DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 410, 414, 424, 480, and 498

[HCFA–3002–F]

RIN 0938–AI96

Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

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

ACTION: Final rule.

SUMMARY: This final rule implements section 4105 of the Balanced Budget Act of 1997 (BBA) by expanding Medicare coverage for outpatient diabetes self-management training and establishes outcome measurements for evaluating the improvement of the health status of Medicare beneficiaries with diabetes. These services include education and training furnished to a beneficiary with diabetes by an approved entity deemed to meet certain quality standards established in this final rule. The physician (or qualified nonphysician practitioner) treating the beneficiary's diabetes must certify that these services are needed as part of the beneficiary's comprehensive plan of care.

EFFECTIVE DATE: These regulations are effective February 27, 2001.

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I. Background

A. Legislation

Section 4105(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997) provides coverage for diabetes self-management training in outpatient settings without limiting this coverage to hospital outpatient departments. The BBA stipulates that training may be furnished by a physician or other individual or entity that also provides other items or services payable under Medicare, and that meets certain quality standards. The payment amount for the services must be established under the physician fee schedule in consultation with organizations representing persons with diabetes. Additionally, section 4105(c)(1) of the BBA requires the Secretary to establish outcome measurements for purposes of evaluating the improvement of the health status of Medicare beneficiaries with diabetes.

On February 11, 1999, we published a proposed rule (64 FR 6827) to implement the BBA provisions addressing the coverage, payment, and accreditation requirements for outpatient diabetes self-management training. An overview of that proposed rule is given in section II of this preamble, the comments on the proposed rule and our responses to those comments are in section III, and a summary of changes in the final rule appears in section IV.

B. Program Instructions

In June and September of 1998, we issued program memoranda (PM AB–98–36 and PM AB–98–51) that implemented the outpatient diabetes self-management training benefit. We reissued these program instructions in 1999 and most recently on July 20, 2000.

C. Office of Inspector General Report

The Office of Inspector General (OIG) issued a draft report titled ''Medicare's Expanded Coverage of Outpatient Diabetes Self-Management Training Services'' (A–14–99–00207, June 2000) which reviewed the reasonableness of the individual and group session payment rates proposed by HCFA for diabetes self-management training. The OIG concluded that our proposed rates were inflated.

In our response to the draft report, we did not concur with the recommendation that the payment rates should be adjusted downward. We did agree, however, that we should refine our payment rates as we gain additional experience and knowledge about diabetes self-management training. We will periodically review the payment rates as part of our review of services furnished under the physician fee schedule and include any revisions in our annual updates to the physician fee schedule payment rates.

II. Provisions of the Proposed Rule

On February 11, 1999, we published in the **Federal Register**, a proposed rule (64 FR 6827) to implement section 4105(a) of the BBA concerning the expanded coverage of, and payment for, outpatient diabetes self-management training.

In the preamble of the February 1999 proposed rule, we noted that, as required by section 4105(a)(3) of the BBA, we consulted with representatives of various groups or organizations active in the field of diabetes education and training. These organizations or groups included the following:

- American Diabetes Association.
- The American Medical Association.
- 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.
- The National Community Pharmacy Associations.

We also worked extensively with diabetes experts from the Centers for

Disease Control and Prevention (CDC) and the Department of Veterans Affairs. In addition, we visited a number of diverse hospital-based training programs.

These consultations and visits revealed that there is no clear consensus on several important issues. The issues include critical questions concerning: (1) Who should be eligible to receive training; (2) how, when, and where the training should be furnished; and (3) who should furnish the training (and the specific qualifications necessary). We specifically solicited public comments on these issues and requested clinical data describing the impact of our proposed requirements on beneficiary health outcomes.

The parties that we consulted about diabetes self-management training agree that it is an interactive, collaborative process involving individuals with diabetes, their physicians, and their educators. The diabetes educational process will furnish the beneficiary with the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes to successfully manage the disease. The goal is to enable the beneficiary to become an active participant in a four-step process that includes assessment of the beneficiary's needs, development of an individualized educational plan, educational interventions, and evaluation of the beneficiary's success in achieving self-management goals.

The major provisions of the proposed rule are as follows:

A. Outpatient Diabetes Self-Management Training

We proposed in § 410.141(a) that Medicare Part B would cover an outpatient diabetes self-management training program when ordered by the physician or qualified nonphysician practitioner treating the beneficiary's diabetes. To ensure access to these services, we would recognize training ordered by certain nonphysician practitioners who treat a beneficiary's diabetes and whose services would be covered under Medicare as physician services if they were furnished by a physician. We would require these nonphysician practitioners to operate within the scope of the statutory benefit and their authority under State law or regulations. We further stated that we would not cover patient self-referral services.

B. Conditions for Coverage

In § 410.141(b), we proposed that we would cover outpatient diabetes self-management training under Medicare Part B if the following conditions are met: The physician (or qualified nonphysician practitioner) must order the training; the physician (or qualified nonphysician practitioner) must prepare a comprehensive plan of care that describes the content, number, frequency, and duration of the diabetes self-management training; the physician (or qualified nonphysician practitioner) must determine if the diabetes self-management training is reasonable and necessary for the treatment of the beneficiary's diabetes; and the services must be furnished in a group setting of 2 to 20 individuals (or on an individual basis if a group session is unavailable or if the beneficiary has special needs resulting from medical conditions that would hinder the beneficiary's participation in a group training session). All individuals in the group do not have to be Medicare beneficiaries.

C. Types and Frequency of Training

1. Initial Training

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

2. Additional Training

In § 410.141(c)(2), we proposed that a beneficiary who receives the initial training program would be eligible for a single follow-up training session of no more than 1 hour 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 § 410.141(d)) that warrants the additional training.

D. Beneficiaries Who May be Covered

1. Medical Conditions

In § 410.141(d)(1), we proposed that any beneficiary who has one or more 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 from an approved entity:

- New onset diabetes.
- Poor glycemic control as evidenced by a glycosylated hemoglobin (HbA1C) of 9.5 percent 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.

2. Other Conditions

In § 410.141(d)(2), we proposed that beneficiaries who are inpatients in a hospital, skilled nursing facility, hospice, or nursing home would not be simultaneously eligible for services under this benefit. It is the responsibility of the staff at these facilities to furnish effective disease management training as a 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 is furnished in a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) setting by a nonphysician practitioner, the services would be bundled into the facility rate. The payment made to the FQHC or the RHC under the all-inclusive rate specifically accounts for these professional services because the facility payment rate reflects the costs of these services.

E. Approved Entities

In proposed § 410.141(e), we identified the conditions we would require an approved entity to meet. In order to be an ''approved entity,'' we would require that the physician, individual, or entity 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 set forth in §§ 424.73 and 424.80.

We also stated that we would require an approved entity to provide us with any documentation that we may request, which may include information that is necessary for us 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 if it meets the quality standards prescribed by us; the National Standards for Diabetes Self-Management Education Program (NSDSMEP), previously the National Diabetes Advisory Board (NDAB) standard; or standards developed by a national organization that is either a nonprofit or not-for-profit organization (approved by us) with demonstrated experience in representing the interest of individuals with diabetes. In order to show that these quality standards are met, an approved entity must show proof that it has been accredited by a HCFA-approved accreditation organization.

F. HCFA's Process for Approving National Accreditation Organizations

Section 410.142 proposed that we may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training. We proposed to require an accreditation organization to submit documentation outlining how its quality standards are substantially equivalent to the HCFA quality standards as outlined in § 410.144(a) of the proposed rule. In addition, we proposed that the prospective organization verify and comply with information requirements in the application process as described in § 410.142(b).

G. Requirements for Approved Accreditation Organizations

In § 410.143, we proposed the requirements for an approved accreditation organization. We included the proposed ongoing responsibilities of an approved accreditation organization as well as set forth our oversight responsibilities for an approved national accreditation organization, our requirements for recognition and withdrawal, and our reconsideration process.

H. Quality Standards for a Deemed Entity

We proposed in § 410.144 that 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 and set forth in the proposed rule; the NSDSMEP quality standards; or standards of a national accreditation organization (approved by us) that represents individuals with diabetes.

I. Requirements for Deemed Entities

In § 410.145 of the proposed rule, we specified the conditions under which an entity may be deemed to meet our quality standards. We also proposed a procedure for determining the effective date and requirements for deemed entities, as well as a procedure for the removal of deemed status.

J. Payment for Outpatient Diabetes Self-Management Training Services

In accordance with section 4105(a) of the BBA, we proposed in § 414.63 that Medicare payment for outpatient diabetes self-management training would be made under the physician fee schedule described in § 414.1 through 414.48. Section 1848 of the Act requires that payments under the physician fee schedule be based on national uniform relative value units (RVUs) that are based on the resources used in furnishing a service. We proposed in the preamble of the February 1999 proposed rule to pay $55.41 (using the proposed RVUs) for individual sessions and $32.62 per person within a group session. We stated that these same payment rates would apply for the 1-hour annual refresher training. We also stated that 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).

K. Time Limits for Filing Claims

We proposed 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 requires the Secretary to establish outcome measurements, 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. In order to obtain adequate clinical documentation used in developing outcome measurements, we proposed to direct Peer Review Organizations (PROs) to collect this information from a physician (or qualified nonphysician practitioner) treating a beneficiary with diabetes.

In § 476.111, ''PRO access to records and information of institutions and practitioners,'' (now designated § 480.111) we proposed to reimburse all Medicare providers and suppliers for the cost of photocopying and mailing copies of requested beneficiary medical records for any Medicare covered services to the PROs. We proposed payment of $.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 based on the photocopying payment rates previously established for hospitals.

M. Appeals

In § 498.2, ''Definitions,'' we proposed adding to the definition of ''supplier,'' for the purposes of appeals, the words ''an entity approved by HCFA to furnish outpatient diabetes self-management training,'' following ''(OPO).''

III. Comments and Responses Based on the Proposed Rule

We received approximately 1,900 items of correspondence in response to our request for public comments on the February 1999 proposed regulation on diabetes self-management training. Commenters included individuals, professional associations, providers of care, and various health care professionals. A summary of those comments and responses follows:

Conditions for Coverage (§ 410.141(b))

Comment: One commenter suggested that in § 410.141(b)(1), there was no rationale to permit qualified nonphysician practitioners to order diabetes self-management training and that only physicians should be able to order the services.

Response: We highly regard the contributions and quality of care furnished by physicians in the United States. We will, however, retain the requirement in § 410.141(b)(1) that permits qualified nonphysician practitioners (such as, clinical nurse specialists, physician assistants, nurse practitioners, and nurse midwives) to order the training because this provision is consistent with section 1842(b)(18)(D) of the Act. We believe that the required State licensure requirements will ensure that this care is provided in an appropriate manner by qualified nonphysician practitioners. We believe, moreover, that the availability of training to improve the quality of life for Medicare beneficiaries should not be denied, particularly to beneficiaries who receive their medical care from qualified nonphysician practitioners. Permitting

qualified nonphysician practitioners to order this training will facilitate access to our beneficiaries, particularly in rural areas.

Comment: Many commenters did not agree with our requirement in proposed § 410.141(b)(2) that the physician (or qualified nonphysician practitioner) develop the entire plan of care or our requirement in proposed § 410.141(b)(2)(iii) that the physician (or qualified nonphysician practitioner) sign for any changes in the plan of care. The commenters contended that the treating physician should initiate the plan of care, but the diabetes educator should be the primary administrator of diabetes education and training.

