PART A

SUPPORTING STATEMENT

MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION EVALUATION

A. Background

Since the inception of Medicaid, inpatient care provided to adults ages 21 to 64 in institutions for mental disease (IMDs) has been excluded from federal matching funds. The Emergency Medical Treatment and Active Labor Act (EMTALA), however, requires IMDs that participate in Medicare to provide treatment for psychiatric emergency medical conditions (EMCs), even for Medicaid patients for whose services they cannot be reimbursed. Section 2707 of the Patient Protection and Affordable Care Act (ACA) of 2011 (P.L. 111-148; Attachment A) directs the Secretary of Health and Human Services to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services provided by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64. This project, the Medicaid Emergency Psychiatric Demonstration (MEPD), and its evaluation are being implemented by the Centers for Medicare & Medicaid Services (CMS). On May 10, 2011, CMS received Paperwork Reduction Act (PRA) approval to collect application information from states interested in participating in the demonstration (OMB control number 0938-1131, now discontinued) and, in March 2012, selected 11 states and the District of Columbia to participate. Within these states, the participation of 27 private IMDs was approved. The goal of the 3-year demonstration is to assess whether the expansion of Medicaid coverage to include services provided in private, free-standing inpatient psychiatric facilities improves access to and quality of medically necessary care and whether this change in reimbursement policy is cost-effective. Focusing on psychiatric emergencies, the demonstration is also an attempt to explore a potential remedy to alleviate one of the factors contributing to psychiatric boarding, one of the consequences associated with the Medicaid IMD exclusion. The current PRA submission requests approval to collect data in association with the mandated evaluation of the demonstration.

Section 2707 of the ACA specifies that the evaluation shall include the following:

1. An assessment of access to inpatient mental health services under the Medicaid program; average lengths of inpatients stays; and emergency room (ER) visits;
2. An assessment of discharge planning by participating hospitals;
3. An assessment of the impact of the demonstration project on the costs of the full range of mental health services (including inpatient, emergency, and ambulatory care);
4. An analysis of the percentage of consumers with Medicaid coverage who are admitted to inpatient facilities as a result of the demonstration project as compared to those admitted to these same facilities through other means; and
5. A recommendation regarding whether the demonstration project should be continued after December 31, 2013, and expanded on a national basis.

The ACA further mandates that "not later than December 31, 2013, the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation."

In addition to the requirements for the evaluation, the ACA specifies the following aspects of the demonstration:

1. The population served by the demonstration is limited to individuals who require medical assistance to stabilize a psychiatric EMC, defined as a situation where the individual "expresses suicidal or homicidal thoughts or gestures, if determined dangerous to self or others." CMS expanded the eligibility criteria, as of October 1, 2012, to also include Medicaid enrollees who may not have suicidal or homicidal thoughts, gestures, or ideations but are, nevertheless, determined to be dangerous to self or others.
2. States are required to establish a mechanism for determining whether or not participants have been stabilized, meaning that "the EMC no longer exists…and the individual is no longer dangerous to self or others." The stabilization assessment mechanism must commence before the third day of the inpatient stay.

Understanding the manner in which these requirements have been operationalized and the way in which they may affect outcomes of the demonstration is important for informing possible continuance and expansion of the demonstration on a national basis.

In addition to the ACA specifications regarding the demonstration, many stakeholder groups believe that the IMD exclusion, coupled with a general shortage of specialized inpatient psychiatric beds, contributes to extended psychiatric boarding—the practice of holding a patient with a psychiatric EMC in an ER or general hospital nonpsychiatric medical unit (known as "scatter beds") because no specialized beds are available. Psychiatric boarding is thought to contribute to overcrowding of ERs and to result in substandard care for beneficiaries in facilities that are not well equipped to treat psychiatric conditions. The expectation is that by increasing access to IMDs, the demonstration will decrease psychiatric boarding and use of scatter beds, thereby improving quality of care for beneficiaries with psychiatric EMCs. Therefore, an assessment of changes in psychiatric boarding, use of scatter beds, and quality of care is essential for understanding the extent to which the demonstration results meet stakeholder expectations.

To respond to the ACA evaluation requirements, CMS is planning a comprehensive, mixed-methods evaluation of the MEPD. CMS is requesting approval from the Office of Management and Budget (OMB) for the collection of qualitative data through site visits and key informant and beneficiary interviews as part of the evaluation.

