CMS Response to Public Comments Received for CMS-2012-0049

The Centers for Medicare and Medicaid Services (CMS) received comments from a national organization and a Program of All-Inclusive Care for the Elderly (PACE) organization related to the For-Profit PACE Study (CMS-10427). Below we present the comments and responses to the questions.

1. Language on p. 2 references two for-profit PACE providers participating in the forprofit PACE demonstration. Currently, four for-profit PACE plans are operating in Pennsylvania under common ownership. A fifth plan, entirely distinct from the others, terminated its contract as of May 1, 2012. Applications for two additional plans have been submitted to CMS and are under review; one of these plans is anticipated to be operational in the first quarter of 2013.

Response: We will update the supporting statement to reflect this development, which occurred after the submission of the OMB package for the 60 day Federal Register Notice.

2. In general, we are concerned about the reliance on self-reported data to determine participants' use of medical care, and long term services and supports. More specifically, we are concerned about the ability of participants or caregivers to recall the specifics of prior health care utilization including hospital and nursing home stays and the use of other services that may have occurred many months earlier. Our understanding is that the decision was made to use a participant/proxy survey to collect utilization information because the utilization data available from PACE organizations may not be consistently reliable. Is this a determination that was made at the time of the not-for-profit evaluation or has a more recent assessment been made? We recommend that the evaluators consider comparing the utilization data obtained from responses to the participant/proxy survey to data available from the PACE organizations participating in the study to verify the completeness of the self-reported information. At a minimum, we recommend that the evaluators consult these PACE organizations about the availability of such information.

Response: The decision to use a participant/proxy survey to collect information was made recently for purposes of this study, while taking into consideration the collection methods of the previous PACE evaluation. We recognize the concern that medical care utilization information collected through interview responses could suffer from under or over reporting, particularly in an elderly population with high rates of frailty and disabilities. However, we conclude that the use of self-reported data from PACE enrollees is appropriate for the purposes of the for-profit PACE study and data from the PACE sites is unwarranted for the following reasons: (1) the risk to reliability is minimized because we ask enrollees to recall whether an event has occurred over the past 12 months (yes/no) rather than recall the number of visits or the details of the event, (2) we do not expect that there will be any differences in under or over reporting for for-profit PACE enrollees and the comparison group, not-for-profit PACE enrollees, (3) the majority of utilization data proposed for use in this study will not be used to assess

differences in access to and quality of care between for-profit and not-for-profit sites, but rather to help determine (collectively, along with other information obtained from CMS administrative data) whether there are differences in general health and needs of enrollees, and (4) the extraction and standardization of utilization data from PACE sites is likely to impose a substantial burden on the sites, CMS, and Mathematica and any differences in the collecting and categorizing of information across PACE sites could introduce site-level bias to the results.

Self-reported information will be adequate to serve the role we've proposed for utilization data in the for-profit PACE study. Although the literature shows mixed evidence regarding the ability of elderly patients to accurately report numbers of medical visits^{1,2,3}, we believe that enrollees are more likely to be able to accurately recall whether a major event such as a hospitalization or nursing home admission has occurred at least once over the past 12 months. In addition, we do not expect any differences in under or over reporting between the for-profit and not-for-profit populations. In this case, although there could be error in the measurement of utilization, there will be no bias in comparisons of utilization between for-profit and not-for-profit sites.

Furthermore, most of the utilization information will be used to determine whether the underlying health and health needs of the two populations are different on average, rather than as outcome measures to compare quality and access to care. To this end, the utilization information will be used along with administrative data provided by CMS to control for differences in underlying health as potential confounding factors when comparing access to and quality of care. Thus, any potential over or under reporting of utilization (again, consistent across sites) will be muted in its impact on our results. Only the questions about use of preventive health services (B20 – B24) will be used as outcome measures for this study. Consistent with other studies and the evaluation of the not-for-profit PACE plans, these preventive health utilization measures will be used to measure differences in access to or quality of care.

The use of data collected at the various PACE sites is likely to impose a substantial additional burden to the project. While the PACE sites may collect utilization data, we recognize that the sites have flexibility in the format and systems used to maintain this data. Any differences in the reporting of utilization across PACE sites could introduce site-level bias to our results, particularly if the differences are observed between the for-profit and not-for-profit sites. Collecting this information across PACE sites sites could place a significant burden on the PACE sites to extract this information and submit it in a standardized format. CMS and Mathematica staff would also be required to

¹ Bhandari, A. and T. Wagner. "Self-Reported Utilization of Health Care Services: Improving Measurement and Accuracy." *Medical Care Research and Review*, vol.63, no. 2, April 2006, pp. 217-235.

