Supporting Statement for Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations

A. Background

Among Americans aged 65 and older, 11.2 million persons (25.9 percent of this group) are estimated to have diabetes. (Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014) 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 National Diabetes Statistics Report. (2014) Retrieved from https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf.

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. Blood glucose control reduces the risk of blindness, lower extremity amputations, heart disease and stroke. (Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.). 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). A literature review documented in The Diabetes Educator states, " that the benefits associated with education on self-management and lifestyle modification for people with diabetes are positive and outweigh the costs associated with the intervention". (http://tde.sagepub.com/cgi/content/abstract/35/1/72) It is imperative to address the need of self-management education for diabetes and improve the quality of overall quality of care provided to the diabetic community.

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, section 4105, detailed the congressional requirements for coverage, payment, and outcome measures. One of the goals of the BBA were to empower Medicare beneficiaries to manage and control their conditions. The Expanded Coverage for Diabetes Outpatient

Self-Management Training and Diabetes Outcome Measures Rule was enacted due to the BBA. The Expanded Coverage for Diabetes Outpatient Self-Management Training and Diabetes Outcome Measures Rule provides 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.

B. Justification

1. Need and Legal Basis

Section 4105(a) of the Balanced Budget Act of 1997(BBA) (Pub. L. 105-33 was enacted on August 5, 1997) provides Medicare coverage for Diabetes Self-Management Training (DSMT) in outpatient settings. A proposed rule (64 FR 6827) was published in the Federal Register on February 11, 1999 to implement the BBA provisions addressing the coverage, payment, quality standards, and accreditation requirements for DSMT. The final rule (65 FR 83130) was published on December 29, 2000.

Section 1861(qq) of the Social Security Act (the Act) provides the statutory authority to regulate Medicare outpatient coverage of DSMT services. This section also permits DSMT programs to be deemed to have met Medicare regulatory quality standards if they are accredited by an organization approved by CMS. Section 1865(b) of the Act provides the authority whereby the Secretary may find that a national accrediting organization's standards meet or exceed all of the applicable Medicare conditions or requirements for the health care entity. Where the Secretary approves a national accrediting organization whose accredited entities furnish diabetes services under §410.145(a), these entities are deemed to meet the DSMT requirements found at 42 CFR 410.140 through 146. The specific requirements that approved national accreditation organizations must meet are found at 42 CFR 410.143.

There are the two national accreditation organizations that are approved to deem entities furnishing DSMT as meeting the Medicare requirements. The American Diabetes Association (ADA) and American Association Diabetes Education (AADE) are approved for a six-year deeming authority term. The two accreditation organizations are required to submit a collection of materials to CMS for each deeming authority term. The details of materials required for

submission are stated in attachment 1A titled, *"Information Collected from DSMT AO's and Entities"* CFR section 410.143(b) specifies that CMS, or its agent, performs oversight activities to ensure that an approved accreditation organization and the entities the organization accredits continue to meet the NSDSMES quality standards as described in §410.144

2. Information Users

The knowledge gained by diabetic Medicare beneficiaries during Outpatient Self-Management Training will support their efforts in making the necessary lifestyle changes to decrease the complications and comorbidities of diabetes. Outcome measures mandated by the Balanced Budget Act of 1997, monitors the 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 . The outcome measures will provide an assessment of the effectiveness of the care provided to Medicare beneficiaries and the oversight of entities provided by the accreditation organizations.

The outcome measures may be periodically reported by the Secretary to the Congress for the purpose of making recommendations to modify coverage under the Medicare program.

CMS provides external oversight of the DSMT accreditation organizations and the entities that are accredited to ensure that federal requirements are met when providing DSMT services. Through a validation mechanism, manual charts audits are performed and results are reported back to CMS for documentation of the outcome measures.

3. Improved Information Technology

The collection of information is completed by manual chart audits. These information collection requirements (ICR) do not lend themselves to improved information technology.

4. Duplication of Similar Information

There is no duplication of information.

5. Small Businesses

Accredited entities must complete the information collection requirement for DSMT under 410.145(a)(1)(i); however there is no impact on small businesses

The time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

6. Less Frequent Collection

An approved entity must systematically collect and record outcome measures for diabetics receiving training under the Expanded Coverage for Diabetes Outpatient Self-Management Training and Diabetes Outcome Measures rule. All entities must provide the assessment data at least quarterly to be compliant with §410.146. The consequence for an entity not complying with the collection of data for outcome measurement would be the loss of accreditation and Medicare payments for their Diabetes Education program.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register Notice published on July 22, 2016 (81 FR 47807). There were no public comments received.

The 30-day Federal Register Notice published on September 26, 2016 (81 FR 66031). There were no public comments received.

