Supporting Statement for Expanded Coverage for Diabetes
Outpatient Self-Management Training Services
and Supporting Regulations Contained in
42 CFR 410.141, Section 410.142, Section 410.143, Section 410.144, Section 410.145,
Section 410.146, and Section 414.63.

A. Background

In 2010, as reported by the Department of Health and Human Services' Centers for Disease Control and Prevention, (CDC), 25.8 million people in the United States had diabetes, nearly 8.3% of the United States population (Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and pre-diabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.). This medical condition is the seventh leading cause of death due to disease in the United States.

Among Americans aged 65 and older, 10.9 million persons (26.9 percent of this group) are estimated to have diabetes. According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No 95-1468-1995: 553-570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. Ten percent of these hospitalizations are a direct result of uncontrolled diabetes, and more than half of these admissions occur in beneficiaries 65 and older (National Hospital Discharge Survey, U.S. National Center for Health Statistics, U.S. Department of Health and Human Services, 1990). In expanding the Medicare program to include diabetes outpatient self-management training services, the Congress intended to empower Medicare beneficiaries with diabetes to better manage and control their conditions. The Conference Report indicates that the conferees believed that "this provision will provide significant Medicare savings over time due to reduced hospitalizations and complications arising from diabetes." (H.R. Conf. Rep. No. 105-217, at 701 (1997)).

B. Justification

1. Need and Legal Basis

The HCFA-3002-F provided for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non-physician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule established the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It set forth payment amounts that have been established in consultation with appropriate diabetes organizations. It implements section 4105 of the Balanced Budget Act of 1997.

2. Information Users

The information may be used in future reports to Congress.

3. Improved Information Technology

These information collection requirements (ICR) do not lend themselves to improved information technology.

4. Duplication of Similar Information

These ICRs do not duplicate information currently collected information.

5. Small Businesses

These ICRs do not affect small businesses.

6. Less Frequent Collection

If this information would be collected less frequently, we would be out of compliance with the law.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register Notice for the latest submission of this information collection published on May 10, 2013.

HCFA-3002-F was published in December 2000. In keeping with the legislation, we met with all groups or organizations in the field of diabetes. These organizations or groups include the American Diabetes Association (ADA), the American Medical Association (AMA), the American Academy of Family Physicians, the Endocrine Society, the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Dietetic Association, the Health Industry Manufacturers Association, Merck-Medco, the Diabetes Treatment Centers of America,

American Pharmaceutical Association, the National Association of Chain Drug Stores, and the National Community Pharmacy Associations. We also worked extensively with diabetes experts from the CDC and the Department of Veterans Affairs. In addition, we visited a number of diverse hospital-based training programs to obtain an understanding of the current training programs that are available to Medicare beneficiaries. In some cases, multiple meetings were held. Each group was asked to address specific questions that covered all aspects of this regulation and to provide scientific evidence to support each of their responses to these questions. These meetings and the information obtained from them were extremely useful to us. There was a general consensus among the industry that there was not conclusive evidence and data on several issues involved addressed in the rule. As a result, the responses of these groups were very diverse and often conflicting. Thus, the final rule required sifting through available evidence and balancing diverse interests and opinions, with the benefit to the beneficiary, on both an individual and population level, being the major concern.

9. Payment/Gift To Respondent
There is no payment/gift to respondents.

10. Confidentiality
This information is confidential.

11. Sensitive Questions
There are no questions of a sensitive nature.

12. Burden Estimate (Total Hours & Wages)
We solicited public comment on each of these issues for the information collection requirements discussed below.

Section 410.141 Outpatient diabetes self-management training.
Section 410.141(b) states that diabetes self-management training must be included in a comprehensive plan of care and documented in the patient's medical record by the physician or qualified non-physician practitioner treating the beneficiary for training services that meet the requirements of this section. In addition, this section requires that CMS-approved entities submit their plan of care to CMS upon request. While the documentation and recordkeeping requirement imposed by this section is subject to the PRA, the requirements to disclose information to CMS 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.
No comments were received regarding this burden reported in the proposed rule.

For the proposed rule, we counted the plans of care developed by a physician or qualified non-physician practitioner as a burden that would be imposed under this rule. However, upon further development, we determined that physicians and qualified non-physician practitioners develop plans of care during the normal course of their activities whether or

not a patient will be referred for diabetes training. Therefore, we did not count plans of care as a burden in the final rule.

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

While this ICR is subject to the PRA, we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We received no comments regarding the provision's burden before or after the rule was published.