Fully assessing all of the areas mandated by the ACA as well as the interests of critical stakeholders necessitates a mixed-methods approach. Quantitative data on service utilization and expenditures are critical to successfully evaluating the MEPD's impact in ACA-mandated evaluation areas A, C, and D. Only a qualitative approach, however, can provide a full assessment of discharge planning by participating hospitals, as mandated by ACA evaluation area B, and of psychiatric EMC determination and stabilization processes utilized to ensure compliance with ACA demonstration requirements; in addition, few if any data are available on the use of scatter beds and psychiatric boarding times in ERs, so an understanding of the extent and impact of these practices may only be possible through qualitative methods.

Quantitative Data Collection

To the extent possible, the evaluation will use publicly available data to minimize burden on the demonstration states and facilities. Medicaid and Medicare enrollment and claims data submitted to CMS will be used to address ACA evaluation areas A and C. Variation in the quality, timeliness, and completeness of Medicaid data across states will necessitate that the demonstration states assist the evaluation contractor to develop a clear understanding of claims data submitted by their particular states. In addition, because not all data needed to address the ACA evaluation mandates are included in claims data, the evaluation will ask the states and facilities to submit relevant administrative data that they collect for other purposes. In particular, because of the IMD exclusion, data on IMD inpatient psychiatric admissions are not available through claims data. Information about admissions as a result of the demonstration will be available through claims that the states submit to CMS for demonstration payment and monitoring purposes, but data for comparison group admissions will have to be obtained from state or facility administrative sources. Comparison data for admissions before the demonstration began are needed to determine the extent to which IMD admissions, lengths of stay, and costs during the demonstration represent a change from IMD admissions, lengths of stay, and costs prior to the demonstration. In addition, data from non-participating IMDs are needed to determine the extent to which such changes are due to the demonstration itself rather than non-demonstration factors. In addition to IMD admissions, identification of psychiatric EMCs may also not be fully possible through Medicaid and Medicare data alone, and quantitative data on psychiatric boarding times, if available, must also be obtained directly from states or facilities.

Qualitative Data Collection

Information on processes of care that are critical to the success of the demonstration are not available through quantitative data. Nonetheless, CMS has an interest in ensuring the proper conduct of discharge planning to (1) achieve positive health outcomes for Medicaid beneficiaries, (2) limit costs related to readmissions that may occur when discharges are premature, and (3) ensure that clients are served in community-based settings whenever possible. While these outcomes of discharge planning will be assessed through analysis of quantitative data, information about the processes used to conduct discharge planning itself can only be obtained through qualitative approaches. Qualitative data are critical for understanding the relationships among length of stay, initiation of stabilization assessments and discharge planning, stabilization of emergency psychiatric conditions, and discharge. The qualitative data collected will enrich the evaluation's understanding of quantitative results, permit consideration of alternative explanations for significant changes over time, examine the circumstances under which varying effects might be expected if Congress expands the demonstration, and help generate hypotheses about outcomes for further exploration through quantitative data analysis.

Because the demonstration operates at state, facility, and beneficiary levels, CMS proposes a systematic qualitative data collection approach that addresses each of these levels. Key informant interviews and document review conducted for each level will be used to cross-validate one another. Two rounds of site visits will be conducted. The first will occur about 24 months after the start of the demonstration (spring 2014) and focus on admission, stabilization, and discharge-planning procedures before and after the demonstration. The second round of visits will occur about a year later (spring 2015) to allow the evaluation team to gather detailed

information on changes in these procedures, as well as lessons learned and sustainability of changes made. For each state, during each round an evaluation contractor will visit all participating IMDs and, for each IMD, one ER that refers patients to that IMD and one general hospital that admits patients with psychiatric EMCs to general medical units when no psychiatric bed is available.

During the site visits, the evaluation contractor will interview facility staff regarding processes of care that are critical to the success of the demonstration, namely procedures for psychiatric EMC determination, inpatient admissions, stabilization assessment, stabilization, and discharge planning. Interview questions for staff at each type of facility are included in Attachment B. In addition, during each site visit, purposive sampling will be used to select 10 medical records to review at each facility. (See Attachment C for sampling procedures.) From IMD and general hospital records, information regarding stabilization and discharge-planning procedures and interventions administered will be extracted. From ER records, CMS proposes extracting information regarding length of time spent in the ER, psychiatric EMC determination, interventions administered, and inpatient referral procedures. The medical record review tool is included in Attachment D. Records from both pre- and post-demonstration time periods will be reviewed to assess how care has changed.

