A) Lack of feeling in the foot or other foot complications such as foot ulcer or amputation.

(B) Pre-proliferative or proliferative retinopathy or prior laser treatment of the eye.

(C) Kidney complications related to diabetes, such as macroalbuminuria or elevated creatinine.

(2) *Other conditions.* The beneficiary—

(i) Has not received initial training; or

(ii) Is not receiving services as an inpatient in a hospital, SNF, hospice, or nursing home.

(iii) Is not receiving services as an outpatient in an RHC or FQHC.

(e) *Who may furnish services.* Services may be furnished by a physician, individual, or entity that meets the following conditions:

(1) In addition to furnishing diabetes training services described in § 410.141, furnishes other services for which direct Medicare payment may be made.

(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by HCFA under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to HCFA, as requested.

§ 410.142 HCFA process for approving national accreditation organizations.

(a) *General rule.* HCFA may approve and recognize an organization that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training services.

(b) *Required information and materials.* An organization requesting HCFA's approval and recognition of its accreditation program must furnish to HCFA the following information and materials:

(1) The standards that the organization uses to accredit entities to furnish training services.

(2) A detailed comparison (including a crosswalk if the organization does not use standards described in § 410.144 in their entirety) between the organization's accreditation requirements and standards and the HCFA standards described in § 410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify an entity of deficiencies in its outpatient diabetes self-management training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform evaluations for the organization, including all of the following information:

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices with respect to the participation, in the accreditation process, by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system with respect to its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against a

deemed entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and HCFA.

(7) A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if HCFA approves the organization.

(9) A list of all entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

(10) The name and address of each person with an ownership or control interest in the organization.

(11) Documentation that demonstrates its ability to furnish HCFA with electronic data in HCFA-compatible format.

(12) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

(13) A statement acknowledging that, as a condition for approval and recognition by HCFA of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.144.

(14) Additional information HCFA requests to enable it to respond to the organization's request for HCFA approval and recognition of its accreditation program to accredit entities to furnish training services.

(c) *Onsite visit.* HCFA may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

(d) *Notice and comment*—(1) *Proposed notice.* HCFA publishes a proposed notice in the **Federal Register** announcing its intention to approve an organization's request for HCFA approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training services. The notice includes the following information:

(i) The basis for approving the organization.

(ii) A description of how the organization's accreditation program applies and enforces quality standards that have been determined by HCFA to be substantially equivalent to the quality standards for training services described in § 410.144.

(iii) An opportunity for public comment.

(2) *Final notice.* (i) After considering public comments, HCFA publishes a final notice in the **Federal Register** indicating whether it has approved an organization's request for HCFA approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training services.

(ii) If HCFA approves the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(e) *Criteria HCFA uses to approve national accreditation organizations.* In deciding to approve and recognize an organization's accreditation program to accredit entities to furnish training services, HCFA considers the following criteria:

(1) The organization applies and enforces quality standards that have been determined by HCFA to be substantially equivalent to the quality standards described in § 410.144.

(2) The organization meets the requirements for approved organizations in § 410.143.

(3) The organization is not owned or controlled by the entities it accredits, as defined in § 413.17(b)(2) or (b)(3), respectively, of this chapter.

(4) The organization does not accredit any entity it owns or controls.

(f) *Notice of HCFA's decision.* HCFA notifies the prospective organization in writing of its decision. The notice includes the following information:

(1) Statement of approval or denial.

(2) Rationale for denial.

(3) Reconsideration and reapplication procedures.

(g) *Reconsideration of adverse decision.* An organization that has received HCFA's notice of denial of its request for HCFA approval and recognition of its accreditation program to accredit entities to furnish training services may request reconsideration of HCFA's decision in accordance with part 488 subpart D of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an organization that has received HCFA's notice of denial of its request for HCFA approval and recognition of its accreditation program to accredit entities to furnish training services may submit a new request to HCFA if it meets the following conditions:

(i) Has revised its accreditation program to correct the deficiencies HCFA noted in its denial notice.

(ii) Demonstrates, through documentation, that the quality standards used by the deemed entities are substantially equivalent to the HCFA quality standards for training services described in § 410.144(a).