Section 410.141(c)(1)(ii)(B) states that the beneficiary's physician or qualified non-physician practitioner must document in the beneficiary's medical record that the beneficiary has special needs, such as severe vision, hearing, or language limitations that would hinder effective participation in a group training session.

While this ICR is subject to the PRA, we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We received no comments to the proposed rule or since then regarding the provision's burden.

Section 410.141(e) requires that an entity is accredited by an accreditation organization approved by CMS under §410.142 to meet one of the sets of quality standards described in §410.144. The burden associated with this requirement is the time and effort necessary for an entity requesting to be deemed to submit the necessary documentation to an accreditation organization. It is estimated that it will take each of the estimated 5,327 entities 60 hours to complete these requirements every 3 years, for an annual burden of 20 hours. Therefore, the annual burden imposed for submission of the information is estimated to be 106,540 hours.

In addition, we are adding burden based on the collection of 3 months of data required by accreditation organizations in response to OMB's previous comments. However, since those quality standards are not created or approved by CMS, we still disagree that this burden should be counted in our PRA submission. The amount of time to collect the additional information for the 3 months of data is estimated to be ½ hour per week because it is just a compilation of data collected as a business function. We multiply ½ hour by 12 weeks for a subtotal of 31,962 hours for all entities. The total for this requirement is now 138,502 hours. The increase includes additional burden for this reporting due to an increase in the number of entities from 2,008 to 5,327. We have also added in the start-up cost of accreditation to $1,265 an increase from $1,100.

We did receive some comments to the proposed rule that we had underestimated the burden of this requirement. However, we noted that the additional information (record

keeping for each patient) would be collected during the normal course of business activities even if the patient was not a Medicare beneficiary. Therefore, we did not increase the associated burden except in the final rule to adjust the amount to reflect the increase in training programs currently recognized by the American Diabetes Association and the Indian Health Services that are now eligible under our quality standards since the final rule became effective.

Section 410.142 CMS process for approving national accreditation organizations.
Section 410.142(b) states that a national organization requesting accreditation approval by CMS must furnish to CMS the information and materials described in this section.
The burden associated with these requirements is the time and effort to furnish to CMS the information and materials described in this section. We currently have 2 approved accreditation organizations and no pending applications. Since the PRA applies only to ICRs affecting 10 or more persons (entities), this requirement is exempt from the PRAs as it affects only 2 entities.

Section 410.142(j) states that at least 6 months before the expiration of CMS' approval and recognition of the accreditation organization's program, an accreditation organization must request from CMS continued approval and recognition. Since the PRA applies only to ICRs affecting 10 or more persons (entities), this requirement is exempt from the PRAs as it affects only 2 entities.

Section 410.143 Requirements for approved accreditation organizations.
Section 410.143(a)(1) states that an accreditation organization approved by CMS must provide to CMS in a written form and on a monthly basis all of the information required by § 410.143(a)(1)(i) through (a)(1)(iv). Since the PRA applies only to ICRs affecting 10 or more persons (entities), this requirement is exempt from the PRAS as it affects only 2 entities.

Section 410.143(a)(2) states that within 30 days of a change in the CMS standards, an accreditation organization submit to CMS its organization's plan to alter its standards to conform to the revised CMS standards (including a crosswalk between the revised CMS standards and the organization's revised standards) within the timeframes for adopting the revised CMS standards specified in the notification of change it receives from CMS. Since the PRA applies only to ICRs affecting 10 or more persons (entities), this requirement is exempt from the PRAS as it affects only 2 entities.

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

The burden associated with this requirement is the time and effort for an entity to document and maintain the information described above. It is estimated these requirements will take each entity 8 hours. There are approximately 5,327 entities for a total annual burden of 42,616 hours. This is an increase from the previously reported 16,064 hours based on 2,008 entities. The change is based on the increase in the number of entities from 2,008 to 5,327. No comments were received on the burden of this provision.

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

The burden associated with this requirement is captured in §410.141(b) above. No comments were received on the burden of this provision.

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

We believe the burden associated with 410.144(a)(7)(v) 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 CMS 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 5,327 entities for a total annual burden of 15,981 hours, this is an increase of 9,957 over the 6,024 hours reported

previously. The change is based on the increase in the number of entities from 2,008 to 5,327.

Section 410.144(a)(10) states that each deemed entity approved using CMS quality standards must have an agreement with a PRO(now QIO), which has a contract with CMS to perform quality assurance reviews. At a minimum, the agreement must allow the PRO/QIO access to beneficiary or group therapy records, and binds an approved entity to comply with corrective actions or to participate in quality improvement projects that the PRO/QIO determines are necessary, or if a program elects not to participate in a QIO 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 QIO quality improvement project.

