

APPENDIX 4C

DATA COLLECTION PROTOCOLS FOR THE SYSTEMATIC FIELD TEST

This appendix contains the documentation of COCOA-B data collection protocols that was provided in the SYFT training materials. These protocols were established to ensure that all SYFT sites collected COCOA-B data in a systematic and reliable manner. Hardcopy and electronic versions of the training materials were provided to all PACE site representatives at the national training meeting with the expectation that they would use the materials to train staff members at their own sites. Research Center contacts encouraged PACE site staff to refer to the protocol documentation to address data collection issues that arose during the SYFT.

SECTION 4

DATA COLLECTION PROTOCOLS FOR COCOA-B

A. PARTICIPANTS AND INFORMAL CAREGIVERS INVOLVED IN THE SYFT

COCOA-B data will be collected on all participants who consent to participate in the SYFT. Cognitively impaired participants with informal caregivers who provide proxy consent on behalf of the participant also will be included. All item sets¹ other than the Caregiver Satisfaction Questionnaire (CSQ) and the End of Life (EOL) Questionnaire will be used to collect data on the participants involved in the SYFT. (The CSQ and EOL are used to collect data from informal caregivers.)

Informal caregivers are defined as those individuals (e.g., family members, friends, and neighbors) who provide unpaid, informal care to a PACE participant at least once a month. Informal caregivers who consent to participate in the SYFT will be asked to respond to three items in the Social Work item set at two time points (four months apart) during the SYFT. In addition, a 50% sample of informal caregivers will be administered the Caregiver Satisfaction Questionnaire one time during the SYFT (in July). The informal caregivers of deceased participants will be asked to complete the EOL Questionnaire two to four months after the participant's death.

B. DATA COLLECTION PROTOCOLS APPLICABLE TO ALL COCOA-B ITEM SETS

1. Confirm Participant and Informal Caregiver Consent Have Been Obtained

- a. All staff members should confirm that consent has been obtained before completing COCOA-B item sets for participants or informal caregivers.
- b. Each site will need to determine the most appropriate approach to obtaining informed consent (e.g., a group of staff members obtain consent for all participants and informal caregivers before beginning any data collection; the first care provider to complete a COCOA-B item set with a particular participant obtains consent from the participant immediately before conducting the assessment, etc.).

2. Review the COCOA-B Item Sets Prior to Starting Data Collection

- a. Please review the COCOA-B item set prior to completing the items for a participant. The more familiar you are with the format and content of the form, the easier it will be to complete it for each participant.

¹ The term *item set* refers to any of the ten item sets contained in COCOA-B, whether integrated into site assessment materials or used as a stand-alone document.

- b. The majority of the items in the item sets -- with the exception of the Participant Satisfaction Questionnaire (PSQ), Caregiver Satisfaction Questionnaire (CSQ), and End of Life Questionnaire (EOL) -- are care provider response items. The Social Work and Nursing items include a small number of items that are for direct participant response. Three items for informal caregiver response also are included in the Social Work item set.
- c. All participant response items include the option of "UA" (unable to answer) to indicate that the item was asked but information could not be obtained due to the participant's cognitive impairment.
- d. To help maximize the efficiency of the time needed to spend with the participant present, note in advance the items that require participant (or informal caregiver) response as opposed to care provider response items that you can complete prior to, during, or immediately after your time with the participant.

3. **Ensure Data Quality and Submit Completed Item Sets to the DQCC or SCC²**

- a. Please review completed item sets to ensure that the data are accurate and comprehensive (e.g., selected responses are clearly legible, skip patterns are followed, all appropriate items are completed) before you submit the item set to the DQCC or SCC. Correct any problems immediately, increasing the accuracy of the data and minimizing future follow-up. If you deliberately do not complete an item due to a particular circumstance, please indicate next to the item the reason it was not completed.
- b. Submit completed item sets to your DQCC or SCC as you complete them, rather than waiting to submit completed materials for multiple participants. (The DQCC will retain the original for site documentation and send a copy to the Research Center.)
- c. The DQCC or SCC will review each COCOA-B item set to identify any missing data or problems. If data are missing or problematic, the DQCC or SCC will ask you to provide the missing information (or provide documentation of the reason why an item could not be completed) and help resolve any data issues, prior to sending the item set to the Research Center.

² For many SYFT activities, the role of the DQCC and SCC are interchangeable. Sites should determine specific DQCC and SCC responsibilities prior to the start of data collection.

- d. DQCCs at each site will receive Data Quality Reports from the Research Center. The reports will identify missing data, inconsistent responses among items, and other data issues. Staff members will need to work with the DQCC to resolve identified problems and provide corrections to the Research Center.