Response: We continue to believe that the primary care physician (or qualified nonphysician practitioner) treating the beneficiary must order the training because he or she is most qualified to manage the beneficiary's care. Section 4105 of the BBA suggests that the person managing the individual's diabetic condition must certify that the training is needed under a comprehensive plan of care. Therefore, we will retain the requirement in § 410.141(b)(2) that the physician (or qualified nonphysician practitioner) develops the comprehensive plan of care, which includes the education and training needs of the individual beneficiary. We note that in § 410.141(b)(2)(ii) the referring physician (or qualified nonphysician practitioner) must identify the beneficiary's medical conditions. This is intended to help the educator to address the appropriate training.

We will also retain the requirement in § 410.141(b)(2)(iii) that the physician (or qualified nonphysician practitioner) sign any changes to the plan of care for the beneficiary before those changes are implemented. Diabetes self-management training is an interactive, collaborative process involving a beneficiary with diabetes, the beneficiary's physician (or qualified nonphysician practitioner) and educator. For that reason, we do not believe that the only role the physician should have is to refer the beneficiary for education and training. Under our quality standards on review of the plan of care and goals at § 410.144(a)(7), we have added requirements for the approved entity to forward a copy of the documentation to the referring physician and to periodically update the referring physician of the beneficiary's educational status. In a collaborative environment as described above, we believe that training will successfully change the beneficiary's self-management behavior.

Before Congress mandated Medicare coverage of diabetes training, some Medicare payments for diabetes training were made under the physician services benefit, usually in the context of outpatient or inpatient visits with the physician for diabetes management and counseling. We believe that physicians will continue to provide this type of education for their Medicare beneficiaries in addition to the diabetes training now available under this final regulation. We view these benefits as complementary and we believe both are appropriate for the management of a beneficiary's care.

Types and Frequency of Training (§ 410.141(c))

Comment: Many commenters suggested that we revise our provision in § 410.141(c)(1) to require more than 10 hours of initial training to cover all the subject areas required in the proposed rule.

Response: When developing the proposed rule, we conducted discussions and on-site visits with many diabetes self-management training programs. One of the purposes of these visits was to determine how many hours we should cover for a one time initial training benefit. We found that for most programs training averaged 10 hours. Training consists of 15 content areas. We observed that attendance dwindled and beneficiaries began to have compromised attention spans when the total number of training hours exceeded 10. We believe training outcomes are more effective when the training curriculum is concise and focused. Therefore, we conclude that 10 hours is a reasonable amount of time to cover the 15 content areas as described in § 410.144(a)(5). Although commenters suggested that 10 hours of initial training was not enough, they did not provide compelling arguments to support their opinions. We will continue to monitor and reassess the amount of hours needed to cover the required curriculum to ensure that our beneficiaries receive quality training service.

Comment: Many commenters indicated that we should permit educators more flexibility to conduct training in group or individual sessions (§ 410.141(c)). They stated that the NSDSMEP quality standards require that staff develop and update an individualized assessment for each patient. Also, certain aspects of diabetes education, such as a needs assessment, individualized instruction on medication or insulin delivery, and development of an individualized meal plan, can only be furnished on a one-to-one basis.

Response: We believe the commenters are correct that there should be more flexibility in our training coverage in § 410.141(c). We have increased the flexibility of how educators may furnish the training by changing the requirements in § 410.141(c)(1)(i)(F) and (c)(2)(i), respectively, to allow 1 hour of initial training and 2 hours of follow-up training to be individual training without the beneficiary meeting one of the special conditions in § 410.141(c)(1)(ii). This change will accomodate the requirement for individual assessment and special circumstances requiring individual training. Further, we revised the requirements for initial and follow-up training in § 410.141(c)(1) and (2) to permit training in half-hour increments.

Even though the attending physician specifies the medical condition the training must address, there will be instances in which the educator will be determining how the training will be conducted. For example, if a beneficiary has not complied with his or her diabetic diet after initial training, the educator will determine the appropriate intervention. However, if the physician specified that the beneficiary needs training on the delivery of insulin or other training, the training should address this specific need. Under this final rule, the educator is to perform training in adherence to the instructions from the referring physician (or qualified nonphysician practitioner).

Comment: Many commenters expressed concern that we revise our requirement in § 410.141(c)(2) to require more than 1 hour per year of follow-up training. The suggestions for more than 1 hour per year ranged from 2 hours to 10 hours per year, or up to 10 additional hours over a 5-year period. The most frequently stated comment was to increase the amount of follow-up training to 2 hours.

Response: Before we published the February 1999 proposed rule, our consultations with the diabetes community indicated that 1 hour of follow-up training would be sufficient to accomplish the goal of properly educating a diabetic patient. The comments on the proposed rule provided compelling arguments that more time is needed to reassess the training needs of the beneficiary and provide new training in some situations. An example of a situation when 1 hour of follow-up training may not be sufficient is when a beneficiary with Type 2 or non-insulin dependent diabetes becomes insulin dependent. A reassessment of the beneficiary's

training needs must be completed and the beneficiary might need additional training on how to perform injections and how to self-monitor glucose levels. Multiple educational interventions to stabilize the beneficiary's condition might be needed in a single year, which we agree could require more than 1 hour of follow-up training. However, we have determined it will not take more than 1 additional hour of training. Also, based on comments from the public, 2 hours of follow-up training is standard practice for diabetes educators. We received no evidence to support allowing more than 2 hours of follow-up training.

We have accepted commenters suggestions and increased the amount of follow-up training in § 410.141(c)(2) to 2 hours each year starting in the calendar year after the beneficiary completes the initial training (See § 410.141(c)(2)(iii).) In addition, educators may provide follow-up training on four different occasions during the year using the half-hour increments in the final rule. The follow-up training may be provided in individual training sessions or group sessions. A beneficiary is not required to meet any special requirements in order to obtain an individual follow-up session.

Comment: A major national organization and other individual commenters urged us to furnish coding and payment for educational training in increments of 30 minutes instead of 1 hour for individual training sessions. The commenters indicated that shorter intervention sessions may be more appropriate for older beneficiaries.

Response: We have considered the comments for the 30-minute increment billing code for diabetes education and are adopting this comment. We agree that the shorter intervention sessions may be more appropriate for older Medicare beneficiaries and will allow more flexibility in training schedules. As stated above, we will allow a 30–minute increment code for individual and group training for both initial and follow–up training instead of a 1-hour increment.

Comment: Some commenters noted that a system needs to be developed to track diabetes training to tell providers the number of hours available to beneficiaries.

Response: We agree with the commenter that there is a need to track the number of hours of diabetes training furnished to a beneficiary. However, in light of other system and privacy demands, we are unable to announce a specific system at this time.

Beneficiaries Who May Be Covered (§ 410.141(d))

Comment: Many commenters stated that the HbA1C level of 9.5 percent as proposed in § 410.141(d)(1)(ii) would result in an increased risk of complications before diabetes education would be available to the beneficiary. The comments suggest that this would be especially true for individuals of certain ethnic backgrounds because they are at a higher risk for complications. Commenters suggested that the HbA1C level should be lowered. The suggestions among the commenters for a lower level ranged from 7.0 to 8.5 percent.

Response: We agree with the commenters that establishing an appropriate glycohemoglobin requirement as an eligibility criterion for the diabetes training benefits is important. In order to do this, we reviewed the medical literature for both the relationship of the glycohemoglobin level to the risk of developing complications of diabetes and the effect of diabetes training in reducing the glycohemoglobin level both in terms of the amount of reduction and the lowest glycohemoglobin level attained.

The medical literature was useful in supporting a direct relationship between the level of glycohemoglobin and the risk of developing diabetes complications. Specifically, lower levels of glycohemoglobin reduce the risk of developing complications. Lowering the glycohemoglobin, however, from 10 percent to 9 percent results in a much greater reduction in risk than lowering the glycohemoglobin from 8 percent to 7 percent; while lowering the glycohemoglobin from 9 percent to 8 percent results in an intermediate reduction in risk.

Much of the literature on diabetes training consists of studies with patients who have poor glycemic control (for example, glycohemoglobins higher than 9.5 percent), and generally measured the effect of diabetes training for short periods of time. Some studies involved concurrent changes in diabetes medications making the effect of diabetes education hard to measure. Although some studies demonstrated a reduction in glycohemoglobin levels, this reduction was generally less than or equal to 1 percent and was short-lived.

We have found that the medical literature is not conclusive regarding the efficacy of diabetes training alone in reducing glycohemoglobins below 8.5 percent, in effectuating long term improvement of glycemic control below 8.5 percent, or in reducing the risk of diabetes complications. Therefore, until strong medical evidence becomes available showing the efficacy of diabetes training in achieving these goals we have established a glycohemoglobin level of 8.5 percent as a criterion for eligibility for the diabetes training benefit. We believe that this level satisfies the concerns of the commenters. We will revisit this requirement when the medical literature indicates it is appropriate.

In determining the eligibility criteria we considered the magnitude of the impact of an elevated glycohemoglobin on a beneficiary's health, such as a high risk of developing heart disease or hypertension. Our eligibility criteria ensure that not only patients at significant risk for developing complications of diabetes will have access to the diabetes training service, but that patients with diabetes at risk for other illnesses such as strokes and heart attacks will also be eligible for diabetes training. This impact is related to the degree and the duration of the elevation in glycohemoglobin. We believe that making all beneficiaries with two consecutive glycohemoglobin levels of 8.5 percent or more (3 months apart in the year prior to entry into the training program) eligible for this service will ensure that beneficiaries at significant risk for complications of diabetes will be able to get diabetes training. We believe that this lower level is sufficient to ensure the availability of training for individuals of any ethnic background. In consideration of the risks of elevated HbA1C levels in the Medicare population and concerns expressed by the commenters, we revised § 410.141(d)(2) to reduce the level of HbA1C required for initial training to a level of 8.5 percent or more on 2 consecutive HbA1C determinations 3 or more months apart in the year before the beneficiary begins receiving training.

Comment: Many commenters suggested in § 410.141(d)(1)(v)(C), that we add criteria for a diagnosis of microalbuminuria documented by two positive microalbuminuria screening tests in the absence of urinary tract infections, fever, or infection in the year before a beneficiary receives training.

Response: We agree with the commenters that a criteria for a diagnosis of microalbuminuria should be added. Therefore, in § 410.141(d)(5)(iii), we have changed the criteria to read, ''when manifested by albuminuria,'' in response to the comment. The term albuminuria includes both microalbuminuria and macroalbuminuria.

Comment: Commenters also suggested adding to proposed § 410.141(d)(1)(v)(C)

levels of hypertension and hyperlipidemia to the criteria.

Response: We believe the revised criteria in § 410.141(d)(5)(iii), as noted above, will also apply to beneficiaries who have hypertension and hyperlipidemia because the conditions usually occur at the same time as other medical conditions already cited in the regulation. Therefore, we have not included those additional criteria.

Who May Furnish Services (§ 410.141(e))

Comment: Many commenters advised us that they believe our requirements for who may furnish training (proposed § 410.141(e)) would not sufficiently expand the access of training in rural areas.

Response: In order to address the concerns of commenters regarding limited access to training in rural areas, we are making several clarifications.

First, we have allowed an approved entity to delay the implementation of the requirement for a Certified Diabetes Educator (CDE) until February 27, 2004 if the team includes a registered nurse. This delay will allow an approved entity additional time to recruit a diabetes educator that has the required certification from the National Certification Board for Diabetes Educators (NCBDE). (The NCBDE is the only eligible certification organization at this time.)