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

We estimate that it will take an entity 5 minutes on an annual basis to maintain the necessary documentation. Some comments were received regarding this provision that having an agreement with a QIO was overly burdensome. However, if entities are using the National Standards for Diabetes Self-Management Education Programs, which currently all recognized programs are using, then there is no burden.

Only programs accredited using CMS quality standards must have an agreement with a PRO/QIO. We do not anticipate that in future years the reported burden will apply because no accreditation organizations are using the CMS quality standards.

Section 410.145 Requirements for entities.

Section 410.145(a)(2)(i thru ii) states that an entity may be deemed to meet the CMS quality standards described in §410.144 if the entity has (i) submitted necessary documentation and is fully accredited (and periodically reaccredited by an organization approved by CMS under §410.142. (ii) The entity is not accredited by an organization that owns or controls the entity. The burden associated with meeting these requirements is captured in §410.141(e)(3). Some comments were received that meeting quality standards by becoming accredited was burdensome. However, Congress mandated in the statute that quality standards be met by programs receiving payment from Medicare. Therefore, the requirement has not been changed.

Section 410.145(b)(1-4) states that an entity may be deemed to meet the CMS quality standards described in §410.144(a) if the entity--(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an organization approved by CMS 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 CMS (or its

agent) to validate its approved organization's accreditation process. (3) Authorizes its approved organization to release to CMS a copy of its most recent accreditation evaluation, and any accreditation-related information that CMS may require. (4) At a minimum, allows the QIO (under a contract with CMS) access to beneficiary or group training records. 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 5,327 respondents for a total of 443.9 hours. This is an increase from 2,008 respondents with a total of 167.3 hours. The change is based on the increase in the number of entities from 2,008 to 5,327.

Section 410.146, Diabetes Outcome Measurements, states that an entity must 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, 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 that beneficiary participation in training sessions must be documented on attendance sheets. While this ICR is subject to the PRA, we have not accounted for the burden of this ICR because we believe the burden associated with this ICR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We solicited comment on our preliminary conclusion that this activity would be done in the normal course of business and, thus, would have no burden for providers. We received no comments on the burden of this provision.

The total burden for all of the above information collection requirements is 197,542.9 hours. It is estimated that it will cost $$3,950,858(197,542.9X $20 per hour) to collect this information. Additional costs of $$632,500(500 new entities X $1,265/entity for accreditation) added to the cost of $3,950,858for a total of $ $4,583,358is the updated total cost to collect this information. This $4,583,358 total cost is an increase of $2,482,978 (the difference between the costs cited in the last report of $2,100,380 and the costs in this report of $4,583,358). This

increase is due to the increase in the number of entities from 2,008 to 5,327 and includes the cost per 500 entities for accreditation ($1,265 per accreditation).

13. Capital Costs (Maintenance of Capital Costs)
There are no capital costs.

14. Cost to Federal Government
There are no costs to the Federal Government.

15. Program or Burden Changes
The information provided in the background section of the summary statement has been updated to reflect more recent data and statistics regarding diabetes and the number of people effective, national estimates, and general information. Throughout the rest of the document, the numbers are updated to show the increase in programs and sites through our accrediting organizations, ADA and AADE.

There is an increase of 109,023.9 hours (from the previous burden estimated to be 88,519 to 197,542.9 hours). This is due to the increase in the number of accredited entities from 2,008 to 5,327. There is also the cost for 500 new entities for accreditation ($1,265 per accreditation) outlined in #12 above.

16. Publication and Tabulation Dates
There are no publication and tabulation dates.

17. Expiration Date
These information collection requirements do not lend themselves to an expiration date.

18. Certification Statement
There are no exceptions to the certification statement.

Further Explanation of Burden Requests & Terms of Clearance

In the paperwork clearance received May 9, 2001, OMB stated that they wished CMS (then HCFA) to base its estimates upon State experience. Unfortunately, that information was not available and would have not been comparable to the national accreditation procedure. We believe that it would have greatly understated the burden imposed by a national accreditation organization. To our knowledge, there are no state accreditation organizations accrediting diabetes education programs at this time.

The natural question from that information is, "Why did CMS chose national accreditation organizations?" Our legal counsel informed us during the regulation development process that we were only allowed to use national accreditation organizations. Our sole authority for using accreditation organizations comes from Section 1865 of the Social Security Act.

OMB also noted they did not agree with our determination that burdens due to the accreditation process are not Medicare burdens. Therefore, we are adjusting our burden estimates to include those imposed by the current accreditation organizations based on information we have received from the American Diabetes Association and American Association of Diabetes Educators.