Supporting Statement – Part B

Collections of Information Employing Statistical Methods

1. *Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, state and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.*

Across the United States, there is wide variation in the number and intensity of services provided to Medicare beneficiaries, and while there are large variations in the utilization of care among beneficiaries – especially those with chronic illnesses – this does not always equate with better health outcomes. As part of the Federal Coordinated Health Care Office (FCHCO)'s efforts to reduce the fragmentation of services provided to beneficiaries, the Centers for Medicare & Medicaid Services (CMS) has begun studying variations in costs and quality across the country, specifically focusing on those dually eligible for Medicare and Medicaid (duals), those with serious and/or multiple chronic conditions, and beneficiaries who may require palliative or hospice care. Generally, these populations have more complex care needs, are more financially vulnerable and, as a result, tend to require more frequent services from a large array of providers in addition to better care coordination. Because such significant needs are often addressed through an increasingly fragmented delivery system where providers are often not financially or logically aligned to provide continuity of care, CMS considers it a high priority to first generally understand the factors and practices driving variations in the cost and quality of care for these individuals and, second, ultimately determine ways to improve that care through policy changes. This study is the first step in addressing the former need.

Rationale for selecting hospital referral regions

CMS chose hospital referral regions (HRRs), developed by researchers at Dartmouth University, as an emerging best practice for measuring geographic variations. Dartmouth researchers defined HRRs by documenting where patients were referred for major cardiovascular surgical procedures and neurosurgery. The researchers examined each hospital service area to determine where most of its residents went for these services, so it could take on the characteristics of a "medical marketplace" of services and patients. This resulted in the aggregation of 306 HRRs, each of which had at least one city where both major cardiovascular surgical procedures and neurosurgery were performed. Maps were used to ensure that the small number of "orphan" hospital service areas – those surrounded by hospital service areas allocated to a different HRR – were reassigned, in almost all cases, to ensure geographic contiguity. HRRs were pooled with neighbors if their populations were less than 120,000 or if less than 65 percent of their residents' hospitalizations occurred within the region. The regions sometimes cross state boundaries, and they were named for the hospital service area containing the referral hospital or hospitals most often used by

residents of the region.

CMS selected seven low-cost and high-quality HRRs and seven high-cost and low-quality HRRs, ensuring each HRR contained a mix of duals, especially those with serious chronic conditions and who die in a given year. These data on quality and cost are based on the information from the Dartmouth researchers and have been enhanced with additional quality and utilization-related data with CMS. CMS also has utilization profiles available that are specific to each HRR, which will guide discussions in those areas.

In addition to the 14 HRRs, another two HRRs were selected for guided discussions with health care leaders regarding PACE programs (Programs for All-Inclusive Care for the Elderly), which are programs designed to provide long-term care services and supports to individuals who need skilled nursing care and strive to remain at home. The L&M research team will identify best practices and barriers for interesting models of PACE programs in terms of their ability to improve quality and lower costs for the populations they serve.

Identifying key stakeholders for qualitative interviews

To provide CMS with a basic foundation of knowledge related to patters of care and best practices associated with these population groups, L&M will conduct interviews with key stakeholders during site visits to 16 HRRs across the country. With the goals of the project in mind, the research team has identified four main groups of stakeholders from which it will ultimately seek input: providers, including health systems, hospitals, large primary care practices, specialty practices, community health centers, skilled nursing facilities, home health care providers, and hospices; purchasers, including Medicare Advantage plans, Special Needs Plans (SNPs), and other payers; community-based organizations, including area agencies on aging, consumer advocacy organizations, and state health insurance assistance programs; and state Medicaid offices. Representatives from each of these groups will provide a different perspective on the regional health care system and, when taken together, will depict a larger picture of the factors driving care delivery. Certainly, these individuals will not be able to identify every nuance associated with practice patterns but, if selected prudently, will give the research team a flavor of the forces at play in each region so that it may effectively synthesize and analyze trends across the regions.

In order to structure the site visits and identify the most relevant stakeholders in each HRR, the research team will engage in rigorous pre-site research. A lead senior researcher from the L&M team has been assigned to each site and is responsible for coordinating the preparatory efforts related to each. The pre-site research incorporates four components: 1.) a market research report, 2.) a literature search, 3.) a Web-based search to confirm market research or fill in any remaining gaps, and 4.) discussions with representatives from quality improvement organizations (QIOs).

