**Supporting Statement – Part A**

Evaluation of Practice Models for Dual Eligibles and Medicare Beneficiaries with Serious Chronic Conditions

Supporting Statement For Paperwork Reduction Act Submissions

**A. Background**

The Affordable Care Act (ACA) established the Federal Coordinated Health Care Office (FCHCO) to more effectively integrate benefits under Medicare and Medicaid and improve coordination between the federal government and states for dual eligibles (duals), those individuals with both Medicare and Medicaid coverage. Duals are among the most vulnerable beneficiaries – most face multiple and severe chronic conditions that require complex and intense care – and must navigate two separate health care programs that often lead to fragmented, inefficient, and costly care. This project will explore patterns of care and best practice models for duals, other Medicare beneficiaries with complex health needs, and those participating in the Program for All-Inclusive Care for the Elderly (PACE). Findings from this qualitative research will provide the FCHCO and the newly established Center for Medicare and Medicaid Innovation (CMI) with an improved understanding of the potential reasons and range of issues associated with variations in practice patterns across the country and the impact they may have on the cost and quality of care delivery. In this capacity, the information gleaned from this study will inform the pressing work of the FCHCO and CMI, supporting follow-up studies and demonstrations to further test promising methods for improving care coordination for duals, as well as other provisions outlined in the ACA regarding coordination of care for beneficiaries with serious chronic conditions.

This study will comprise qualitative information-gathering through open-ended discussions with a wide variety of providers, local health care leaders, patient advocates, quality improvement specialists, and professionals involved in health care delivery to include those implementing care coordination initiatives. These discussions will be held in person during site visits to 16 hospital referral regions (HRRs) that vary in cost and quality to help determine factors associated with that variation. The researchers will have discussions with individuals and groups representing approximately 10 to 15 different organizations in each HRR. The interviews will take place with either individuals or small groups of professionals representing the key health care leaders and market players, as well as those involved in delivering services to duals. While these individuals and the organizations are not a randomly selected sample, they will provide important insights into the possible reasons for variations of cost and quality that may not become as apparent through quantitative analysis. The Centers for Medicare & Medicaid Services (CMS) will select HRRs to reflect a mix of duals enrollment levels, severe chronic illness prevalence rates, and diversity in geography, urban/rural balance, and socio-economic considerations through a process described in more detail in supporting statement B of this application. The range and variety of HRRs to be visited will help expand policy makers’ understanding of the potential forces associated with practice pattern variation and the extent to which there may be common patterns driving this variation across different HRRs. Prior to visiting each HRR, the research team will conduct pre-site research to gain a better understanding of the unique composition of the region to be visited, taking into consideration the nature of the area’s provider networks, health systems, community service organizations, payer mix, and recently publicized health system challenges and initiatives. Broad topic areas that will be addressed during these discussions will include:

* History, goals and objectives of care models/interventions in the HRR;
* Community-, provider-, patient-level factors associated with higher/lower quality, costs, outcomes;
* Barriers/opportunities to participation in models that improve care; and
* Role of health information technology and personal health records in interventions.

In addition to market reports and literature and Web-based searches conducted about recent activities in the health arena for the selected HRRs, the research team will rely on publicly available resources and government-based contacts to develop a background understanding of each HRR and key stakeholders. The contacts made prior to PRA approval will include individuals at CMS regional offices and the contracting officers responsible for the Quality Improvement Organizations overseeing the HRRs in question. The information gathered will help the research team formulate a plan of approach for each HRR tailored to the make up of that HRR’s composition. The targeted organizations will include providers, payers, community-based organizations, and government agencies such as state Medicaid program staff. However, additional detail may be needed to fill in information gaps for any one of these categories and confirm the accuracy of the initial list of key organizations and significant players within the HRR. Therefore, a limited number of telephone-based discussions with individuals who have local-area knowledge will likely be required prior to the site visits. These discussions will help confirm that the appropriate site visit respondents have been identified and supplement basic background information on the HRR not otherwise available through public sources and government staff.