4. Provide Input to Research Center Staff

We are interested in your feedback related to implementing COCOA-B at your site. Please feel free to provide comments to your Research Center contact at any time (via your DQCC or, if desired, individually). Later in the SYFT, you also may be asked to provide written feedback on particular topics (e.g., suggestions to clarify specific data items and response options, input on data collection protocols, suggestions for streamlining or improving the approaches to integrating and implementing COCOA-B into site practices).

C. DATA COLLECTION PROTOCOLS FOR SPECIFIC ITEM SETS

1. Clinical Record Items

Six clinical record items are included on most of the COCOA-B item sets. For some item sets, only the relevant clinical record items are included (e.g., C0040 - *Reason for Assessment* is not included on the Disenrollment Form).

2. Clinical Item Sets

- a. The COCOA-B clinical item sets (Primary Care Provider, Nursing, Social Work, and Rehabilitation Therapy), whether integrated into site assessment forms or used as separate documents, should be completed as part of routine participant assessment. Care provider assessment of a participant may include observation and clinical judgment; interactions and discussion with the participant, family or other informal caregivers; and/or discussions with other PACE staff.
- b. The clinical item sets should be completed at **two time points, four months apart**, for two cohorts of participants, and completed at one time point during the SYFT for two cohorts of participants.
 - Presuming a data collection start date of June 1, the item sets will be completed for Cohort A in June. Cohort A will include participants who are scheduled for reassessment in June and new enrollees who will have their initial assessment in June. This is the first SYFT data collection time point for these participants. The item sets will be completed again in October for the participants in Cohort A.

- An analogous schedule holds for Cohort B -- the item sets will be completed as part of routine assessment for participants scheduled for reassessment or initial assessment in July (the first SYFT time point). The item sets will be completed again in November (the second SYFT time point) for the participants in Cohort B.
 - The item sets will be completed and submitted to the Research Center for only one time point for Cohort C and Cohort D participants (those scheduled for reassessment or initial assessment during the months of August and September, respectively).
- c. For participants who newly enroll at your PACE site during the SYFT, complete all items on the integrated COCOA-B item sets (as part of the initial assessment), with the exception of the items noted in point B.2.e below.
- d. For participants who are scheduled for reassessment during the months of the SYFT, complete all items included in the clinical item sets at all time points (regardless of being the first or second SYFT data collection time point for the participant).
- e. Social Work Items: Two Social Work items (C0570: *Day Health Center Attendance* and C0800: *Satisfaction with Care Provided for Pain*) should be skipped during the initial assessment for a newly enrolled participant, since a new enrollee would not have attended the Day Health Center over the past four months nor would be able to comment on care provided by the PACE site for pain over the past four months. Please complete these items at both time points for currently enrolled participants (at both the first and second SYFT data collection time points).
- f. Nursing Items: In addition to the Nursing item set, a set of four Supplementary Nursing Items also is to be completed by the nurse. The Research Center is coordinating field test efforts with another CMS contractor involved in the development of a frailty adjuster for risk-adjusted payment of PACE sites. The Supplementary Nursing Items are included as part of this coordinated effort. (The same items are included in the Nursing item set -- the nurse is to administer those items directly to the participant for response.)

3. Participant Tracking and Demographic Item Set

- a. This item set is to be completed at all time points for all participants (including the initial assessment for new enrollees and first and second SYFT time points for current enrollees).

- b. For participants who enroll during the SYFT, complete all items in the Participant Tracking and Demographic Items at the initial assessment time point.
- c. For currently enrolled participants who are scheduled for reassessment during the months of the SYFT, complete all items included in the Participant Tracking and Demographic Items at the first SYFT data collection time point (i.e., the participant's reassessment time point) **except** the following two items, which refer to events during the 14 days prior to initial enrollment in the PACE program:
 - C0170: *Inpatient Facilities*; and
 - C0180: *Formal Services Received Prior to Enrollment*.
- d. At the second SYFT time point for all participants, review the information that was recorded on the Participant Tracking and Demographic item set completed at the first time point for that participant. Determine whether any changes have occurred since the first time point for any of the items. (Note that responses to items C0170 and C0180 listed above will never change and do not need to be reviewed at reassessment time points.)
 - If change has occurred for one or more items, mark the correct response for those items on a blank Participant Tracking and Demographic Items form (i.e., not the completed form from the first time point) and submit the new document to the DQCC.
 - If no change has occurred for the participant under consideration, mark the checkbox indicating "No changes have occurred since the last assessment for the items below" and submit the new form to the DQCC.
 - In either situation described above, please complete the Clinical Record Items (C0010 - C0050 and *Staff Member Name*) at the top of the form before submitting the form to the DQCC.