(iii) Resubmits the application in its entirety.

(2) An organization that has requested reconsideration of HCFA's denial of its request for HCFA approval and recognition of its accreditation program to accredit entities to furnish training services may not submit a new request until all administrative proceedings have been completed.

(i) *Withdrawal.* An organization requesting HCFA approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

(j) *Reapplying for accreditation.* At least 6 months before the expiration of HCFA's approval and recognition of the organization's program, an organization must request from HCFA continued approval and recognition.

§ 410.143 Requirements for approved accreditation organizations.

(a) *Ongoing responsibilities of an approved accreditation organization.* An organization approved and recognized by HCFA must undertake the following activities on an ongoing basis:

(1) Provide to HCFA in writing and on a monthly basis all of the following:

(i) Copies of all accreditation decisions and any accreditation-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA standards).

(ii) Notice of all complaints related to accredited entities.

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an entity's deemed status) against a deemed entity, information describing the remedial or adverse action and the circumstances that led to taking the action.

(iv) Notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without HCFA approval, HCFA may withdraw its approval and recognition of the organization's accreditation program.

(2) Within 30 days of notification of a change in the HCFA quality standards, submit to HCFA its organization's plan to alter its quality standards to conform

to the revised HCFA standards (including a crosswalk between the revised HCFA standards and the organization's revised standards) by the effective date specified in HCFA's notification of the change in HCFA's quality standards.

(b) *HCFA oversight of approved national accreditation organizations.* HCFA performs oversight activities to ensure that an approved organization and the entities the organization accredits continue to meet the quality standards described in § 410.144. HCFA may contract with an entity to perform these oversight activities. HCFA (or its agent) uses the following procedures:

(1) *Equivalency review.* HCFA compares the organization's standards and its application and enforcement of its standards to the comparable HCFA standards (described in § 410.144(a)) and processes when any of the following conditions exist:

(i) HCFA imposes new requirements or changes its process for approving and recognizing organizations.

(ii) The organization proposes to adopt new standards or changes its accreditation process.

(iii) The organization reapplies to HCFA for continuation of its approval and recognition by HCFA of its program to accredit entities to furnish training services.

(2) *Validation reviews.* HCFA validates the organization's accreditation process by conducting evaluations of deemed entities accredited by the organization and comparing its results to the results of the organization's evaluation of the deemed entities.

(3) *Onsite inspections.* HCFA may conduct an onsite inspection of the organization's operations and offices to verify information and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Withdrawal of HCFA approval and recognition*—(i) *HCFA decision to withdraw.* HCFA gives the organization written notice of HCFA's intent to withdraw its approval and recognition of the organization's program to accredit entities if HCFA determines through an equivalency review, validation review, onsite inspection, or HCFA's daily experience with the organization that any of the following conditions exist:

(A) The quality standards that the organization applies and enforces are not substantially equivalent to HCFA's quality standards described in § 410.144(a).

(B) The organization has failed to meet the requirements for accreditation in §§ 410.142 through 410.144.

(ii) *Request for reconsideration.* An organization may request a reconsideration of HCFA's decision to withdraw its approval and recognition of the organization in accordance with part 488 subpart D of this chapter.

§ 410.144 Quality standards for a deemed entity.

An organization approved and recognized by HCFA may accredit an entity to meet one of the following sets of standards:

(a) *HCFA standards.* Standards prescribed by HCFA, which include the following:

(1) *Organizational structure.* (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(2) *Environment.* Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) *Program staff.* (i) Requires a program coordinator who is responsible for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 14 hours of continuing education about diabetes, educational principles, and behavior change strategies every 2 years.

(4) *Team approach.* Furnishes services using a multidisciplinary instructional staff who are qualified to teach the training content areas required in paragraph (a)(5) of this section.

(i) *General rule.* The team must include at least a registered dietitian and a Certified Diabetic Educator (CDE) who have recent didactic and experiential preparation in diabetes clinical and educational issues.

(ii) *Delayed effective date for a CDE.* If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until [3 years after the effective date of the final rule].