In-person discussions during the site visits will focus on understanding programs and initiatives aimed at the key populations of interest (duals, Medicare beneficiaries with severe chronic conditions, and those in the last year of life), as well as identifying potential factors in the HRR related to documented trends in care patterns and associated cost and quality outcomes. No personally identifying information on patients or any other individuals will be collected or discussed at any time. Notes from each discussion will be summarized and entered electronically into an Access database (one record per interview) and then reviewed for themes and trends to describe:

* Similarities and differences in the care provided among and across HRRs;
* Experience and challenges serving Medicare beneficiaries and dually eligible individuals who have serious chronic conditions to identify best practices which merit further exploration; and
* Detailed findings of the two site visits focusing on PACE programs along with identifying best practices and barriers for PACE models.

**B. Justification**

1 . Need and Legal Basis

Section 2602(d)(2) of the ACA (P.L. 111-148) mandates that CMS’s new FCHCO effectively integrate benefits under Medicare and Medicaid. To accomplish this, CMS requires a better understanding of the issues and challenges associated with coordinating and managing care under the Medicare and Medicaid programs, as well as the reasons for significant variation in cost and quality of services provided to duals and those duals and Medicare beneficiaries with serious chronic illness. While CMS has conducted a number of internal quantitative analyses to examine the variation in costs and quality of services, documenting data patterns, these analyses have been insufficient in pinpointing the driving factors behind such variations. In particular, the data do not capture any nuances related to practice patterns, nor do they identify the best practices in care coordination, which are better explored and understood through qualitative research. The findings from this research will guide future program and policy development at CMS for all Medicare beneficiaries with serious chronic illness. In particular, under Section 2602 (e) of ACA, the Secretary is required to submit an annual report to the Congress, as part of the budget transmittal, with recommendations for legislation to improve care coordination and benefits for duals. An aggressive schedule for this research is needed in order to inform policy development during the summer of 2011 in preparation for the annual report.

CMS’s Office of Policy contracted L&M Policy Research, LLC, beginning Sept. 27, 2010, to conduct this qualitative study in 16 HRRs. The research team has been tasked to complete all of the data-collection activities by the end of April 2011 so a final report can be submitted to CMS by mid-June 2011. This aggressive timeframe calls for the team to be in the field conducting the site visits by January 2011 to complete the site visits to 16 different HRRs and meet the report deadline. These visits will be three to four days in length each, involve 10 to 15 different organizations, potentially including multiple individuals during each discussion. The individuals will speak from widely different perspectives on the variation in costs, quality, and utilization in their organization(s) and the HRR, providing, to the extent possible, perspective and further insight on these issues within the HRR.

Due to the urgency and the short timeframes associated with this requirement, CMS does not have sufficient time to follow the Paperwork Reduction Act (PRA) notice and comment periods associated with the normal PRA approval process. An emergency review and approval has therefore been requested for the information collection request so that the team may begin field work as soon as possible but no later than by mid-January 2011.

2. Information Users

Findings from this qualitative research will be used to inform the work of CMS’s Office of Policy (OP), FCHCO and CMI to support initiatives and policies that improve care coordination for duals, as well as other priorities set forth in the ACA to coordinate care for vulnerable beneficiaries such as those with serious chronic conditions. This research is exploratory in nature and, thus, the findings are meant to aid the OP and FCHCO as they take steps to identify promising practices related to the cost and quality of care delivery. The qualitative nature of the study will aid in identifying the range of issues and the nuances contributing to variations in practice patterns among diverse regions in the country. In doing so, the information acquired from this study will serve as a baseline for future studies and demonstrations designed to improve programs and policies related to care coordination for duals and those with multiple chronic conditions.

3. Use of Information Technology

Information will be collected through telephone-based or in-person discussions. No automatic, electronic, mechanical, or other forms of information technology will be used to collect information from respondents. The collection of information therefore does not require a signature from respondents. Notes from each discussion will be summarized and entered electronically into an Access database (one record per interview).

4. Duplication of Efforts

CMS does not have information on hand that explains the reasons for variation in the delivery of health services to this vulnerable population. The variation may be better understood through open-ended discussions with local area stakeholders about the complex combination of factors in place in a given HRR. The nuanced information about a large and complex set of variables is not readily or publicly available at this time and can only be obtained through focused, one-on-one or small group interviews. This information gathering will not duplicate any other information-collection effort.

5. Small Businesses

Several of the individuals to be interviewed will likely be staff members of small businesses (e.g. health care providers, community organizations involved in care coordination for the populations of interest). They will be asked to voluntarily spend no more than one to one-and-a-half hours in telephone-based or in-person discussions. It is not anticipated that this work will have an impact on small businesses.