4. Inpatient and Emergency Services Utilization Form

- a. The Inpatient and Emergency Services Utilization Form differs from the other item sets in that it is not completed for an individual participant. Rather, this form is completed based on utilization of inpatient and emergency services by all participants for a particular month.

- b. We recommend that medical records (or other) staff complete the Utilization Form on an ongoing basis, recording information on inpatient stays or emergency services used for any participants enrolled at the site during the month under consideration.
- c. Detailed instructions for completing the Utilization form are provided on the form itself.
- d. The Utilization Form for a completed month should be received at the Research Center by the 10th of the following month (e.g., the Utilization Form for June should be submitted by July 10).
- e. The Utilization Form should be completed and submitted to the Research Center for each month during the period of June through October.

5. Disenrollment Form

- a. The Disenrollment Form includes ten items to be completed when a participant disenrolls from the program, whether due to death or other reasons.
- b. The completed Disenrollment Form should be received at the Research Center within 14 days of the disenrollment date.

6. Participant Satisfaction Questionnaire

- a. The PSQ will be administered in July 2003 to a 50% sample of all participants who have been enrolled at the site for at least four months (excluding participants who are more than mildly cognitively impaired or who are unable to communicate in English).
- b. The staff members responsible for generating the list of participants for the PSQ should be determined by each site.
- c. The PSQ will be administered to participants by individuals who do not provide direct care to PACE participants (e.g., site administrative staff, site volunteers, etc.).
- d. It will be necessary to reserve a private room and schedule a block of time to administer the PSQ to each participant in a face-to-face interview. (The PSQ can be administered at the Day Health Center or at the participant's home.)
- e. Before beginning to schedule participants for the PSQ interviews, check with the DQCC to ensure that all participants on the list have consented to participate.

- f. Please review the PSQ prior to administering the questionnaire to PACE participants. Note if the questionnaire is double-sided, to ensure that you do not overlook some of the questions. The more familiar the interviewers are with the format and content of the PSQ, the easier it will be to administer it to participants.
- g. All of the data items in the PSQ are for participant response, with the exception of the five clinical record items at the top of the first page which are to be completed by the interviewer.
- h. It is critical to maintain the confidentiality of participant responses to the PSQ. Because the PSQ is still under development and refinements will be made based on field testing experiences, the Research Center will not be providing aggregate satisfaction data to the PACE sites participating in the SYFT. Individual responses must remain confidential, and the PSQ interviewers should not share the responses with any other PACE staff.
- i. A sample introduction to the PSQ is provided in Attachment A to this section. This introduction is provided only as a guide; it is not necessary to read it exactly as written.
- j. A brief, required script also is provided on the PSQ form itself, printed in bold. The script on the PSQ must be **read exactly as written**, so that the participants all receive the same introduction to the PSQ items. Review the script prior to administering the questionnaire to a participant, so you are familiar with its content.
- k. After reading the bold-faced script on the PSQ to the participant, review the response options (No problem, Small problem, Serious problem or problems) that will be used with most of the PSQ items to ensure that the participant understands the options. The items on the PSQ should be asked **exactly as written** on the questionnaire.
- l. It may happen that a participant responds to an item using words other than the response options (e.g., "very good" or "fine"). If this occurs, it will be necessary to repeat the response options and ask the participant how he/she would answer the question using one of the response options. If the participant does not use one of the response options to answer the item even after two or three prompts, leave the item blank and indicate next to the data item the reason the item was not completed (e.g., the participant did not provide a valid response).

- m. All of the PSQ items include a response option of "UA" (unable to answer) to indicate that information could not be obtained due to the participant's cognitive impairment (i.e., the participant could not understand the question and/or the response options). Given the varying levels of complexity of some of the items on the PSQ, please attempt to ask the participant as many of the questions as is feasible, rather than stopping the interview if the participant is unable to respond to the first item or two. In particular, please attempt to obtain a response to the last two items (C01050 and C01060) on the PSQ, which may be simpler concepts to understand.
- n. You may wish to use the PSQ Tracking Form provided in Section 7, Attachment D in this manual to facilitate scheduling of PSQ interviews and tracking of completion.

7. Caregiver Satisfaction Questionnaire

- a. The CSQ will be administered in July 2003 to a 50% sample of all informal caregivers of participants who have been enrolled at the site for at least four months (excluding informal caregivers who are cognitively impaired or who are unable to communicate in English).
- b. The staff members responsible for generating the list of informal caregivers for the CSQ should be determined by each site.
- c. The CSQ will be administered to informal caregivers (in-person or by phone) by individuals who do not provide direct care to PACE participants (e.g., site administrative staff, site volunteers, etc.).
- d. Before beginning to schedule informal caregivers for the CSQ interviews, check with the DQCC to ensure that all informal caregivers on the list have consented to participate.
- e. Please review the CSQ prior to administering the questionnaire to informal caregivers of PACE participants. Note if the questionnaire is double-sided, to ensure that you do not overlook some of the questions. The more familiar the interviewers are with the format and content of the CSQ, the easier it will be to administer it to informal caregivers.
- f. All of the data items in the CSQ are for informal caregiver response, with the exception of the five clinical record items at the top of the first page. These data items are to be completed by the interviewer.