Prior to each site visit, the evaluation contractor will conduct a semi-structured phone interview with the state demonstration project director, using questions included in Attachment B. The contractor will also review site documents, such as operation plans, psychiatric EMC determination procedures, and stabilization assessment and discharge-planning policies. After each round of site visits, evaluation teams will conduct telephone interviews with five beneficiaries receiving inpatient services through the demonstration from each participating IMD, for a total of 135 interviews. These interviews will be essential to understanding beneficiaries' experiences with the admission and discharge processes. Moreover, the beneficiaries' viewpoints are critical to understanding if and how quality of care improves as a result of the demonstration. Beneficiary interview questions are included in Attachment E, along with a draft consent form and the recruitment script for beneficiary interviews.

To manage the voluminous qualitative data collected from interviews and site documents, the evaluation contractor will systematically code and analyze the data using Atlas.ti, a qualitative data analysis software package. Data gathered from medical records will be entered into a data entry program called Viking. These data will then be exported as SAS files for analysis at the facility-level.

B. Justification

Need and Legal Basis

Section 2707 of the Patient Protection and Affordable Care Act (ACA) of 2011 (P.L. 111-148; Attachment A) directs the Secretary of Health and Human Services to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services provided by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64.

Information Users

The data will be used by CMS to evaluate the MEPD in accordance with the ACA mandates. This evaluation in turn will be used by Congress to determine whether to continue or expand the demonstration. If the decision is made to expand the demonstration, the data collected will help to inform CMS and their stakeholders about possible effects of contextual factors and important procedural issues to consider in the expansion, as well as the likelihood of various outcomes. Although the results of this data collection will not be included in the report to be submitted to Congress by December 31, 2013, we anticipate that Congressional and stakeholder interest will continue until the evaluation results are published. A comprehensive report of the findings will be produced in the final year of the project, and interim results will be described in annual reports and presentations made via webinar during the final two years of the project.

The conceptual framework for the evaluation is presented in visual and narrative form in Attachment F. Table 1, below, lists the specific research questions to be examined, how each relates to the ACA mandates, and the data sources that will be used to answer each question. As shown in the table, CMS Medicaid and Medicare claims data will be the primary data sources for addressing ACA-mandated evaluation areas A and C, state and facility administrative data will contribute importantly to addressing all mandated areas, and the qualitative data sources together will provide the primary information for addressing ACA-mandated area B (discharge planning), as well as psychiatric boarding, which falls under area A, regarding ER visits. In addition to discharge planning, the multiple sources of qualitative data will provide important cross-validating perspectives on processes of care that are critical to understanding the success or failure of the demonstration, including psychiatric EMC determination, inpatient admission, and stabilization procedures.

Table 1. Use of Data to Answer Research Questions Addressing ACA-Mandated Evaluation Areas

Research Question	Data Source	ACA-Mandated Evaluation Area
To what extent do private IMDs increase admissions of Medicaid beneficiaries with psychiatric emergencies as a result of the demonstration?	CMS demonstration payment and monitoring data State or facility administrative data	(A) Medicaid inpatient access, length of stay, and reduced ER visits (D) The percentage of consumers who are admitted to participating IMDs as a result of the demonstration compared to those admitted to the same facilities with other payment arrangements
Does the demonstration decrease admissions to nonpsychiatric units of general hospitals for Medicaid beneficiaries with psychiatric emergencies?	CMS Medicaid and Medicare claims data—pre- and post-demonstration	(A) Medicaid inpatient access, length of stay, and reduced ER visits (C) Impact on system costs of the full range of mental health services, including inpatient, emergency, and ambulatory care
What is the demonstration's effect on lengths of stay for Medicaid beneficiaries with psychiatric emergencies admitted to private IMDs compared with lengths of stay in these facilities before the demonstration and to lengths of stay in other facilities?	CMS demonstration payment and monitoring data CMS Medicaid and Medicare claims data State or facility administrative data	(A) Medicaid inpatient access, length of stay, and reduced ER visits