6. Less Frequent Collection

Information to be collected for this study will be collected once, at minimal burden to the respondents, each of whom will be participating on a voluntary basis. Failure to collect this information will prevent CMS from gaining important foundational knowledge about the issues surrounding variation in health care utilization and care coordination for vulnerable populations not otherwise available through existing data and information sources, thereby hindering its future policy work related to better integrating services provided to the dually eligible and especially vulnerable Medicare beneficiaries. Failure to collect this information will therefore hinder the work of CMS’s Office of Policy and the FCHCO as established by the ACA.

7. Special Circumstances

There are no special circumstances relevant to this information collection.

8. Federal Register/Outside Consultation

Not applicable.

9. Payments/Gifts to Respondents

There is no provision for any payment or gift to respondents associated with this reporting requirement.

10. Confidentiality

No personally identifying information on patients will be discussed or collected at any time. Furthermore, none of the interviews will be with patients or beneficiaries but, rather, with organization representatives.

11. Sensitive Questions

No questions of a sensitive nature will be asked.

12. Burden Estimates (Hours & Wages)

The research will primarily comprise in-person discussions with individuals or groups within 10 to 15 different organizations in each of 16 different HRRs around the country. Each HRR is likely to include a different combination of individuals to be interviewed, including top-level executives and clinicians, managers, various health care provider types, and front-line staff. Depending on the participating organization, a discussion may involve one individual or a small group (e.g. three to four individuals), for a maximum of 45 individuals for each site (assumes each discussion will be with three people on average). These discussions will be approximately one to one-and-a-half hours in length, depending on the number of individuals involved, and occur only once.

As noted in the background section, the research team will conduct a limited set of pre-site telephone-based discussions with HRR-level experts to confirm the proposed set of site visit discussants and supplement gaps in background understanding of the HRR not otherwise available to the research team via the sources listed in the background section, to include government staff familiar with the HRRs in question. These pre-site discussions are expected to be conducted with between three and seven individuals in each of the 16 HRRs depending on the outstanding questions remaining about the HRR, key players, and the initially drafted organization/discussant list prior to PRA approval. Pre-site discussions will be used to help the study team ensure it has identified the best possible combination of organizations and discussants on its list for interviews and thereby make efficient use of its time in the field. These pre-site interviews are expected to take approximately 20 minutes each. Table 1 shows the estimated, one-time, annual burden hours and the estimated, one-time, annual cost burden for the respondents’ time to participate in the project. Thus, annualizing the maximum estimated burden for the pre-site and site visit discussions, combined over the number of respondents aggregates to 1,114 hours in total, represents a one-time projected cost burden of $50,008.

**Table 1. Estimated Cost Burden for In-Person Discussions**

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| **Data Collection Mode** | **Number of Respondents** | **Burden Hours per Respondent** | **Total Burden Hours** | **Average Hourly Wage Rate** | **Total Maximum Cost Burden** |
| Pre-site Discussions | 112  (7 individuals across 16 sites) | 0.3 | 33.6 | $54.451 | $1,829.52 |
| In-person Discussions | 720  (45 individuals across 16 sites) | 1.5 | 1,080 | $44.612 | $48,178.80 |
| **TOTAL** | **832**  **(52 individuals across 16 sites)** | N/A | **1,113.6** | N/A | **$50,008.32** |
| 1 Based on the mean hourly wage estimates for health care and social assistance chief executives and state government chief executives from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. The research team anticipates speaking with up to three chief executives (health care leaders) and four state government official across 16 sites.  2 Based on the mean hourly wage estimates for select Sector 62, Health Care and Social Assistance occupations (chief executives, medical and health services managers, social and community service managers, and health care practitioner and technical occupations) from the May 2009 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. The research team estimates that of the up to 45 individuals interviewed within each HRR, it will speak to nine in each of the above-listed occupational categories. | | | | | |

13. Capital Costs

There are no capital costs associated with this collection of information.

14. Cost to Federal Government

CMS has contracted with L&M Policy Research to conduct the necessary qualitative research and provide a written summary report describing its findings. This one-time total cost for the labor and travel, including four- to five-day visits to 16 HRRs across the U.S., is $540,762.00.

15. Changes to Burden

This is a new data-collection activity.

16. Publication/Tabulation Dates

The resulting report from this qualitative information collection will be for internal CMS use only and not published.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the statements in the certification form.