Second, we have revised the final rule to allow for an exception to the team approach in rural areas (§ 410.144(a)(4)(ii)). Under the exception, an individual who is qualified as a registered dietitian and as a CDE currently certified by the NBCDE (or as a registered nurse until February 27, 2004) may furnish training in a rural area and will be deemed to meet the requirement in (§ 410.144(a)(4)(ii)).

In addition, as stated in the proposed rule an approved entity must properly receive Medicare payment under § 424.73 or § 424.80 which set forth prohibitions on assignment and reassignment of benefits. Diabetes training programs may provide services at any location if the educators are W–2 employees of the approved entity. Thus, even if the employee is part-time, Medicare payment to the employer would still be appropriate.

We also wish to clarify that the reassignment rules allow a ''facility'', such as a hospital, to use an independent contractor to provide training services with in the facility. This option may be particularly helpful to certain facilities in rural areas.

Quality Standards for a Deemed Entity (§ 410.144)

Comment: Many commenters believe that we exceeded our authority by including the requirement in proposed § 410.144(b) that changes in the NSDSMEP quality standards must be approved by HCFA.

Response: We have reviewed the comments questioning our authority to approve or disapprove any subsequent revisions to the NSDSMEP quality standards, as well as our proposed rule preamble discussion on § 410.143 (which states we reserve the right to approve or disapprove any changes made by the ADA). After reconsidering this issue in light of the comments, we believe that the statute could be interpreted to authorize payment to entities that are found to meet revised standards, even if those standards are subsequently modified to be less stringent. Therefore, in § 410.144(b), we removed ''approved by HCFA''.

Individuals or entities that meet the quality standards originally established by the NDAB or subsequently revised are recognized under the Medicare statute. Reviewing the quality standards of entities, however, is a separate issue from monitoring accreditation organizations in their capability to apply and enforce the quality standards. Section 1865 of the Act, as amended in 1996, requires us to determine whether the accreditation of a provider or supplier entity by the national accreditation organization ensures that the applicable Medicare health and safety conditions or requirements will be met or exceeded. It is our responsibility to ensure accreditation organizations will apply and enforce the quality standards set forth in § 410.144. We expect the accreditation organizations to develop other procedural and administrative activities to demonstrate the accreditation process is solid and, most important of all, ensures that the applicable quality standards are being successfully enforced. Therefore, we have concluded it is necessary for us to review the accreditation organization's program as a whole, as set forth in § 410.142 in order to ensure that the organizations that were found to have met the quality standards do so on a continuous basis.

We still have the responsibility for ensuring that organizations that enforce the quality standards in § 410.144 perform adequate oversight to assure that approved entities continually meet the quality standards. We have extensive experience with review and oversight of national accreditation organizations that deem other entities to meet our quality standards. This oversight consists, in part, of reviewing how well the accreditation organizations enforce their standards and assure that the Medicare requirements are met. In the interest of improving our quality oversight activities, we are currently refining and strengthening our validation activities with regard to national accreditation organizations. That said, we believe we must assure that any national accreditation organization that uses the NSDSMEP quality standards also performs adequate oversight and enforcement activities.

Given that our major concerns are the application and the enforcement of the quality standards, we will oversee these accreditation organizations and delegate certain responsibilities to the accreditation organizations as set forth in § 410.143 to ensure beneficiaries will receive quality diabetes self-management training.

Comment: Several commenters questioned our proposed requirement in § 410.144(a)(3) which describes the requirements of the program coordinator and asked us to clarify their qualifications. Some commenters recommended that a physician should be the program coordinator or the team leader.

Response: In order to allow greater flexibility, we have not specified who must be the program coordinator, nor have we identified specific qualifications of the program coordinator. We expect the program coordinator to be an individual with experience in diabetes and program management that can ensure effective coordination of the different aspects of the training services.

Comment: Some commenters recommended our proposed requirements, in § 410.144(a)(3)(ii), for nonphysician professional program staff should be reduced from 14 hours every 2 years to 12 hours every 2 years.

Response: We agree that the requirement for nonphysician professional program staff to obtain 12 hours of continuing education every 2 years is reasonable and adequate to ensure quality. We recognize that nonphysician professional staff have other requirements for continuing education, or they will acquire additional clinical experience through direct contact with patients. Based on commenters suggestions, we have revised the requirement in § 410.144(a)(3)(ii) from 14 hours to 12 hours to decrease the burden associated with the benefit.

Comment: Many commenters were concerned that § 410.144 did not allow

sufficient time for those hospital outpatient diabetes self-management training programs that had billed Medicare before July 1, 1998, and that did not have ADA accreditation, to achieve accreditation by the time the final rule is published. Some of these commenters suggested that we should allow from 1 to 5 years additional time to accomplish accreditation.

Response: While we understand the concerns regarding these outpatient hospital programs, the statute does not give us the authority to deem that these programs meet the NSDSMEP quality standards. We are aware that the ADA requires a 12-month data collection period, before programs can submit the application for education recognition. However, the ADA has approved approximately 250 providers since the February 1999 publication of the proposed rule. Based on information obtained from the ADA, they specified that they do not have a backlog of applications and are working to maintain timely processing. This demonstrates to us that outpatient hospital programs not recognized at the time of the proposed rule have been rapidly recognized by the ADA. We are also amending this final rule to continue to recognize those hospitals with NSDSMEP quality standards certificates until July 1, 2002. This will allow adequate time for new programs to be deemed during the interim period while other approved accrediting organizations are recognized. Additionally, we believe ADA will not remain the only accreditation organization once the 18 month transition period that exclusively allows ADA recognized programs to receive Medicare payment for diabetes training expires.

Comment: Many commenters stated that many of the existing diabetes self-management training programs chose not to seek ADA recognition for a number of reasons. These included the lack of staff support by the ADA, the burden of recordkeeping, cost, and the amount of time involved in the ADA application process. They stated that this hardship is even more intensified in smaller, rural programs, which will be forced to go out of business.

Response: We expect other organizations will apply, and we will approve more accreditation organizations that will use one of a variety of quality standards that meet the requirements of § 410.144. Other accreditation organizations that currently evaluate Medicare providers may seek to become approved to accredit for this service. As the statute is fully implemented, we anticipate a variety of accrediting choices will become available that may be procedurally faster and less expensive. However, currently the ADA offers the fastest way for an entity to demonstrate that they meet the quality standards requirements. We will monitor the number of accreditation choices and their impact on rural providers. This will assist us in determining the need to make future adjustments.

Comment: One commenter questioned the superiority of ADA-certified programs versus non-ADA-certified programs. Also, commenters recommended grandfathering entities that are Medicare-certified for a period of 1 year.

Response: We do not automatically assume that ADA-certified programs are superior to non-ADA certified programs. By statute, Congress has recognized that those programs that have been approved as meeting the NSDSMEP quality standards meet our quality standards. Other programs may apply to become an accrediting organization. Also, we must fulfill the statutory requirement that all approved entities meet a set of quality standards. The statute does not provide for a transition period for the quality requirement. Therefore, we do not believe that it is prudent to grandfather older programs for any period of time under our new payment systems.

Comment: A few commenters questioned if we have studied the capacity of ADA-certified programs to furnish services to the Medicare population.

Response: We studied the access issue and the growth rate of ADA-recognized programs. As of June 2000, ADA has recognized 819 diabetes self-management training programs and 482 satellite offices. The number of existing ADA-recognized programs has increased significantly since the publication of the proposed rule in 1999, when the number of ADA-recognized programs was 575. At this steady growth rate, we believe the existing ADA-recognized programs, coupled with the anticipated increased number of programs certified by other accreditation organizations, will be adequate to serve the Medicare beneficiaries and resolve the access issue.

HCFA Process for Approving National Accreditation Organizations (§ 410.142)

Comment: Some commenters suggested that the accreditation requirement was not clearly stated in § 410.142 and we should explain how we will evaluate quality standards.

Response: We sometimes use national accrediting organizations to determine whether a provider entity meets some or all of the requirements that are necessary in order to provide a service for which Medicare payment can be made. Entities not currently recognized by the ADA, must become accredited by a HCFA-approved accreditation organization or recognized by the ADA until August 27, 2002. Given the number of Medicare providers or suppliers who are permitted to bill for this service if they are found to meet the quality standards, we have determined that it will be more efficient to use a national accrediting organization to evaluate a prospective diabetes educator, rather than increasing our workforce in order to conduct the necessary evaluations.

Before we can approve an accrediting organization, we must know what quality standards the organization plans to use to evaluate applicants. Also, we normally must determine that those standards meet or exceed our quality standards. As we have stated, we will not review any changes to the NSDSMEP quality standards. Still, we need to make sure that the accrediting organization will be properly evaluating prospective applicants based on one of the three sets of quality standards described in § 410.144.

For any accreditation organization, to become approved by us, we would need to determine that the organization would be using either the HCFA quality standards, the NSDSMEP quality standards, or some other standards that meet or exceed our quality standards in § 410.144(a). These alternative standards could include the standards of a national accreditation organization that represents individuals with diabetes, that we have approved. When the standards of a national accreditation organization vary in any way from either the HCFA quality standards or the NSDSMEP quality standards, they must meet or exceed the HCFA quality standards. If an organization proposes the use of standards that include more quality measures but still meets the core HCFA quality standards, those standards may be determined to ''exceed'' the HCFA quality standards.

In developing our standards, we used the NSDSMEP quality standards as a model. The Congress found that individuals or entities that met the NSDSMEP quality standards would be deemed to meet the quality standards that we would promulgate by regulation. Therefore, we believed it was important to consider the same topics and issues as had been previously considered by the diabetes community.

After evaluating the quality standards the accrediting organization would use, we will look at its processes to ensure

that the organization meets our accreditation requirements. We will use these requirements to evaluate all organizations that request our approval as an accreditation organization for diabetes self-management training programs.

We are committed to implementing quality standards that impose a minimum burden to entities seeking to become approved accredited organizations while simultaneously ensuring access to quality diabetes self-management training for Medicare beneficiaries.

Comment: Commenters were concerned about the use and timeliness of our approval process for accreditation organizations.

Response: The 210-day deadline for completing the approval process is specified in section 1865(b)(3)(B) of the Act. However, we will strive to complete the process as expeditiously as possible. The process includes our publication of two notices in the **Federal Register**. The first notice would solicit comments on the accreditation organization's accreditation program, and the second notice notifies the community of the approval or disapproval of the accreditation organization. The nature of the process requires that sufficient time be included for essential correspondence between us and the accreditation organization. The time required to complete the process will be substantially reduced if an organization requesting approval as an accreditation organization submits a comprehensive application that addresses all the requirements in this final rule.

We recognize that the normal time frames for approving accrediting organizations may cause a delay. We remain committed to ensuring that beneficiaries receive, and that providers can bill for these expanded services, as quickly as possible. Thus, in order to ensure access to expanded quality services while accrediting organizations are being approved, we are amending the final rule to deem an entity to meet the NSDSMEP quality standards described in § 410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program it furnishes meets the NSDSMEP quality standards described in § 410.144(b). All organizations (including the ADA) may apply to HCFA to become a national accreditation organization after January 29, 2001. We will strive to review and approve the applications as expeditiously as possible. We expect after the initial 18 month period expires, that there could be several accrediting organizations thereby eliminating any access concerns.

Comment: Many commenters were concerned with our proposed provisions in § 410.142 to approve only national accreditation organizations. They believe this would severely limit a Medicare beneficiary's access to diabetes self-management training in some rural and nonmetropolitan areas where State (not national) certification programs exist. Commenters noted that State-certified programs use standards that are comparable to the NSDSMEP quality standards. They believed that we should allow the use of both national and State accreditation organizations or grandfather the State-certified programs in for a period of 3 years. Commenters further contended that national accreditation incurs high costs, recordkeeping burdens, and resource management issues; and that beneficiaries in rural and nonmetropolitan areas would be required to travel many miles to reach a nationally accredited program.