Through a market research service provided by Thomson Reuters the team will request reports on 14 of the HRRs (excluding the PACE sites) by the individual zip codes that make up each of the regions. These reports will be tailored to the needs of the team and will likely include: a demographic profile, a map of the service area showing all of the hospitals, a bar graph with the Medicare market share by facility, a chart with insurance coverage estimates, a payer profile that includes the largest health plans in the HRR (preferably by Medicare enrollment), and a profile of

the market volume by physician office (defined by Medicare patients if possible but only including group practices).

The team will also submit a request through another service at Thomson Reuters that will produce a literature report for the team, compiling major relevant characteristics of each HRR's health care delivery system. Approximately 10 to 30 pages in length (depending on the region), the report will provide the team a picture of the overall health care market – including service area and profiles of major health care facilities – in addition to a list of major distinctions attributed to the HRR and citations for major articles and reports previously published on the health care system.

In addition to the market research reports and the literature searches, two to three people from the L&M study team will conduct a Web-based search on each HRR to fill in any gaps and confirm the information already in hand. Such information will be compiled into a previously developed "fact sheet" template – vetted with the greater team – that will also be circulated to the site visit teams when completed. The team will use a range of sources for these searches – from information accumulated by the Institute for Healthcare Improvement (IHI) when applicable, the Beacon profile, articles lifted from general internet searches.

In conjunction with these searches, each team leader will then identify and speak with CMS regional office staff and QIO representatives from each HRR to confirm the accuracy of the information gathered and supplement it with potential names of interviewees. Key informants will be asked about characteristics of a given HRR that may be especially relevant to local provider practices and networks, culture, key initiatives, regulatory issues, and best practices and important lessons learned.

These combined efforts will yield an initial list of potential interviewees for each site that the team leader will further vet with individuals in the targeted HRR. The team leaders will conduct brief telephone discussions with health care leaders and discuss whether the list of potential interviewees is appropriate given the research goals of the project. Following OMB approval of discussion guides and screening questions, if team leaders conclude additional vetting of the interviewee lists is necessary, they will further verify the information gathered and refine the interviewee list based on information gathered from more in-depth screening within a specific HRR. Further vetting conducted following OMB approval will incorporate a screening tool (submitted as part of the PRA approval process). Pre-site discussions will be used to help the study team make efficient use of its time in the field and are expected to take approximately 20 minutes each. The team will take all of this information into consideration before finalizing a list of HRR interviewees and subsequently sending out invitations to the site visit discussions.

2. *Describe the procedures for the collection of information including:*

> - *Statistical methodology for stratification and sample selection,*
> - *Estimation procedure,*
> - *Degree of accuracy needed for the purpose described in the justification,*
> - *Unusual problems requiring specialized sampling procedures, and*
> - *Any use of periodic (less frequent than annual) data collection cycles to reduce burden.*

The site visit team leaders will review and refine the preparatory correspondence and screening tools to be used in confirming site visit interviews and tailor them to the selected organizations and individuals. With the assistance of at least two additional staff members, site visit team leaders will make all the necessary logistical arrangements to include up to 20 interviews per HRR, with individuals or groups representing between 10 and 15 organizations. More specifically, the PACE site visits will include discussions with individuals representing the following areas: executive management (administrator, chief medical officer, chief financial officer, chief operating officer), quality improvement, clinical operations/nurse management, care management and discharge planning, social and behavioral services, and member services. The other 14 HRRs will likely include a different combination of individuals to be interviewed, including but not limited to: 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 discussions will be with three people on average). These discussions will be approximately one to one-and-a-half hours in length and occur only once.

The site visits will be scheduled over four to five days to facilitate interviews with individuals from multiple organizations and providers located across the HRR. To fully explore variations in care delivered to the beneficiary groups of focus, the team developed a broad discussion guide (part of this package submitted for OMB review) – in conjunction with CMS – divided into thematic areas from which the team will pull questions more specifically targeted at the individual stakeholders it is interviewing. Thematic areas will broadly include but are not limited to: organization background and operations, factors impacting variations in cost and quality, and patient population and care delivery patterns – specifically as they relate to duals and those with chronic conditions. Whenever possible, at least two team members will be present during each interview to facilitate comprehensive note-taking, except when splitting a three-person team into two groups facilitates the gathering of more vital and otherwise unobtainable information. All team members will have laptops with electronic protocol templates – developed prior to commencing the 16 visits – for data collection/note taking on site. In cases where it is not feasible to conduct in-person discussions while on site (i.e. when a state Medicaid office is located far outside the parameters of the targeted HRR), the team will conduct its discussions over the phone – either during the time spent on site or following the trip. The team will use the same discussion guide and note-taking template, however.

During the last afternoon of the site visit, the team members will meet internally to discuss overarching findings and begin to synthesize some of the more prevalent themes. Following the visit, 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.