² Wallihan, D.B., T.E. Stump and C. M. Callahan. "Accuracy of Self-Reported Health Services Use and Patterns of Care Among Urban Older Adults." *Medical Care*, vol. 37, no. 7, 1999, pp. 662-670.

³ Parminder, P., V. Torrance-Rynard, M. Wong, and C. Woodward. "Agreement between Self-reported and Routinely Collected Health-care Utilization Data among Seniors." *Health Services Research*, vol. 37, no. 3, June 2002, pp. 751-774.

spend considerable resources working with the PACE sites to properly prepare the data and to review and process any non-standardized data submitted by the PACE sites. Conducting a comparison of the self-reported survey data with the administrative data from the PACE organizations is not within the current scope of work and would require a considerable increase in the budget for this project.

After considering the factors described above, we believe that self-reported utilization information will be suitable and efficient for the purposes outlined in this study, and utilization data from the PACE sites will not be needed to supplement this information.

3. In Section A there are multiple questions related to participants' use of medical care and long term services and supports. Consistent with our comment above, we encourage the evaluators to consider the quality and accessibility of utilization data available from the PACE organizations participating in the study and, if possible, to compare the utilization information reported by the participant or his/her proxy with the relevant PACE organization's data. In addition, there may be additional sources of utilization information, e.g. prescription drug event data reported to CMS by PACE organizations for information on prescription drug use.

Response: Please see response to #2. The survey question about prescription drug use (QA4a) is included only to determine whether the respondent will receive or skip the question measuring satisfaction with the assistance they have received from PACE center staff in following the medication instructions of their doctor.

4. Referring to question 19 on p. 22, will participant/caregiver responses to this question take into account plan-specific differences in how therapy services are provided, i.e. account for the fact that therapy services may be delivered only in the PACE center in some plans (other than for nursing home residents)?

Response: In addition to the question about therapy services provided outside of the PACE center (A19), the survey includes a question about therapy services received at the PACE center (A23). These two questions will take into account the delivery of therapy at or outside of the center under the various PACE plans.

5. Referring to question 8 on p. 25, again, information on use of transportation services may be readily available from PACE organizations. In addition, although some participants may request transportation, in most cases the need for transportation is assessed as part of the care planning process and an explicit request for transportation may not be made, yet transportation is provided. Consequently, the wording of this question may create confusion.

Response: We will modify question (A8) from:

"In the past year, did (you/SAMPLE MEMBER) ask the PACE center for help with transportation to take (you/him/her) to or from the PACE center?"

"In the past year, did (you/SAMPLE MEMBER) receive help with transportation to take (you/him/her) to or from the PACE center?"

6. Referring to question 14 on p. 26, appointments with medical specialists are often coordinated by the PACE organization; hence, participants are seen by specialists but do not themselves make appointments. Again, the wording of this question may create confusion.

Response: We will modify question (A14) from:

"In the past year, did you try to make any appointments for (yourself/SAMPLE MEMBER) to see a specialist doctor outside of the PACE center?"

to:

"In the past year, did (you/SAMPLE MEMBER) think (you/he/she) needed to see a specialist doctor, either inside or outside of the PACE center?"

7. Referring to question 3 on p. 29, PACE organizations submit diagnostic data for purposes of risk adjustment. Diagnostic data are readily available to PACE organizations and may be used to assess the completeness of self-reported information.

Response: Please see response to #2. Enrollees should be able to reliably answer whether they have been diagnosed with major conditions and this wording has been using in a number of major national surveys. In addition, these questions (B3) will be used only to describe and control for differences in the populations served by the for-profit PACE and not-for-profit plans, not as outcome measures of access to and quality of care.

8. Consistent with the comment above regarding the number of for-profit PACE plans in operation, currently four for-profit PACE plans are operating in Pennsylvania under common ownership. A fifth plan, entirely distinct from the others, terminated its contract as of May 1, 2012. Two applications are pending at CMS.

Response: Please see response to #1.

9. We believe there are 11 not-for-profit PACE sites in PA, fewer than the 19 referenced on p. 5.

Response: We confirmed the list of 11 not-for-profit PACE sites and will revise the OMB package accordingly.

to:

10. In Pennsylvania, the PACE program is known as the Living Independently for Elders (LIFE) program because PACE is an acronym for the Pharmaceutical Assistance Contract for the Elderly program. Therefore, to avoid confusion, we recommend using the acronym LIFE rather than PACE in the advance letter to PACE enrollees and the accompanying brochure.

Response: We will customize the advance mailing to refer to the specific PACE program name for each enrollee and explain that this program is operated under the Medicare Program of All-Inclusive Care for the Elderly (PACE) to eliminate confusion regarding the PACE acronym.