- g. It is critical to maintain the confidentiality of informal caregiver responses to the CSQ. Because the CSQ is still under development and refinements will be made based on field testing experiences, the Research Center will not be providing aggregate satisfaction data to the PACE sites participating in the SYFT. Individual responses must remain confidential, and the CSQ interviewers should not share the responses with any other PACE staff.
- h. A sample introduction to the CSQ is provided in Attachment B. This introduction is provided only as a guide; it is not necessary to read it exactly as written.
- i. A brief, required script also is provided on the CSQ form itself, printed in bold. The script on the CSQ must be **read exactly as written**, so that the informal caregivers all receive the same introduction to the CSQ items. Review the script prior to administering the questionnaire to an informal caregiver, so you are familiar with its content.
- j. Read all of the data items on the CSQ **exactly as written**.
- k. It may happen that an informal caregiver responds to an item using words other than the response options (e.g., "very good" or "fine"). If this occurs, it will be necessary to repeat the response options and ask the informal caregiver how he/she would answer the question using one of the response options. If the informal caregiver does not use one of the response options to answer the item even after two or three prompts, leave the item blank and indicate next to the data item the reason the item was not completed (e.g., the informal caregiver did not provide a valid response).
- l. You may wish to use the CSQ Tracking Form provided in Section 7, Attachment D in this manual to facilitate scheduling of CSQ interviews and tracking of completion.

8. End of Life Questionnaire

- a. The EOL Questionnaire is to be mailed to the primary informal caregiver of the deceased participant two to four months after the death of the participant. An individual receiving the questionnaire will meet the following criteria:
 - the individual was the primary informal caregiver of a PACE participant who passed away during the past two to four months and the participant was enrolled in the program for a minimum of three months; and
 - the individual is English speaking.

- b. A packet of materials will need to be assembled for mailing the EOL Questionnaire to informal caregivers. The EOL Questionnaire packet includes:
- a cover letter explaining the purpose of the questionnaire (a sample is provided in Attachment C);
 - the EOL Questionnaire (customized by each site, as described below);
 - two copies of the Informal Caregiver Consent Form for the End of Life Questionnaire;
 - if possible, a list of local resources for bereavement support; and
 - a postage-paid, pre-addressed envelope for caregivers to use when mailing the completed questionnaire and signed consent form to the Research Center.
- c. If you choose to use or adapt the sample cover letter provided in Attachment C, replace references to **(PACE site)** with your site/center name. Ideally, the cover letter also would be personalized with each informal caregiver's name.
- d. Prior to assembling the packets, please fill in the following information on the EOL Questionnaire:
- Your site's SYFT ID number (in the upper right hand corner);
 - the participant's ID number (the ID number that is used in site medical records), also in the upper right hand corner; and
 - the responses to items 3 and 4 (C0030: *Name of Associated Participant* and C0210: *Date of Participant's Death*, respectively).
- e. Also complete the following information on the last page of the Informal Caregiver Consent Form for the EOL Questionnaire:
- Participant Name and ID
 - SYFT Site ID
- f. It is desirable, but not necessary, for a site care provider who is familiar with the participant and family/informal caregivers to contact the primary informal caregiver by phone prior to mailing the EOL Questionnaire packet. The objective of such a call would be to let the caregiver know that the mailing is coming, the purpose of the questionnaire, and who to call at the site if any

questions arise. Site staff often are aware of the informal caregivers who might feel more comfortable with a preparatory call, those who would prefer the privacy of the mailed questionnaire without a phone call, etc. The call also provides an opportunity for site staff to "check in" with the informal caregiver as they go through the bereavement process.

- g. Each site will need to establish a mechanism for identifying the "eligible" informal caregivers. Obtain a list of the participants who passed away during February, March, April, May, and June, and their primary informal caregiver, if any. Send the EOL Questionnaire packet to the informal caregivers identified on the list, two to four months after the death of the participant.
- h. Obtaining the list will facilitate your mailing and tracking of the EOL Questionnaire packets. The EOL Questionnaire packets will be mailed back to the Research Center, using postage-paid envelopes. Please notify the Research Center, via your DQCC, of the number of packets that are mailed each month. (It is not necessary to provide the names of the individuals who received the packets.)