Response: Section 1865(a) of the Act requires the use of ''national'' accreditation organizations for the accreditation of providers and suppliers of Medicare services. Permitting the use of State-accreditation organizations for this purpose would require a statutory change.

Team Approach (§ 410.144(a)(4))

Comment: The HCFA quality standards require, in § 410.144(a)(4), that diabetes self-management training services are to be furnished by a multidisciplinary team. One commenter suggested that the multidisciplinary team approach may cause discomfort for some beneficiaries. One commenter stated that the delivery of services using a multidisciplinary team is impractical in small communities due to the difficulty in assembling a full team in this environment. However, other commenters agreed that patients with diabetes are best served by a multidisciplinary team.

Response: We have consulted several groups and organizations active in the field of diabetes education and training. They all agreed that diabetes self-management training should be an interactive collaborative process involving beneficiaries with diabetes, their physicians, and their educators. We continue to believe that the multidisciplinary team concept set forth in § 410.144(a)(4), is the best way for Medicare beneficiaries to receive diabetes self-management training. The multidisciplinary team members are necessary to bring the appropriate expertise to educate beneficiaries in the 15 training areas described in § 410.144(a)(5). Therefore, we are requiring that all appropriate team members be present during the portion of the training for which they are responsible and must directly furnish the training within their scope of practice. Also, we believe that educators serving diverse populations will use their experience, interpersonal skills, and sensitivity to meet a Medicare beneficiary's individual needs.

Further, consistent with our understanding that interactive, collaborative, skill-based training methods are required for effective diabetes education, in § 410.144(a)(6)(iii) we will require entities to maximize the use of interactive training.

Given the need to address each patient's individual needs, maximize the effectiveness of training, and facilitate interactive learning during group training sessions, we anticipate that in most circumstances more than one team member will need to be present for the entirety of each training session. For example, each patient in a group training session will likely have individual concerns regarding diet, exercise, and home glucose monitoring. In order to adequately address these concerns, one-on-one interaction between a patient and a team member will frequently be needed. This interaction between each team member and patient is important to develop a bond of trust. In fact, a single training session may involve teaching several content areas due to the educational requirements of each patient. Such situations may require the presence of more than one team members for the entire training session, as needed. We encourage approved entities in rural areas to create arrangements to meet the team approach objective while still meeting Medicare and State general requirements.

Comment: Some commenters suggested we replace the CDE requirement in proposed § 410.144(a)(4) with a less stringent alternative certification requirement, that is, to limit the amount of diabetes training to a certain number of hours or days. One commenter recommended that practitioners from any health care professions should be allowed to apply as a CDE.

Response: Based on the available literature, we continue to support the CDE requirement to ensure quality. We believe the comprehensive scope and standards of practice for CDEs will be beneficial to diabetes patients and will

ensure the quality of services furnished. Also, we do not regulate the process for becoming a CDE. The NCBDE is currently the sole entity that meets our requirements for CDE certification, including the specific health care professions that are eligible to apply as CDEs. This does not preclude us from considering other organizations in the future, if comparable certification organizations are formed that will also ensure quality.

Comment: Some commenters believe that the requirement of a multidisciplinary team approach will have a negative effect on access to training in rural areas, due to the varying accessibility of specific team members in those locations. For this reason they believe that mandatory members of the team should be expanded to include such professionals as pharmacists.

Response: The proposed rule required that the team consist of at least a registered dietitian and a CDE who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.) We found that registered dietitians and registered nurses bring unique qualifications to the team that are essential for furnishing adequate training, such as specific assessment of patients metabolic needs, plan of care, and refinement of nutrition therapy. Pharmacists, though not mandatory members of the team, can participate as optional team members, program coordinators, or team sponsors if they qualify as approved entities. Furthermore, pharmacists have the option of becoming CDEs, which would enable them to be included as core team members.

Comment: Many commenters voiced concern that the proposed requirement in § 410.144(a)(4)(i)(A) for the team to include at least a dietitian and a CDE would create hardship for programs in rural areas.

Response: The purpose of this final rule is to expand access to beneficiaries with diabetes by providing coverage for outpatient diabetes self-management training. We believe the establishment of a staff quality standard will promote desired outcomes that result in improved health status of beneficiaries with diabetes. Those in the field of Diabetes Self-Management Education, national organizations such as the ADA, the American Association of Clinical Endocrinologists, the Diabetes Treatment Center of America, and the American Medical Association generally accept that team requirements are appropriate.

We closely evaluated the Diabetes Educator Certification requirement that begins with requiring applicants to hold a current unrestricted United States license or registration as a registered nurse, dietitian, pharmacist, physician, physician assistant, podiatrist, or be a health care professional with a minimum of a master's degree from a United States college or university in one of the following areas of health care practice: nutrition, social work, clinical psychology, exercise physiology, health education, or public health. This is followed by a prerequisite certification examination requirement of a minimum of 2 calendar years experience in direct diabetes patient and self-management education, that is, working a minimum of 1,000 hours in direct diabetes patient and self-management education in those 2 years or within a 5-calendar-year period before application for certification. Patient teaching is a skilled service and patient education can affect outcomes of care, for example, HbA1C control, medication management, reduced hospitalization from diabetic complications, and patient compliance.

We believe the comprehensive scope and standards of practice for CDEs will be beneficial to patients with diabetes and will ensure the quality of services furnished. We are aware of a potential shortage of CDEs in some areas, and many primary care physicians may have registered nurses providing diabetes education at present. Therefore, we will delay the implementation of the requirements for a CDE until February 27, 2004, if the team includes a registered nurse. Furthermore, we added a provision in § 410.144(a)(4)(ii) to allow programs in rural areas that have a single individual who is qualified both as a registered dietitian and as a CDE to meet the multidisciplinary team requirement.

Performance Measurement and Quality Improvement § 410.144(a)(9))

We requested comments on the requirement for standardized performance measures in the preamble of the proposed rule, following the discussion on HCFA's quality standards. We did not receive any comments.

However, standardized performance measurement for continuous quality improvement is an effective methodology for the development, implementation, maintenance, and enhancement of quality diabetes self-management education. The effectiveness of any systematic educational effort is dependent on clearly defining set organizational goals, collecting and analyzing data, and identifying and implementing process improvement measures. Continuous quality improvement involves continuing quantitative and qualitative analysis of processes and health and satisfaction outcomes. Therefore, we are maintaining performance measurements and quality improvement as part of the HCFA quality standards.

The continuous quality improvement process relies on a demonstrated organizational commitment to provide quality diabetes self-management education, and an ongoing effort by all organization and diabetes self-management education team members to meet the needs and expectations of individuals with diabetes and other consumers. Quality improvement goals and objectives are consistent with the organizational goals and are based on an assessment of the diabetes self-management education entity's target populations.

We will establish the performance standards under a separate rulemaking.

Peer Review Organization Review (§ 410.144(a)(10))

Comment: Some commenters stated the opinion that the PRO review described in proposed § 410.144(a)(10) is a costly, bureaucratic, and unnecessary measure to require of diabetes self-management training programs. Commenters expressed concern over their mandatory participation in PRO projects. Many commenters warned against promulgating a final regulation that is too prescriptive. They emphasized that what is needed, above all, is flexibility to design a program that meets the needs of all sizes and specialties, rather than a ''one-size-fits-all'' regulation.

Response: We believe that quality improvement initiatives are necessary to improve the health care furnished to Medicare beneficiaries. PROs are tasked with improving quality of care for beneficiaries and have experience in evaluating quality initiatives. In response to public comments, we are implementing a more flexible approach in our final rule. We are providing flexibility with the appropriate amount of accountability. Specifically, we have modified the requirement for participation in a PRO project for an entity that uses the HCFA quality standards. An entity, having an agreement with a PRO may either: (1) Participate in a quality improvement project defined by the PRO, or (2) if the entity elects not to participate in the PRO project, it must be able to demonstrate a level of achievement

through a project of its own design. The alternative project must be comparable to, or better than, the achievement to be expected from participation in the PRO-designed project, and must focus on maximizing outcomes by improving patient safety and quality of care. An entity must measure, analyze, and track quality indicators, including adverse patient events or other aspects of performance that reflect processes of care and program operations. This approach will allow an entity the flexibility to invest appropriate efforts in its quality improvement project and the freedom to make decisions about the best way to improve the quality of care. The NSDSMEP have a similar provision. Standard 10 requires an entity to use a continuous quality improvement process to evaluate performance of its program and to determine opportunities for improvement. An entity using the process described in the NSDSMEP must define organizational goals, collect and analyze data, and identify and implement process improvement measurement. The NSDSMEP standard is substantially equivalent to the HCFA quality standards but does not require an agreement with a PRO.

To aid an entity in developing its own quality improvement projects, we are providing the following guidance:

• *Improvement projects*—These projects are based upon an entity's own assessments of its performance and must show measured, sustained results that actually benefit patients. Because most organizations usually identify more improvement opportunities than they can initiate, improvement project priorities must be set. Therefore, these priorities must be established by the entity. Although we do not require a specific number of projects, we do expect an entity to improve its performance on at least one outcome or quality indicator each year as stated in this rule (§ 410.144 (a)(9)(B). An entity can use certain factors such as, the expected impact on performance or the selection of high-risk, high-volume, or problem-prone processes. These factors are helpful in setting project improvement priorities.

• *Peer Review Organization Projects*—We developed criteria to help PROs select clinical topics for quality improvement projects. These criteria were designed to ensure that a project has the greatest possible likelihood of significantly impacting the health outcomes of Medicare beneficiaries. An entity may use these same criteria in determining which projects best encompass its particular needs, and in determining if projects the entity identifies will be comparable to the expected outcomes of those projects identified by the PRO.

There are two basic areas of consideration used when establishing criteria for selection of PRO projects: (1) Identifying clinical topics, and (2) prioritizing clinical topics. The following information is provided as guidance for an entity in choosing clinical topic areas for quality improvement projects.

Identifying Clinical Topics

There are four criteria to assess when identifying clinical topics: prevalence, science, measurability and the opportunity to improve care (OIC). These criteria address the issues central to identifying appropriate clinical topics and quality indicators.

• *Prevalence/Incidence and Disease Impact*—The burden (morbidity/mortality) of the clinical condition or medical procedure under consideration is great for the population affected. The burden within a sub-population (for example, minority, disabled, at-risk, etc.) may be another consideration that is taken into account.

• *Science*—There should be scientific consensus through multiple independent observations and/or clinical trials that changing a process or procedure of care will measurably improve patient outcomes.

• *Measurability*—The process(es) or outcome(s) of care for the topic can be stated in clearly defined, discrete, quantifiable data elements from data sources which are valid and reliable; accessible in a timely manner; from appropriate care settings; and when necessary, span the continuum of care. In addition to the final measures of outcome, interim measures of progress toward achieving the quality improvement goal are desirable.

• *Opportunity to Improve Care*—Not only should the process or outcome be measurable, there should be a gap between current performance and what can reasonably be achieved. The wider the gap between the present situation and what is feasibly achievable, the greater the opportunity is for improvement. Additionally, there must be a feasible means of narrowing that gap. Measuring the problem is not sufficient. The entity must also be reasonably certain that the actions can improve the situation.

Prioritizing Clinical Topics

Clinical topics meeting identification criteria above should be further prioritized. The following criteria should be helpful in that process. Although it is likely that no topic will consistently meet all of the criteria, proposed topics can be compared on the basis of the number and degree to which the criteria are met.