(5) *Training content.* Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal-setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) *Training methods.* (i) Offers individual and group instruction for effective training services.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(7) *Review of plan of care and goals.* (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration with each beneficiary, that includes relevant medical history, present health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors. Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's permanent medical record.

(8) *Education intervention.* Offers appropriate and timely educational intervention based on referral from the beneficiary's physician or nonphysician practitioner and based on periodic reassessments of health status,

knowledge, skills, attitudes, goals, and self-care behaviors.

(9) *Performance measurement and quality improvement.* Establishes and maintains a performance measurement and quality improvement program that meets the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetic control, beneficiary understanding, or beneficiary compliance) and provides for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators, such as, monitoring for compliance, lost work or school days, metabolic control, or others.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using these measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(C) If requested, report to HCFA nationally standardized performance measures to the extent that they become available in the future and the Secretary determines they are appropriate.

(D) Meet minimum performance levels on performance measures described in this paragraph (a)(9) established by HCFA, which are based on national or local empirical experience and are prospectively announced to allow sufficient time for compliance.

(10) *Peer Review Organization review.* Has an agreement with a PRO, which has a contract with HCFA to perform quality assurance reviews. At a minimum, the agreement allows the PRO access to beneficiary or group therapy records and binds an approved entity to comply with corrective actions or to participate in quality improvement projects that the PRO determines are necessary.

(b) *The National Standards for Diabetes Self-Management Education Programs.* Each of the educational standards contained in the National Standards for Diabetes Self-Management Education Programs (NSDSMEP) as of (insert the date the final rule is published in the **Federal Register**) or any NSDSMEP standards subsequently approved by HCFA.

(c) *Standards of a national accreditation organization that represents individuals with diabetes.* Standards that have been developed by an organization (and approved by HCFA) that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals, including health care professionals and Medicare beneficiaries, with diabetes.

§ 410.145 Requirements for deemed entities.

(a) *General rule.* An entity may be deemed to meet the HCFA quality standards described in § 410.144 if the following conditions are met:

(1) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by HCFA.

(2) The entity is not accredited by an organization that owns or controls the entity.

(b) *Effective date of deemed status.* The date on which an entity is deemed to meet the HCFA quality standards described in § 410.144(a) is the later of one of the following dates:

(1) The date HCFA approves and recognizes the organization to accredit entities to furnish training services.

(2) The date the organization accredits the entity to meet one of the quality standards described in § 410.144(a).

(c) *Requirements for deemed entities.* An entity may be deemed to meet the HCFA quality standards described in § 410.144(a) if the entity meets the following conditions:

(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an approved organization indicating that the entity meets the HCFA quality standards described in § 410.144(a).

(2) Agrees to submit to evaluation (including onsite inspections) by HCFA (or its agent) to validate its approved organization's accreditation process.

(3) Authorizes its approved organization to release to HCFA a copy of its most recent accreditation evaluation, and any accreditation-related information that HCFA may require.

(d) *Removal of deemed status.* HCFA removes an entity's deemed status for any of the following reasons:

(1) HCFA determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet the HCFA quality standards for the training services described in § 410.144.

(2) Sixty days after HCFA withdraws its approval of the organization that deemed the entity to furnish training services.

(3) The entity fails to meet the requirements of paragraph (c) of this section.

B. Part 414 would be amended as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Sections 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

2. A new § 414.63 is added to read as follows:

§ 414.63 Payment for outpatient diabetes self-management training services.

(a) *Payment under the physician fee schedule.* Payment for outpatient diabetes self-management training services is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) *To whom payment may be made.* Payment is made to an entity approved by HCFA to furnish outpatient diabetes self-management training services in accordance with §§ 410.141 through 410.145.

(c) *Limitation on payment.* Payment is made for training sessions actually attended by the beneficiary and documented on attendance sheets.

C. Part 424 would be amended as follows:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 424.44, a new paragraph (d) is added to read as follows:

§ 424.44 Time limits for filing claims.

* * * * *

(d) *Outpatient diabetes self-management training.* HCFA makes payment to an entity for the furnishing of outpatient diabetes self-management training after HCFA approves the entity to furnish the services under part 410 subpart H of this chapter.