These team members will then convene with the larger L&M team during a weekly internal call to further share any major trends. Team leaders will present initial findings from each site visit to CMS during bi-weekly meetings throughout the site visit period and provide two- to three-page written summaries within two weeks of each site visit.

3. *Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield 'reliable' data that can be generalized to the universe studied.*

As part of the information gleaned from conversations with local-area experts during the pre-site research, the study team will identify key health care leaders, stakeholders, and organizations to be included in an initial list of potential discussants or respondents. Once the initial list has been created, the research team will then contact these individuals to further clarify their existing role in the HRRs, determine if they are the appropriate candidate for the research, and develop a final discussant list. Ideally, the team will have the opportunity to interview 10 to 15 organizations in each the HRRs, which will include a combination of individuals.

Given the range of discussant types, many of whom will have competing responsibilities and limited scheduling availability during each site visit, it is likely that some of the identified discussants will not be available to participate in the discussions. The team has developed a number of processes to help maximize the response rate, however. These processes include: sending the interview candidates an official letter from the sponsoring agency (CMS) that briefly describes the purpose and importance of the project and requests their assistance in the research; when possible, having senior researchers – some of whom may be known by the potential interviewees due to their extensive experience in the research topic – make the initial calls to the discussant, particularly those who are more senior or top-level in their organization, to request their participation; and conducting regular follow up-calls with the potential discussants to confirm their participation. In addition, the team will offer potential discussants the opportunity to meet after regular business hours – either early in the morning or during the evening – to maximize the discussants' availability. Prior to conducting the site visit, the team will develop a final schedule of times and places for the meetings with the organizations. In the event that a previously identified organization is unable to participate, the team will return to its initial draft list of potential discussants to draw replacement candidates from that list.

Given that all of the potential discussants will be contacted by phone prior to finalizing the site schedule, and along with the above-mentioned processes, the research team believes the non-response rate will be minimal. It is always possible, however, that potential discussants will not be able or willing to participate. In order to account for these potential non-responses, the team has included a wide range and type of potential discussants as well as a large enough overall target sample of interviewees to minimize any non-response bias. For example, the team intends to speak with 10 to 15 organizations per HRR – but will not include more than three people per

organization. If, for example, one individual is unable to attend, the team will still be able to conduct the interview with other members of that organization. Ultimately, due to the qualitative, exploratory nature of the research, the study team believes the results will not be compromised as a result of individuals being unable to participate.

4. *Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.*

Following the completion of all the site visits, the research team will synthesize the site visit notes and develop a final report outline and first draft for CMS's review. The synthesis of findings will profile the environment, communities, population, programs, and other key characteristics of health care delivery in each HRR and incorporate data from CMS's HRR analyses. This will be performed by culling the coded interview notes from the electronic database, systematically comparing patterns within and across HRRs, and highlighting apparent best practices. The research team will then assess the factors that appear to be associated with program outcomes – whether singular factors or potential clusters.

At a minimum the report will include: 1.) an executive summary; 2.) a background and purpose section; 3.) a methodology section; 4.) a section synthesizing and summarizing the similarities and differences in the care provided among the seven low-cost and high-quality HRRs and among the seven high-cost and low-quality HRRs; 5.) a section describing findings from the two PACE site visits; and, 6.) appendices with the site visit protocol, data profiles of each HRR, and any other relevant supporting information. Thus, the report will discuss the similarities and differences in the care provided among the HRRs and detail findings from each site. To the extent possible, it will also describe the discoveries made by the teams about best practices, models, and key initiatives in care coordination designed to serve targeted population groups within the HRRs. Ultimately, findings described in the report will serve as the foundation for future CMS research efforts intended to target specific areas of improvement related to regional variations in the cost and quality of care delivery for these vulnerable populations. With this in mind, the report will seek to give CMS a flavor of the patterns that exist among the range of HRRs selected for this study – and the potential policy implications such patterns may have on the coordination of care. CMS recognizes that the driving factors resulting in regional variations in cost and quality are at times multi-pronged and difficult to discern; as such, while the agency ultimately seeks to enact policy related to remedying some of these variations and promoting higher quality and more cost-efficient care, it views this report as exploring the first layer of questions associated with these complicated issues. This report is by no means intended to provide all of the answers.

The research team will submit a draft report to the COTR for review and refinement and a final report soon thereafter. At the project's end, the research team will also meet with the CMS team to discuss the final report on site at CMS headquarters.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the

design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

Lisa Green, PhD
Principal (& Research Project Director)
L&M Policy Research, LLC
240.476.6663