• *Previous Project or Pilot Studies*—Demonstrate previous experience with the proposed project methodology or demonstrate that a project of similar design can reasonably be expected to improve health care outcomes. Potential priority topics should have been the subject of previous successful projects by PROs or other organizations. Here, the focus is on selecting topics for which quality improvement has previously been demonstrated or on replicating successful project methodologies.

• *Adequate Program Resources*—The entity would consider the adequacy of the resources (time, personnel, and funding) to implement the quality improvement project. Alternative potential projects with similar costs should be compared for their relative potential benefit. Whenever feasible, topics that make use of existing data sets should be selected.

• *Availability of Partnerships*—The entity would select topics that allow collaboration with other providers and national, regional, and local organizations with similar goals. Collaboration with other organizations is encouraged for several reasons: planning, implementation and analytic costs can be shared; planned, coordinated differences in project methods can be compared for efficacy and cost; local lessons learned can be shared and compared; and ideas for second and subsequent improvement cycles can be gathered.

• *Ability to Enable or Facilitate Ongoing Quality Improvement*—The entity would select topics and interventions that foster or enhance the development of quality improvement efforts that extend to care processes and conditions beyond those targeted by the improvement project. Some topics may be selected, in part, because of the learning value to the intended user (for example, demonstrating principles and methods that can be applied by the user to other topics) and the sustain ability of the improvements they trigger.

• *Likelihood of Success (Readiness)*—The entity would identify topics that are of interest to the relevant stakeholders who will be asked to make improvements. This criterion recognizes the fact that significant improvement is not likely to occur if some pivotal individuals do not welcome or are not capable of participating in the project.

The criteria will be used as a guide for programs to establish priorities when considering whether to implement a PRO project, or conduct a project of

their own. This will aid hospitals in determining if internal projects have the potential to yield benefits comparable to, or exceeding expectations set by PRO projects.

Comment: A commenter recommended that the PRO review the State diabetes education database to track the differences in health outcomes among ADA-recognized programs and non-ADA-recognized programs.

Response: We plan to track the differences in health outcomes among ADA and non-ADA-recognized programs. These plans, however, have not yet been finalized and the possibility of a PRO review of State diabetes education databases may be considered.

Requirements for deemed entities (§ 410.145)

We proposed under the HCFA quality standards that programs have an agreement with a PRO, which has a contract with us to perform quality assurance reviews. Among other things, the proposal would have allowed the PRO access to beneficiary records. We did not receive any specific comments on this point. However, in the final rule, we are extending the requirement that all approved entities must provide access to beneficiary or group training records to a PRO. Since the review of effectiveness of an educational program will rely on evaluation of clinical data, we believe the expertise of a PRO is needed to give a fair and equitable evaluation of the data. This requirement is currently in § 410.145(b)(4), and will facilitate preparation of the outcome measures mandated by Congress.

Recent data shows that diabetes has reached epidemic proportions among certain subsets of the Medicare population (Morbidity and Mortality Weekly Report 4643, 1014–1018, 1997). We believe that participation in quality improvement projects and continuous improvement activities are ways that we can encourage better diabetes outcomes for Medicare beneficiaries. We believe it is important to measure beneficiaries progress as a result of improved education and training. Therefore, providing the PRO access to beneficiary and group records, will provide us with the raw data we need to measure improvement. This is important not only for the programs meeting HCFA quality standards, but also for the programs that use alternative quality standards.

With regard to outcome measures, we have only required that information be collected on a quarterly basis, in a organized manner, which will facilitate the PRO review as well as reduce the burden on the approved entities. By making needed information more accessible, it will prevent reviewers from spending undue hours locating appropriate information. It would also enable approved entities to better evaluate their own program. We continue to believe that providers, in this case diabetes self-management training programs, must ensure that there is an effective, quality-assurance program to evaluate patient care.

Comment: Some commenters were confused by our use of the term ''deemed entity'' in this regulation, stating that it does not conform with our traditional use of the term in previous regulations.

Response: In this regulation, we have used the term ''deemed entity'' to denote an entity that has been accredited by an approved organization as meeting one of the three sets of quality standards established in § 410.144. Though deemed by the accreditation organization, these entities are not yet approved to furnish the training and receive Medicare payment until they have been approved by us. Our reason for making this distinction is to differentiate entities that meet quality requirements (as determined by an accrediting organization) from those that have received final approval from us and can be properly paid under Medicare.

Outcome Measurements

Comment: In response to our specific request, several commenters submitted suggestions for developing outcome measurements. One commenter recommended that we monitor the following: the percentage of patients having an annual dilated examination; the percentage of patients with a glycosylated hemoglobin (HbA1C) level that is 2 percent below the upper normal range; the percentage of patients who filled blood glucose test strip prescription; the percentage of patients with retinal photo-coagulation procedures; the percentage of patients with amputation; the percentage of patients with frequent hospitalization or emergency room visits due to diabetic complications; and the frequency of foot examination. Other alternatives suggested included using the Health Plan Employer Data and Information Set 2000 (HEDIS), and performing a State-based pilot program to determine the evaluation of the feasibility of using outcome measurements.

Response: We evaluated the comments to measure specific items and we also considered using different methods of evaluating outcome measurements that had previously been established, such as HEDIS. We have decided to reduce our collection of information to a few meaningful topics that are a part of the patients medical record, and we are eliminating the collection of information that is duplicative or less useful.

As a result of comments, we developed a new provision (§ 410.146) on outcome measurements. Collection of outcome data based on § 410.146 will be required after February 27, 2001.

The following data must be collected and made available to the PRO upon request: educational goals; patient information, including duration of the diabetic condition, use of insulin or oral agents, height and weight by date, results and date of last lipid test, results and date of last HbA1C, information on self-monitoring (frequency and results), blood pressure and the corresponding dates; assessment of educational needs; program goals; plan for assessing achievement of program goals between 6 months and 1 year after the end of the training (obtained from the patient survey, primary care physician contact, and follow-up visit); and documentation of the evaluation of program goals.

Section 4105(c) of the BBA requires the Secretary to establish outcome measures for the purpose of evaluating the improvement of the health status of Medicare beneficiaries with diabetes. The BBA also requires that the health status information of Medicare beneficiaries with diabetes, as measured under the outcome measures, be periodically reported by the Secretary to the Congress for the purpose of making recommendations to modify coverage under the Medicare program.

Outcome measurement information is a quality tool which will measure the effectiveness of care given to beneficiaries. In keeping with the PROs role of quality improvement, the PROs need information to assess the effectiveness of care. Access to outcome measurement data also allows the PROs to engage in quality improvement initiatives with the training programs that meet our quality standards. In § 410.146(a) we require all approved entities to effectively report beneficiary health outcome information to the PROs.

We realize diabetes self-management training will be a new service for many and that there will be varying levels of experience. For this reason, we encourage training programs to use the PRO and other resources to assist in the development and growth of these programs. By requiring an approved entity to collect outcome measures, we set a clear expectation that the training program must take a proactive approach

to monitor, track, and improve, as necessary, their performance and outcomes of care.

We state that information must be organized in a systematic manner, and at least collected on a quarterly basis. By requiring quarterly documentation, we are allowing sufficient time to assess changes in blood levels, compliance, and learning needs. Simultaneously, we will have the needed documentation to track beneficiaries on a regular basis.

Payment for Outpatient Diabetes Self-Management Services (§ 414.63)

Comment: Many dietitians commented that they believe the final regulation should provide for the direct payment to registered dietitians. They believe that to deny direct payment to them is in conflict with the requirement in § 410.144(a)(4), requiring a registered dietitian as a member of the multidisciplinary team providing diabetes self-management training. The commenters believe nutritional counseling is the cornerstone of effective diabetes care and control, and that only registered dietitians are uniquely qualified to provide this service.

Response: The BBA, which established the statutory authority for expanded coverage of outpatient diabetes training, explicitly requires that a 'certified provider' be a physician or other individual or entity that ''in addition to providing diabetes outpatient self-management training, provides other items or services for which payment may be made'' under the Medicare program. Though training furnished by registered dietitians is essential to high quality outcome measurements, dietitians do not furnish other services for which direct Medicare payment may be made. Thus, dietitians do not qualify as approved entities for the purpose of receiving direct payment for outpatient diabetes training. A CDE can be part of a team that can be an approved entity (for example, an employee of a physician who is an approved entity, or as an independent contractor of a hospital that furnishes training onsite at the hospital). Each core member of the multidisciplinary team is essential to the success of the diabetes self-management education program. However, this does not mean that each core team member of an approved entity has a right to be paid directly by the Medicare program.

Comment: Several commenters suggested that we cover core diabetes education for Medicare beneficiaries once in a lifetime, not to exceed $330, and follow-up visits, if needed, not to exceed $170 per year. By limiting the dollar amount instead of the number of hours, these commenters suggest that clinicians could take responsibility for customizing a cost-effective treatment plan to best meet the needs of the patient. For example, $330 could be used for 6 hours of individual training or 10 hours of classroom training. It would save time, paperwork, and preserve the Medicare budget.

Response: Under the proposed rule, payment is made for training sessions actually attended by the beneficiary and not for packages of training sessions. We believe this payment methodology is important to ensure that needed training is received and to give us information that we can later use to evaluate the effectiveness of the benefit. Therefore, in § 414.63(c), we retain the requirement that payment is made for training sessions actually attended by the beneficiary and documented on attendance sheets by half-hour units. We, however, agree that the benefit allows for a once in a lifetime core of training. We provide clarification in § 410.141(c).

Comment: The State of Maine Department of Human Resources recommends that FQHCs be allowed to receive payment for diabetes self-management training similar to that proposed for hospital outpatient department programs. The current practice of bundling into the facility rate does not provide sufficient payment to the health center for coverage of a registered nurse and a registered dietitian with training in diabetes education. In 20 years, only 220 individuals with diabetes have completed the diabetes education program at the Maine FQHC.

Response: We explained in the preamble of the February 1999 proposed rule that if outpatient diabetes self-management training is furnished in a FQHC or a 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 and 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.

Comment: Some commenters requested that we review the payment schedule proposed for the diabetes self-management training. Commenters stated that the proposed payment rates were inadequate and work at cross-purposes to our requirement that approved entities improve patient outcomes. The commenter stated that the rates based on average salaries of RNs and dietitians that are currently employed in institutions may not be comparable with those paid to community pharmacists. Also, the proposed reimbursement rates did not account for the significant administrative costs, costs of peer review, and the costs of accreditation that noninstitutional certified providers would incur to participate in the program.

Response: We believe that the payment rates for outpatient diabetes self-management training are reasonable. The initial payments for outpatient diabetes self-management training are based on resource-based RVUs. The RVUs reflect practice expense and malpractice expense. They were established in a manner consistent with how we establish payments for other new services under the physician fee schedule. Like other services paid under the physician fee schedule, the actual payment amounts will vary among geographic areas to reflect differences in costs of practice as measured by the Geographic Practice Cost Indexes.

Comment: One commenter objected to the methodology used for determining practice expense RVUs on an average group of 10, simply because groups of 2 to 20 participants are allowed under proposed § 410.141(b)(4). The commenter believes this assumption was flawed. The commenter stated that most groups would have fewer than 10 patients.

Response: In the February 1999 proposed rule, we outlined how payment amounts were developed for the training, including our premise that an average group will consist of 10 people. We continue to believe that 10 participants is a reasonable group size for purposes of estimating resource inputs for these services. We will reconsider this in the future once we gain additional experience and information about how these services are being furnished. Any changes to the payment amount will be proposed and finalized in the annual publication of the physician fee schedule.