Research Question	Data Source	ACA-Mandated Evaluation Area
What is the demonstration's effect on lengths of stay for Medicaid beneficiaries with psychiatric emergencies admitted to scatter beds in general hospitals?	CMS Medicaid and Medicare claims data	(A) Medicaid inpatient access, length of stay, and reduced ER visits (C) Impact on system costs of the full range of mental health services, including inpatient, emergency, and ambulatory care
Are fewer Medicaid beneficiaries with psychiatric emergencies seen in ERs as a result of the demonstration?	CMS Medicaid and Medicare claims data—pre- and post-demonstration	(A) Medicaid inpatient access, length of stay, and reduced ER visits (C) Impact on system costs of the full range of mental health services, including inpatient, emergency, and ambulatory care
Does the demonstration reduce psychiatric boarding time in ERs for Medicaid beneficiaries with psychiatric emergencies?	ER administrative data Key informant interviews Beneficiary interviews Medical records review	(A) Medicaid inpatient access, length of stay, and reduced ER visits
Does the demonstration increase the proportion of individuals discharged with a continuing care plan from the participating hospitals?	Quality improvement data obtained from CMS's Inpatient Psychiatric Facilities Quality Reporting program	(B) Discharge planning
Does the demonstration improve the quality of discharge plans? - Does the demonstration increase the length of time spent developing a discharge plan for Medicaid beneficiaries with psychiatric emergencies in participating IMDs? - Does the demonstration increase the proportion of Medicaid beneficiaries with psychiatric emergencies in participating IMDs who are discharged to community-based residences (compared to before the demonstration and compared to nonparticipating IMDs and nonpsychiatric units of general hospitals)? - Does the demonstration increase the level of detail (e.g., appointment times, names of providers) included in the discharge plans for Medicaid beneficiaries with psychiatric emergencies in participating IMDs? - How does the discharge-planning process in participating IMDs compare (in terms of the previous questions) to the processes in nonpsychiatric units of general hospitals?	CMS demonstration payment and monitoring data Key informant interviews Document review Medical record reviews Beneficiary interviews	(B) Discharge planning

Research Question	Data Source	ACA-Mandated Evaluation Area
Does the demonstration reduce 30-day readmissions (all cause and psychiatric) for patients discharged from participating IMDs for a psychiatric emergency (compared to before the demonstration and compared to nonparticipating IMDs and nonpsychiatric units of general hospitals)?	CMS Medicaid and Medicare claims data State or facility administrative data	(B) Discharge planning (C) Impact on system costs of the full range of mental health services, including inpatient, emergency and ambulatory care
What effect does the demonstration have on costs to the IMDs, states, Medicaid, and Medicare? - What are the federal Medicaid costs for care provided by private IMDs as a result of the demonstration? - To what extent do costs incurred by the states for Medicaid emergency IMD admissions decrease after the demonstration's implementation? - To what extent do costs incurred by participating IMDs for Medicaid emergency IMD admissions decrease after the demonstration's implementation? - What is the demonstration's effect on overall costs to Medicaid and Medicare for care provided to beneficiaries with emergency psychiatric conditions (perhaps through cost savings in ER utilization, general hospital scatter bed and inpatient psychiatric unit admissions, nursing home admissions, and so forth)? - What additional administrative costs are incurred by states and participating facilities to fully implement the demonstration's service-delivery models?	CMS demonstration payment and monitoring data CMS Medicaid and Medicare claims data State or facility administrative data Key informant interviews	(C) Impact on system costs of the full range of mental health services, including inpatient, emergency, and ambulatory care
Within participating IMDs, how does the percentage of inpatients who are Medicaid beneficiaries admitted as a result of a psychiatric emergency change relative to the percentage of inpatients admitted through other means (i.e., with payment sources other than Medicaid and/or not as a result of a psychiatric emergency) after the demonstration's implementation?	CMS demonstration payment and monitoring data State or facility administrative data	(D) The percentage of consumers who are admitted to participating IMDs as a result of the demonstration compared to those admitted to the same facilities with other payment arrangements
How does the process of assessing stabilization in participating IMDs compare to the processes used before the demonstration and to processes in nonpsychiatric units of general hospitals?	Document review Key informant interviews Beneficiary interviews Medical records review	ACA Demonstration Requirement for "Stabilization Review"

Use of Information Technology

States and facilities will submit quantitative administrative data electronically through secure file-transfer programs or encrypted CD-ROMs. These means are necessary to ensure the security of the data in transit.

Digital audio recording of all interviews (with respondents' permission) will be the primary electronic method for ensuring the completeness and quality of interview data. Recording also enhances efficiency and reduces respondent burden by allowing researchers to review and edit their written or typed notes without calling respondents for clarification or to check quotes.

Obtaining high quality data through semistructured interviews requires flexible exchange and conversational rapport between interviewer and respondent. Although information technology can greatly enhance the smooth administration of large-scale surveys with complex skip patterns, in qualitative interviewing, it is often best to avoid complex skip patterns in the first place. For this data collection, the contractor will minimize the skip patterns an interviewer must navigate during interviews by customizing the protocols in advance. The interview protocols accompanying this package have been customized for five types of respondents: state demonstration project directors; staff of IMDs, general hospitals, and ERs; and beneficiaries. In addition, the site visit teams will be led by trained, experienced interviewers. The interviewers will be thoroughly familiar with protocol content so they can readily move back and forth within the protocol without disrupting the conversational flow or asking questions the respondent has already answered.