D. Part 476 would be amended as follows:

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

1. The authority citation for part 476 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 476.111, new paragraph (d) is added to read as follows:

§ 476.111 PRO access to records and information of institutions and practitioners.

* * * * *

(d) A PRO may reimburse for requested information at the rate of $.10 per page for photocopying plus first class postage. The photocopying amount includes the cost of labor, supplies, equipment, and overhead.

E. Part 498 would be amended as follows:

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/MR AND CERTAIN NFS IN THE MEDICAID PROGRAM

1. The authority citation for part 498 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 498.2 [Amended]

2. In § 498.2, the definition of *supplier* is amended to add the words ''an entity approved by HCFA to furnish outpatient diabetes self-management training,'' following ''(OPO)''.

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

Dated: September 30, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: November 23, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 99–3083 Filed 2–10–99; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 98–203; DA 99–255]

Ancillary or Supplementary Use of Digital Television Capacity by Noncommercial Licensees

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This action extends the deadline for filing comments and reply comments to the *Notice of Proposed Rule Making (NPRM),* released November 23, 1998. It is taken in response to the request to extend the comment and reply comment period submitted by the Association of America's Public Television Stations (AAPTS). The intended effect of this action is to allow AAPT's membership to have additional time in which to file comments and reply comments.

DATES: Comments are due on or before February 16, 1999; reply comments are due on or before March 16, 1999.

ADDRESSES: Federal Communications Commission, 445 12th Street, Room TW–A325, SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jane Gross or Robert Somers, Policy and Rules Division, Mass Media Bureau (202) 418–2130.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Order granting an extension of time for filing comments and reply comments in MM Docket No. 98–203; DA 99–255, adopted January 28, 1999. The complete text of this Order is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Synopsis of Order Granting Extension of Time for Filing Comments

1. On November 23, 1998, the Commission released an NPRM in this proceeding, 63 FR 68722 (December 14, 1998), regarding the ancillary or supplementary use of digital television capacity by noncommercial educational (NCE) television licensees. Comments in this proceeding are presently due January 28, 1999, and reply comments are due March 1, 1999.

2. On January 27, 1998, AAPTS submitted a Motion for Extension of Time to file comments in response to the NPRM. AAPTS states that additional time is necessary to allow the AAPTS board to reflect in its filing industry-wide discussions scheduled for the end of January, and to review in its end of January board meeting the policy positions that it plans to present to the Commission. AAPTS requests a brief extension of the comment and reply comment deadlines, which it contends will serve the Commission's goal of generating a full and complete record that reflects the views of all affected parties.

3. As set forth in Section 1.46 of the Commission's Rules, 47 CFR 1.46, it is our policy that extensions of time for filing comments in rulemaking proceedings shall not be routinely granted. However, because of the importance of the instant proceeding to the future of public television, and the potential benefits of the petitioner's developing a more complete record through discussion of these issues with its members, we believe an extension of the comment and reply deadlines for the NPRM is warranted.

4. Accordingly, *It is ordered* that the Motion for Extension of Time filed in MM Docket No. 98–203 by the Association of America's Public Television Stations *Is granted*. The time for filing comments *Is extended* to February 16, 1999.

5. *It is further ordered* that the time for filing reply comments *Is extended* to March 16, 1999.

6. This action is taken pursuant to authority found in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 USC 154(i) and 303(r), and Sections 0.204(b), 0.283, and 1.45 of the Commission's Rules, 47 CFR 0.204(b), 0.283, and 1.45.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 99–3328 Filed 2–10–99; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 567

[Docket No. NHTSA–99–5073]

RIN 2127–AH49

Vehicle Certification; Contents of Certification Labels for Altered Vehicles

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to amend NHTSA's regulations on vehicle certification that specify the contents of the certification labels that vehicle alterers are required to affix to motor vehicles that they alter. The amendment would require the certification label affixed by the alterer to state that the vehicle, as altered, conforms to all applicable Federal motor vehicle safety, bumper, and theft prevention standards affected by the alteration. Under the existing regulations, the certification