Comment: Several commenters stated that end stage renal disease (ESRD) facilities fall under the definition of approved entities that furnish outpatient

diabetes training. The commenters recommend that a method be established to ensure that dialysis facilities can be directly paid under this initiative.

Response: The requirements in § 414.63 state that payment for outpatient diabetes self-management training is made under the physician fee schedule. We agree, however, that these facilities that are not normally paid under the physician fee schedule may qualify to be an approved entity if they meet all the criteria for providing this service. In this final rule, we added a new § 414.63(d), to provide for ''Payments made to those not paid under the physician fee schedule''. ESRD facilities that qualify will bill the fiscal intermediary for these services using the appropriate HCFA Common Procedure Coding System (HCPCS) codes. The same quality standards and other requirements apply in any setting. The payment amount for a qualifying ESRD facility will be the same as the amount established for an entity paid by a carrier.

Comment: Commenters expressed some concern regarding the differing payment methodologies for homebound beneficiaries.

Response: Homebound beneficiaries under the prospective payment system (PPS) bundled payment for home health services receive diabetes education in the form of a home visit from a qualified practitioner with diabetes knowledge. We note, however, that home health agencies do not receive a separate payment under this benefit for services furnished to homebound beneficiaries. We will not pay twice for similar services under two different benefits.

Billing for Training in 30-minute Increments (§ 424.44(d))

Comment: Many commenters requested that we change the billing codes to 30-minute increments and that we explain how payment rates are developed.

Response: In response to comments, we have revised proposed § 424.44(d) to require billing of initial and follow-up training in half-hour increments. Also, we are revising the HCPCS codes for diabetes outpatient self-management training so that training session units are now equal to 30-minute increments. The codes are G0108 for individual diabetes outpatient self-management training per 30 minutes and G0109 for a group session (2 to 20) diabetes outpatient self-management training per 30 minutes. Before the effective date of the final regulation, we will issue program instructions that will implement the 30-minute billing increment.

The payment rates for these services are part of the physician fee schedule, which is updated annually. For calendar year 2000, the national payment rate is $60.41 (practice expense relative value unit (RVU) of 1.65) per hour for individual session and $35.88 (RVU of .98) per beneficiary per hour in a group session. The malpractice expense RVU is 0.1 for both individual and group training. While the current physician fee schedule reflects the amount for hourly sessions for both individual and group sessions, the revised training codes are now equal to 30 minute sessions, the payment rates are billable at one half of the fee schedule amount (that is, $30.21 for individual training and $17.94 for an individual in a group). Like other services paid under the physician fee schedule, the actual payment amounts will vary among geographic areas to reflect differences in costs of practice as measured by the Geographic Practice Cost Indexes (GPCIs). The Part B carrier will furnish payment amounts including the GPCIs to the fiscal intermediary for each calendar year.

In the case of payments made to other approved entities, such as hospital outpatient departments, ESRD facilities, and durable medical equipment suppliers, the payment will be equal to amounts established under the physician fee schedule and made under the appropriate payment systems.

Comment: One commenter was concerned that all indirect and direct resource costs have to be included in the payment rate. The commenter asserted, for example, that 30 minutes chart time was not accurate and the cost of coverage for vacations and sick time was not included. A few commenters suggested that we recalculate the payment schedule to include the amount of time it takes to complete the documentation required for recognition and to meet the Joint Commission on Accreditation of Health Care Organizations (JCAHO) standards.

Response: The estimates we used to establish the proposed payment amount were based on consultations with professional groups. As noted above, all comments regarding payment amounts were considered during the updates to the physician fee schedule. Payments under the physician fee schedule are determined in part, by the ''typical'' resource inputs (that is, staff, equipment, and supplies needed to furnish each service). Because the Congress designated that payment for the service would be established under the physician fee schedule, the rules regarding development of the rates under the fee schedule apply.

Comment: Some of the commenters stated that the payment rates to approved entities are too low. The proposed fee schedule in 1999, based on the average salaries of registered nurses and dietitians, was insufficient for other health care providers who could furnish these services. The commenters believe that the proposed salary levels would prevent many providers from participating in the program.

Also, one professional association stated that the payment rates grossly underestimated the time and administrative costs involved (that is, costs for photocopying, achieving CDE accreditation, and general administrative expenses) in applying for accreditation as well as maintaining the accreditation.

Response: We do recognize that there are variations among individual entities in how they provide services. The 1999 payment amounts for these services were established under the physician fee schedule in a manner consistent with how we establish payments for other services paid under the fee schedule and as required by statute. As noted earlier in this section, for calendar year 2000, however, adjustments were made to reflect more relative value units for the service.

IV. Summary of Changes to the Proposed Rule

In response to comments on the proposed rule and to provide policy clarifications, we made a number of changes in the final rule, which are summarized as follows:

- Add to the definitions section, definitions for the American Diabetes Association (ADA), National Standards for Diabetes Self-Management Education Program (NSDSMEP), and rural. (*See* § 410.140)
- Clarify that the 10-hour initial training is a one-time benefit. (*See* § 410.141(c))
- Permit 1 hour of the 10-hour initial training to be used for assessment of the individual's training needs. (*See* § 410.141(c)(1))
- Increase the amount of follow-up training from 1 hour to no more than 2 hours of individual or group training. (*See* § 410.141(c)(2))
- Replace the 90-day provision for evidence of poor glycemic control (HbA1C level of 9.5 percent) with evidence of inadequate glycemic control from HbA1C level determinations of 8.5 percent 3 or more months apart in the year before the beneficiary receives initial training. (*See* § 410.141(d)(2))

• Expand the proposed medical condition criteria for kidney complications related to diabetes to include both macroalbuminuria and microalbuminuria by changing the medical requirement to ''Kidney complications related to diabetes, when manifested by albuminuria, without other cause. * * *'' (*See* § 410.141(d)(5))

• Correct the proposed regulations text by removing the term, ''accreditation requirements'' from the crosswalk requirement in § 410.142(b)(2).

• Clarify the process an accreditation organization must use to notify HCFA of its intent to change its quality standards. (*See* § 410.143(a))

• Require an accreditation program that uses a set of quality standards other than our quality standards or the NSDSMEP quality standards to ''meet or exceed'' our quality standards rather than ''be substantially equivalent to'' our quality standards. (*See* § 410.142(e)(1) and § 410.144(c))

• Reduce the proposed requirement for nonphysician professional staff to obtain 14 hours of continuing education every 2 years to 12 hours of relevant continuing education every 2 years. (*See* § 410.144(a)(3))

• Add a requirement that the certified diabetes educator (CDE) on the multidisciplinary team be currently certified by a qualified organization that has registered with us. (*See* § 410.144(a)(4))

• Add a requirement that the appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish training within the scope of their practices. (*See* 410.144(a)(4))

• In rural areas, provide an exception to the multi-disciplinary team requirement to allow an individual who is qualified as both a registered dietitian and as a CDE certified by a qualified organization that has registered with us (or as a registered dietitian and an RN until 3 years after the effective date of this final rule) to furnish training. (*See* § 410.144(a)(4)) (For purposes of this requirement, a rural area (as defined in § 410.140) includes an area served by the Indian Health Service.)

• Maximize the use of interactive training methods. (We wish to discourage didactic training; that is, simply lecturing beneficiaries.) (*See* § 410.144(a)(6))

• Add a new requirement under our quality standard on review of plan of care and goals, for the approved entity to forward a copy of the documentation to the referring physician. (*See* § 410.144(a)(7))

• Add a new requirement under our quality standard on review of plan of care and goals, for the approved entity to periodically update the beneficiary's referring physician of the beneficiary's educational status. (*See* § 410.144(a)(7))

• Remove requirements for an entity meeting the Secretary's quality standards to report to us nationally standardized performance measures and to meet minimum performance levels that we establish. (*See* § 410.144(a)(9))

• Provide more flexibility under the HCFA quality standards by allowing a program to design an alternate quality improvement project. (*See* § 410.144(a)(10))

• Remove the proposed requirement that we would approve subsequent changes to the NSDSMEP quality standards. (*See* § 410.144(b))

• Provide that we may deem an entity to meet the quality standards for the first 18 months after the effective date of this final rule if the entity provides us with a copy of its certificate or proof of recognition from the ADA that verifies the training it furnishes meets the NSDSMEP quality standards. (*See* § 410.145(a)(2))

• Require that all approved entities allow the PRO, under a contract with us to have access to beneficiary and group training records. (*See* § 410.145(b)(4))

• Add a new section on Diabetes Outcome Measurements. (*See* § 410.146)

• Provide for payment for outpatient diabetes self-management training to entities not routinely paid under the physician fee schedule. (*See* § 414.63(d))

• Require billing of initial and follow-up training in half-hour increments so that training may be furnished in half-hour increments. (*See* § 424.44(d))

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-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

Paragraph (b) of section 410.141 states that outpatient 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 that meets the requirements of this section.

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.

In addition, this section requires that a HCFA-approved entity submit its plans 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.

Paragraph (b)(2)(ii) of § 410.141 requires the physician (or qualified nonphysician practitioner) treating the beneficiary to document in the beneficiary's medical record the specific medical condition that the additional beneficiary training must address.

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 certified providers in the normal course of business activities.

Paragraph (c)(1)(ii)(B) of § 410.141 requires that the beneficiary's physician (or qualified nonphysician practitioner) document 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.

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 be accredited by, an accreditation organization approved by HCFA under § 410.142 to meet one of the sets of quality standards described in § 410.144.

We previously estimated that each accredited certified provider would spend 60 hours to complete the requirements every 3 years for an estimated total annual burden of 15,000 hours. We received a comment that this amount underestimated the effect of the accreditation requirement. However, we believe that 60 hours every year, in addition to the amount of recordkeeping that would be normal business practice for a diabetes self-management training program, is appropriate. We do not believe we should count recordkeeping that would occur even in the absence of the accreditation requirement.

We have updated the burden for this provision based on the increase in number of programs accredited in the year 2000. We estimate that 819 approved entities will take 60 hours to complete these requirements every 3 years, for an annual burden of 20 hours per certified provider. Therefore, the total annual burden imposed by these requirements is estimated to be 16,380 hours.

Section 410.141(e)(4) states that the entity must provide documentation to HCFA, as requested, including diabetes outcome measurements set forth at § 410.146.

Since this documentation will be collected as part of an administrative action, 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 out approval and recognition of its accreditation program must furnish to us 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 after publication of the final rule 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 we 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 this requirement is exempt from the PRA since it will be imposed under the conditions defined in 5 CFR 1320.4 as a result of an administrative action 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); as such, they do not meet the definition of an information collection.

Section 410.142(g) states 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 training may request reconsideration of our 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 our notice of denial of its request for accreditation may submit a new request to us if it meets the conditions in this section.

We anticipate that this requirement will be imposed on fewer than 10 persons on an annual basis, and, therefore, is 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 our 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 and recognized by us must provide to us in a written form and on a monthly basis all of the information 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 furnish the required information. It is estimated that it will take each organization 4 hours to complete these requirements. There will be approximately 5 respondents for a total of 20 annual hours.

Section 410.143(a)(2) states that, if an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that HCFA previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described in § 410.144 and the organization's revised standards. Paragraph (a)(3) states that, if HCFA notifies an organization that uses the HCFA quality standards described in § 410.144(a) that it has changed the HCFA quality standards, the organization must submit to HCFA, within 30 days of HCFA's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in § 410.144(a).

The burden associated with these requirements is 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 will be approximately 5 respondents for a total of 50 hours.