The Expanded Coverage for Diabetes Outpatient Self-Management Training and Diabetes Outcome Measures rule 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
CMS does not collect data. Data collection and validation is completed by the contractor. All entities that are chosen to participate in the chart audits have been asked to remove all patient identifier information for privacy purposes prior to submitting charts to the contractor.

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

12. Burden Estimate (Total Hours & Wages)
Assumptions and estimates used throughout this burden section:

# of entries nationwide	5,663	
Clinical Administrator	$26.16	$52.32 (fringe benefits)
Administrative Assistant	$16.83	$33.66 (fringe benefits)
Internist	$74.55	$149.10 (fringe benefits)

Our estimates of time and salary are based on data obtained from the U.S Bureau of Labor Statistics. This information can be located at https://www.bls.gov/oes/current/naics5_621990.htm#43-0000

The Outpatient Diabetes Self-Management Training (DSMT) Program has two (2) approved accreditation organizations (entities) and 5,663 deemed providers as of February 2017 (entities). We believe the Accreditation Organizations should be exempt from the PRA Burden Estimation because we have less than ten (10) entities. The two Accreditation Organizations, ADA and AADE, are required to provide CMS with a collection of information and materials necessary to review their accreditation program every four years, as set forth in § 410.142. Deemed entities are required to provide outcome measurement data and meet the quality standards established by *The National Standards for Diabetes Self-Management Education Programs* (NSDSMEP). The NSDSMEP standards are developed a workgroup of professional peers in the diabetic community. The NSDSMEP standards are listed on attachment 1A in addition to the reference document at https://doi.org/10.2337/dc12-1707 .

Outcome measurement data yielded from NSDSMEP must be available upon request to the Quality Improvement Organization for audits. A comparison of collected data from the accreditation organization and the entities is listed is the in attachment 1A titled, *Information Collected from DSMT AO's and Entities.*

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.

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 follow-up training must address.

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.

We are estimating each provider to spend no more than fifteen (15) minutes completing assessments, reviewing each beneficiary's plan of care, and all documentation during provider visits. There are currently 5663 entities, with an average of 338 beneficiaries enrolled nationwide. The estimated burden hours is 478,524 hours (1,914,094 Total responses x .25 min). The estimated burden cost for a General Internist to complete an assessment, review the plan of care, and document during a providers visit to be $71,347,928 (478,524 burden hours x $149.10).

Section 410.141(e) requires that an entity is accredited by an accreditation organization approved by CMS under §410.142 and to meet one of the sets of quality standards described in §410.146. 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 5,663 entities 54 hours to complete these requirements every 4 years, for an annual burden of 13.5 hours. The estimated time for document submission was submitted by the two

accreditation organizations. Therefore, the annual burden imposed for submission of the information is estimated to be 76,451 hours. Information collection for this requirement submitted by an office administrative assistant would have an annual cost burden of $454.41 ($33.66 X 13.5 hours) and $706.32 annually ($52.32 X 13.5 hours) for a clinic administrator.

In addition, we are adding burden based on the collection of 3 months of data required by CMS to be collected by the accreditation organizations. 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 33,978 hours (.5 hour X 12 weeks X 5,663 entities) for all entities. The total for this requirement is now 110,428 hours (76,451 + 33,978).

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 5,663 entities for a total annual burden of 45,304 hours. We expect this requirement to be fulfilled by the entities clinic administrators, yielding a burden cost of $ 418.56 ($52.32 X 8 hours).

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

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 are estimating each provider to spend no more than fifteen (15) minutes completing assessments, reviewing each beneficiary's plan of care, and all documentation during provider visits. There are currently 5663 entities, with an average of 338 beneficiaries enrolled nationwide. The estimated burden hours is 478,524 hours (1,914,094 Total responses x .25 min). The estimated burden cost for a General Internist to complete an assessment, review the plan of care, and document during a providers visit to be $71,347,928 (478,524 burden hours x $149.10).

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. There are approximately 5,663 entities for a total annual burden of 16,989 hours, yielding a cost burden for an administrative assistant of $100.98 ($33.66 X 3 hours).

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. 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).

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 5,663 respondents for a total of 472 hours.

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.

The total annual burden hours are 651,718 and the cost is $71,612,731.

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
An increase of 449,428 hours (from 202,290 hours to 651,718 annual hours). An increase in cost to $71,347,875 (from $264,856 to $71,612,731) This increase is due to the added documentation of burden for DSMT providers to complete assessments, document and update care plans, provide DSMT education, and forward required documentation to collaborating providers. There were also 208 new entities since the last PRA submission.

The average number of participants per program nationally was provided by the accreditation organizations. The number of average participants increased the cost and time burden for entities providing DSMT services.

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

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

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