Section 410.143(b) states that we (or our agent(s)) may perform oversight activities such equivalency reviews, validation reviews, and onsite inspections to 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 our approval and recognition may request a reconsideration of our 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 as the result of an administrative action 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); as such, they do not meet the definition of an information collection.

Section 410.144 Quality Standards for Deemed Entities

Section 410.144, in paragraphs (a)(1)(ii) and (iii), requires that a deemed entity clearly define and 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 a approved entity to document and maintain the information described above. It is estimated these requirements will take each entity 8 hours. There are approximately 819 entities for a total annual burden of 6,552 hours.

Section 410.144(a)(7) states that an entity must review each beneficiary's plan of care and 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.

Paragraph (a)(7) also requires that an entity forward a copy of the documentation in paragraph (a)(7)(ii) to the referring physician and periodically update the referring physician about the beneficiary's educational status.

While these information collection requirements are subject to the PRA, we believe the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.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 us 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 us 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 819 entities, we estimate a total annual burden of 2,457 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. We solicit comments on how long fulfilling this requirement will take.

Section 410.145 Requirements for Approved Entities

Section 410.145(a)(1)(i) states that an entity may be approved to meet our 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(b)(1) through (3) states that an entity may be approved if the entity:

- 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.
- Agrees to submit to evaluation (including onsite inspections) by us (or our agent) to validate its approved organization's accreditation process.
- Authorizes for its approved 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 819 respondents for a total of 68 hours.

Section 410.145(b)(4) states that, at a minimum, the entity must allow a PRO (under a contract with HCFA) access to beneficiary or group training records.

The burden associated with this requirement is the time and effort necessary to maintain the necessary documentation and to demonstrate that the approved entity meets the requirements of this section.

We estimate that it will take 819 entities 5 minutes on an annual basis to maintain the necessary documentation or to report the results of an internal quality assessment program to HCFA for an overall annual burden of 68 hours.

Section 410.146 Diabetes Outcome Measurements

This section requires an entity to collect and record specified information for a beneficiary who receives training under § 410.141. The section also requires an entity to make the data it collects available to a Peer Review Organization upon request.

The burden associated with this section is that for collecting the data and for reporting it, upon request. The burden associated with collecting the data, while subject to the PRA, is, we believe, 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. The burden for reporting the data is included with the burden for § 410.144.

Section 414.63 Payment for Outpatient Diabetes Self-Management Training

Section 414.63(c) states payment may be made for training sessions actually attended by the beneficiary and documented on attendance sheets.

While this documentation requirement is subject to the PRA, we have not accounted for its burden 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. Although we solicited comments, we did not receive any on our conclusion that this activity would not be a burden for providers.

We have submitted a copy of this final 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 recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Julie Brown HCFA–3002–F.

and,

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

VI. Regulatory Impact Analysis

A. Background

We have examined the impacts of this final rule as required by Executive Order 12866, section 1102(b) of the Social Security Act (the Act), the Unfunded Mandates Act of 1995, the Regulatory Flexibility Act (RFA) (Public Law 96–354), and Executive Order 13132 (Federalism). 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 in any one year). The statutory provision that this rule further implements will cause this to be a major rule and economically significant rule because we have estimated that the annual costs associated with this rule will be significantly higher than $100 million beginning in 2001.

Section 1102(b) of the Act requires us to prepare an RIA if a rule has a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires agencies to prepare an assessment of anticipated costs and benefits before issuing any rule that may mandate an expenditure by State, local, or tribal governments, in an aggregate, or by the private sector, of $100 million or more in any one year. We believe that this final rule will 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 and not-for-profit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit or not-for-profit status, or by having revenues of $5 million or less annually. States and tribal governments are not considered to be small entities.

This final rule provides additional benefit payments to providers and suppliers for offering classes on diabetes self-management training. In section C. of the RIA we discuss the accreditation approval process and acknowledge that some small entities may encounter a regulatory burden in obtaining accreditation. We discuss measures that we believe will lessen the regulatory burden on these entities.

This final rule sets forth an expanded benefit for Medicare beneficiaries with diabetes who meet the criteria for outpatient self-management training. This final rule also identifies approved entities that may furnish these services, and lists the quality standards that must be met by these approved entities. This regulation will primarily affect beneficiaries with diabetes and certain health care professionals and facilities.

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, will receive outpatient diabetes self-management training. 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 representatives of various groups and organizations active in the field of diabetes education and training, we believe it is reasonable to cover up to 10 hours of initial diabetes self-management training (allowing 1 individual hour and 9 group hours) within a continuous 12-month period and up to 2 hours of additional training annually (allowing both hours to be either individual or group training in any combination of half-hour increments) for each beneficiary that meets the conditions of coverage. We estimate that there will be twenty half-hour increments billed in the first year and possibly four follow-up increments (up to 2 hours) billed each year thereafter.

The following table displays the estimated Federal Medicare outlays for the outpatient diabetes self-management training benefit.

PROJECTED BUDGET IMPACT OF NEW BENEFIT

[$ in millions]

FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
$150	$200	$270	$270	$280

The costs have been recalculated using year 2000 payment rates updated annually, and the following assumptions: (1) Payments reflected in the budget projections are for the revised benefit, not the benefit implemented earlier under program memorandums; (2) utilization is based on capacity of accredited programs; (3) the number of accredited programs will increase by 100 every year; (4) beneficiaries will receive the full amount of the covered service; and (5) approximately 2.25 million beneficiaries are eligible to receive the benefit. Based on the capacity of the ADA recognized programs in 2000 and the number of programs we expect in 2001 through 2005, not all beneficiaries will be able to receive the initial training immediately. The costs associated with initial training are approximately five times greater than the costs that are subsequently incurred for follow-up

training because 10 hours are allowed for initial training and only 2 hours are allowed for follow-up training. Therefore, costs associated with the benefit decline after the backlog of 2.25 million beneficiaries receive initial training even with our assumption that all beneficiaries will receive 2 hours of follow-up training each year. After 2005, with only approximately 300,000 beneficiaries with diabetes becoming eligible annually, costs are expected to drop by approximately 30 percent. These figures assume all payments for the service are made at the full fee-for-service rate minus deductible and coinsurance, for all beneficiaries and that all beneficiaries who are eligible for the service, receive it.

If the referral rate is low, or actual utilization is low, we would expect the stated figures to be reduced by as much as 50 percent. The estimates vary considerably from the proposed rule because we had incomplete data at that time.

The expected costs could be considerable, especially in the first 5 years, but we also expect substantial benefits. When an individual 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 beneficiary with diabetes cannot properly use glucose in the blood, blood glucose levels remain high, unless the individual 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 regarding outpatient diabetes self-management training: (1) When should the person receive the training? (2) How much training should the person receive? Initial training may bring about short term behavioral changes. Some experts express concern about the difficulty individuals with diabetes may 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 will provide, when medically necessary, refresher training in a subsequent year following the initial training. We believe that this provision of coverage will have a positive result on the Medicare program.

We did not receive public comments on the potential cost and impact of the outcome measurement requirement in § 410.146 of this final rule. However, we consider that the collection and integration of this information into a beneficiary's training file or medical plan of care would normally be a part of keeping adequate medical records. We plan to monitor specific outcome measurements to assist us in ensuring quality programs for our beneficiaries. The only sizeable additional cost would be for the photocopying of the records. Under the final rule, these photocopying and mailing costs would be reimbursable by the PRO.

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 authorized the Secretary to develop her own quality standards. We have condensed the standards originally established by the NSDSMEP quality standards and recognized by the ADA. We believe that our standards offer sufficient assurances that the outpatient diabetes self-management training programs will provide quality care and the standards are flexible enough to apply in most health care settings.

The ADA Education Recognition Program is a national voluntary process that identifies diabetes self-management training programs that meet the NSDSMEP quality standards. The ADA currently recognizes outpatient diabetes self-management programs. The ADA has given recognition to approximately 819 education programs. Under the conditions in this final rule, the ADA, along with any other national accreditation organization that wishes to be approved and recognized by us, will be required to submit appropriate documentation requesting accreditation approval from HCFA. Once we have determined that the organization meets our requirements concerning frequency of accreditation, accreditation forms, and that the organization uses 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 us 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.

We recognize that some small entities such as rural-based physicians and free-standing education clinics run by approved entities may find the 12-month collection of data and the start-up fees required by the ADA to be a burden to their business operations. The approximate cost for an entity to get accredited, based on current ADA figures, is $850, which includes all application costs. The subsequent triennial fee is also $850. 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 819 approved entities when this rule is implemented and that the number of approved entities will increase by 100 every year until utilization should drop affecting the number of new applicants for accreditation. The additional private sector cost through 2005 will be $1,121,150.

We acknowledge that some existing programs that are currently accredited by their State or local agency may find it a burden to become accredited by a national organization. However, we expect that at least four other organizations in addition to the ADA will 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 United States territories, and the District of Columbia. This cooperative agreement provides funding for these geographic entities to perform a variety of diabetes-related activities. Ten of the States use a portion of their funds to administer their State diabetes self-management training accreditation programs. Under this final rule, there will be no loss of revenue from this cooperative agreement for any of these geographic entities. The States that currently use funds from the cooperative agreement to administer their State diabetes self-management

training programs can either choose to become an organization or choose 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 postponing the requirement for the CDE to be part of the diabetes self-management multidisciplinary team. Diabetes education programs are allowed to use a registered nurse instead of a CDE for 3 years from the effective date of the regulation. This final rule requires that diabetes educators and dietitians complete 12 hours of approved diabetes-related continuing education every 2 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.) Existing programs will have 3 years from the publication of this final rule to provide outpatient diabetes self-management training while preparing to meet our standard concerning the CDE.

We estimate that there will be 819 approved education programs when this final rule is fully implemented. Each approved entity will need a CDE 3 years from February 27, 2001. We estimate that 1019 approved education programs will be available at the time the CDE requirement goes into effect. The initial certification of a CDE costs $250 and another $300 every 2 years to maintain certification. The initial CDE certification will cost approximately $254,750 (1019 * $250) per year for CDE certification starting 3 years from February 27, 2001.

Under the continuing education requirement, a CDE, RN, or a registered dietitian must complete 12 credits every 2 years. The costs associated with this final rule will be approximately $150 every year. In the first year, the estimated total cost for continuing education for all CDEs/RNs and dietitians will be $245,700 (819 * 2 * $150) for all programs. These costs may be less for those rural areas that have a single individual who is qualified both as a registered dietitian and as a CDE to meet the multidisciplinary team requirement.

D. Conclusions

We anticipate that this final rule will improve the health of Medicare beneficiaries with diabetes by furnishing 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 by both Medicare beneficiaries and the Medicare program.

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

We have reviewed this final rule, under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does not significantly affect the rights, roles, and responsibilities of States.

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 480

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 is amended as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. Part 410 is amended as follows:

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

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

2. In § 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:

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

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

(3) Section 1861(qq)—Definition of the kinds of services that may be covered.

(4) Section 1865(b)—Permission for HCFA to approve and recognize a national accreditation organization for the purpose of deeming entities accredited by the organization to meet program requirements.

(5) Section 1881—Medicare coverage for end-stage renal disease beneficiaries.

* * * * *

3. New subpart H, consisting of §§ 410.140 through 410.146, is added to read as follows:

Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

Sec.

410.140 Definitions.
410.141 Outpatient diabetes self-management training.
410.142 HCFA process for approving national accreditation organizations.
410.143 Requirements for approved accreditation organizations.
410.144 Quality standards for deemed entities.
410.145 Requirements for entities.
410.146 Diabetes outcome measurements.

Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

§ 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

ADA stands for the American Diabetes Association.

Approved entity means an individual, physician, or entity accredited by an approved organization as meeting one of the sets of quality standards described in § 410.144 and approved by HCFA under § 410.141(e) to furnish 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 under § 410.141(e) to furnish training, HCFA refers to this entity as an ''approved entity''.

NSDSMEP stands for the National Standards for Diabetes Self Management Education Programs.

Organization means a national accreditation organization.

Rural means an area that meets one of the following conditions:

(1) Is not urbanized (as defined by the Bureau of the Census) and that is designated by the chief executive officer of the State, and certified by the Secretary, as an area with a shortage of personal health services.

(2) Is designated by the Secretary either as an area with a shortage of personal health services or as a health professional shortage area.

(3) Is designated by the Indian Health Service as a health service delivery area as defined in § 36.15 of this title.

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 if all of the conditions and requirements of this subpart are met.

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

(1) Training orders. Following an evaluation of the beneficiary's need for the training, it is ordered by the physician (or qualified nonphysician practitioner) (as defined in § 410.32(a)) treating the beneficiary's diabetes.

(2) Plan of care. 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 of sessions, 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 is 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) of this section) that the training will 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 medical record for the beneficiary and is made available, upon request, to HCFA.

(3) Reasonable and necessary. 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.

(c) Types and frequency of training—(1) Initial training.—General rule. (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii) Exception. Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

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

(B) 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 will hinder effective participation in a group training session.

(2) Follow-up training. After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) Beneficiaries who may be covered. Medicare Part B covers one course of initial training for a beneficiary who has one or more of the following medical conditions present within the 12-month period before the physician's order for the training:

(1) New onset diabetes.

(2) Inadequate glycemic control as evidenced by a glycosylated hemoglobin (HbA1C) level of 8.5 percent or more on two consecutive HbA1C determinations 3 or more months apart in the year before the beneficiary begins receiving training.

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

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

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

(i) Lack of feeling in the foot or other foot complications such as foot ulcers, deformities, or amputation.

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

(iii) Kidney complications related to diabetes, when manifested by albuminuria, without other cause, or elevated creatinine.

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

(1) 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, including diabetes outcome measurements set forth at § 410.146.

§ 410.142 HCFA process for approving national accreditation organizations.

(a) General rule. HCFA may approve and recognize a nonprofit or not-for-

profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

(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 requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the HCFA quality standards or the NSDSMEP quality standards described in § 410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the HCFA quality 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 a deemed 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 the accreditation requirements and standards.

(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 for 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 for 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 an approved 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 for withholding or removing a certificate 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 will serve as a basis for accreditation if HCFA approves the organization.

(9) A list of all of the approved 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 410.146.

(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.

(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. 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 meet or exceed the HCFA quality standards described in § 410.144(a) or how the organization would use the NSDSMEP quality standards described in § 410.144(b).

(iii) An opportunity for public comment.

(2) Final notice. (i) After considering public comments HCFA receives on the proposed notice, it 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.

(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, HCFA considers the following criteria:

(1) The organization uses and enforces quality standards that HCFA has determined meet or exceed the HCFA quality standards described in § 410.144(a), or uses the NSDSMEP quality standards described in § 410.144(b).

(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) If approved, the expiration date of HCFA's approval and recognition of the accreditation program.

(3) If denied, the rationale for the denial and the 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 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 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, the use of one of the sets of quality standards described in § 410.144.

(iii) Resubmits the application in its entirety.

(2) For 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, HCFA will not consider the organization's new request until all administrative proceedings on the previous request 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) Applying for continued HCFA approval. 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, 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 quality standards described in § 410.144).

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

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an approved entity's deemed status) against an approved 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 (other than changes to the NSDSMEP quality standards described in § 410.144(b)), HCFA may withdraw its approval and recognition of the organization's accreditation program.

(2) If an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that HCFA previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described in § 410.144 and the organization's revised standards. If an organization implements changes in its quality standards without HCFA approval, HCFA may withdraw its approval and recognition of the organization's accreditation program.

(3) If HCFA notifies an organization that uses the HCFA quality standards described in § 410.144(a) that it has changed the HCFA quality standards, the organization must meet the following requirements:

(i) Submit to HCFA, within 30 days of HCFA's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in § 410.144(a).

(ii) Implement the changes to its accreditation program by the implementation date specified in HCFA's notification of the changes in the quality standards.

(b) HCFA oversight of approved national accreditation organizations. HCFA, or its agent, performs oversight activities to ensure that an approved organization and the entities the organization accredits continue to meet a set of quality standards described in § 410.144. 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 a set of quality standards (described in § 410.144) and processes when any of the following conditions exist:

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

(ii) Except for an organization that uses the NSDSMEP quality standards, 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.

(2) Validation reviews. HCFA validates an organization's accreditation process by conducting evaluations of approved entities accredited by the organization and comparing its results to the results of the organization's evaluation of the approved 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 documentation of 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 gives an 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) Except for those accrediting organizations using quality standards in § 410.144(b), the quality standards that the organization applies and enforces do not meet or exceed the HCFA 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 deemed entities.

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

(a) HCFA quality 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) Includes in its operational policies, specific standards and procedures identifying the amount of collaborative, interactive, skill-based training methods and didactic training methods furnished to the beneficiary.

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

(vi) Identifies in its operational policies, the minimal amount that each team member must be involved in the following:

(A) Development of training materials.

(B) Instruction of beneficiaries.

(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 12 hours of continuing diabetes education concerning educational principles and behavior change strategies every 2 years.

(4) Team approach. (i) Except as provided in paragraph (a)(4)(ii) of this section for a rural area, furnishes services using a multidisciplinary instructional team that meets the following requirements:

(A) The team includes at least a registered dietitian, as recognized under State law, and a certified diabetes educator (CDE), certified by a qualified organization that has registered with HCFA, who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.)

(B) The team is qualified to teach the training content areas required in paragraph (a)(5) of this section.

(C) All appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish the training within the scope of their practices.

(ii) In a rural area, an individual who is qualified as a registered dietitian and as a CDE that is currently certified by an organization approved by HCFA (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section.

(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.

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

(iii) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.

(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.

(iii) Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Includes in the education plan, the goals for education, the periodic updates, the specific amount of interactive, collaborative, skill-based training methods and didactic training methods that have been and will be furnished.

(iv) Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's medical record.

(v) Forwards a copy of the documentation in paragraph (a)(7)(ii) through (iv) of this section to the referring physician (or qualified nonphysician practitioner).

(vi) Periodically updates the beneficiary's referring physician (or qualified nonphysician practitioner) about the beneficiary's educational status.

(8) Educational intervention. Offers appropriate and timely educational intervention based on referral from the beneficiary's physician (or qualified 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 an effective internal performance measurement and quality improvement program that focuses on maximizing outcomes by improving patient safety and quality of care. The program must meet the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetes 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.

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

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

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

(10) Quality improvement. Has an agreement with a PRO to participate in quality improvement projects defined by the PRO, or if a program elects not to participate in a PRO project, it must be able to demonstrate a level of achievement through a project of its own design that is comparable to or better than the achievement to be expected from participation in the PRO quality improvement project.

(b) The National Standards for Diabetes Self-Management Education Programs. The set of quality standards contained in the NSDSMEP or any NSDSMEP standards subsequently revised.

(c) Standards of a national accreditation organization that represents individuals with diabetes. Standards that meet or exceed the HCFA quality standards described in paragraph (a) of this section that have been developed by a national

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 entities.

(a) Deemed entities. (1) Except as permitted in paragraph (a)(2) of this section, an entity may be deemed to meet a set of quality standards described in § 410.144 if the following conditions are met:

(i) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by HCFA under § 410.142.

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

(2) Before August 27, 2002 HCFA may deem an entity to meet the NSDSMEP quality standards described in § 410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program it furnishes meets the NSDSMEP quality standards described in § 410.144(b).

(b) Approved entities. An entity may be approved to furnish training 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 organization approved by HCFA under § 410.142 indicating that the entity meets a set of quality standards described in § 410.144, or before August 27, 2002, submits documentation of its current ADA recognition status.

(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.

(4) At a minimum, allows the PRO (under a contract with HCFA) access to beneficiary or group training records.

(c) Effective dates—(1) Deemed to meet quality standards. Except as permitted in paragraph (c)(2) of this section, the date on which an entity is deemed to meet a set of quality standards described in § 410.144 is the later of one of the following dates:

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

(ii) The date an organization accredits the entity to meet a set of quality standards described in § 410.144.

(2) Approved to furnish training. HCFA covers the training furnished by an entity beginning on the later of one of the following dates:

(i) The date HCFA approves the deemed entity as meeting the conditions for coverage in § 410.141(e).

(ii) The date the entity is deemed to meet a set of quality standards described in § 410.144.

(d) Removal of approved status—(1) General rule. HCFA removes an entity's approved status for any of the following reasons:

(i) HCFA determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet a set of quality standards described in § 410.144.

(ii) HCFA withdraws its approval of the organization that deemed the entity to meet a set of quality standards described in § 410.144.

(iii) The entity fails to meet the requirements of paragraphs (a) and (b) of this section.

(2) Effective date. The effective date of HCFA's removal of an entity's approved status is 60 days after the date of HCFA's notice to the entity.

§ 410.146 Diabetes outcome measurements.

(a) Information collection. An approved entity must collect and record in an organized systematic manner the following patient assessment information at least on a quarterly basis for a beneficiary who receives training under § 410.141:

(1) Medical information that includes the following:

(i) Duration of the diabetic condition.

(ii) Use of insulin or oral agents.

(iii) Height and weight by date.

(iv) Results and date of last lipid test.

(v) Results and date of last HbA1C.

(vi) Information on self-monitoring (frequency and results).

(vii) Blood pressure with the corresponding dates.

(viii) Date of the last eye exam.

(2) Other information that includes the following:

(i) Educational goals.

(ii) Assessment of educational needs.

(iii) Training goals.

(iv) Plan for a follow-up assessment of achievement of training goals between 6 months and 1 year after the beneficiary completes the training.

(v) Documentation of the training goals assessment.

(b) Follow-up assessment information. An approved entity may obtain information from the beneficiary's survey, primary care physician contact, and follow-up visits.

B. Part 414 is 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: Secs. 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.

(a) Payment under the physician fee schedule. Except as provided in paragraph (d) of this section, payment for outpatient diabetes self-management training is made under the physician fee schedule in accordance with §§ 414.1 through 414.48.

(b) To whom payment may be made. Payment may be made to an entity approved by HCFA to furnish outpatient diabetes self-management training in accordance with part 410, subpart H of this chapter.

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

(d) Payments made to those not paid under the physician fee schedule. Payments may be made to other entities not routinely paid under the physician fee schedule, such as hospital outpatient departments, ESRD facilities, and DME suppliers. The payment equals the amounts paid under the physician fee schedule.

(e) Other conditions for fee-for-service payment. The beneficiary must meet the following conditions:

(1) Has not previously received initial training for which Medicare payment was made under this benefit.

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

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

C. Part 424 is 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 in half-hour increments to an entity for the furnishing of outpatient diabetes self-management training on or after the approval date HCFA approves the entity to furnish the services under part 410, subpart H of this chapter.

D. Part 480 is amended as follows:

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

1. The authority citation for part 480 continues to read as follows:

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

2. In § 480.111, new paragraph (d) is added to read as follows:

§ 480.111 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 is 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: Secs. 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: October 2, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

Approved: October 20, 2000.

Donna E. Shalala,

Secretary.

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