After information collection, researchers will use Atlas.ti, an electronic software program that enables systematic coding and retrieval of textual data according to a specified scheme.

Data gathered from medical records will be entered into a data entry program called Viking. These data will then be exported as SAS files for analysis at the facility-level.

Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

Because the data to be collected are highly specific to the demonstration, no other relevant data collection effort currently exists. Semistructured interviews will be used only to collect evaluation information that cannot be obtained from other sources. Where possible, to address its research questions, CMS will use existing administrative data and secondary data sources, such as states' demonstration payment data submitted to CMS; Medicaid and Medicare enrollment, claims, and encounter data; and administrative data housed in state data warehouses.

Small Businesses

Many, if not all, of the facilities participating in the demonstration may be small businesses or entities. The site visit and interview protocols have been designed with an effort to minimize burden on these entities. Every effort will be made to schedule site visits and interviews at the convenience of these respondents. Evaluation staff will ensure that visits to each facility last no

more than one day. The information being requested will be held to the minimum required for the intended use.

Less Frequent Collection

If this information is not collected, CMS will not be able to address the ACA-mandated evaluation areas or have a complete and objective understanding of the impacts of the demonstration on quality of care and the lives of beneficiaries.

Qualitative data will be collected through site visits and interviews twice during the evaluation, in spring 2014 through summer 2014 and spring 2015 through summer 2015. Implementation of a complex demonstration project like the MEPD at multiple sites necessarily faced obstacles; some sites were as much as four months late in implementing it. Therefore, the first round of qualitative data collection will occur after all sites are fully operational but early enough to gather reliable data about practices prior to the implementation of the demonstration. Operational refinements at the state level are likely as the demonstration progresses; therefore, the second round of data collection is scheduled to capture these changes and ensure a complete, nuanced evaluation. Not collecting the information at all would seriously impede CMS's ability to answer the questions mandated by the ACA, particularly those regarding discharge planning.

Special Circumstances

This request fully complies with the regulations. There are no special circumstances associated with this information collection.

Federal Register/Outside Consultation

Federal Register Notice

The 60-day notice to solicit public comments was published in the *Federal Register* on July 26, 2013, vol. 78, No. 144, pp. 45205-45208 (Attachment J). Public comments were received from two individuals. These comments and our responses are summarized in Attachment K.

Consultation Outside the Agency

CMS's evaluation contractor presented an overview of the evaluation plans, including timelines and requirements regarding data collection, to the state demonstration project directors on October 24, 2012. The contractor also established a nine-member technical expert panel (TEP) composed of representatives of IMDs, including those involved in the demonstration; consumers; and other individuals who regularly work with emergency rooms, community mental health data and systems, and state mental health and Medicaid authorities. Attachment G lists the members of the TEP and their professional affiliations. On January 16, 2013, the contractor held an initial meeting with the TEP via webinar to obtain their feedback on evaluation plans, including the medical record review protocols and beneficiary interview questions. TEP members have also agreed to be available throughout the project for individual consultation on design, measurement, and analytic challenges.

Payments/Gifts to Respondents

The TEP recommended that incentives be offered to beneficiaries to participate in the beneficiary interviews in order to obtain an unbiased sample; otherwise, the TEP suggested, only beneficiaries who are particularly unhappy with the process are likely to participate. The evaluation team will, therefore, provide a $20 incentive in the form of a check for each beneficiary interview. A $300,000 incentive pool has also been established for distribution among states and facilities to offset the burden of participating in site visits and assisting the evaluation contractor in obtaining and understanding administrative databases. Incentive payments will be offered on a state-by-state, as-needed basis to ensure necessary cooperation. It is likely, for example, that such incentive payments may enhance cooperation from facilities not participating in the demonstration whose staff time, facility access, or data are needed; such may be the case, for example, with ERs and general hospitals to which site visits will be made or from which boarding-time data are solicited. The incentive payment to be provided to each state and facility will vary, depending on the specific types of data requested, the exact number of states and facilities from which data are requested, and the specific amount of burden entailed for each of the respondents to provide the needed data, given variations in their systems.

Confidentiality

Individuals and organizations will be told the purposes for which the information they provide is collected and advised that any identifiable information provided by them will not be used or disclosed for any other purpose. The evaluation contractor will comply with CMS privacy guidelines pertaining to personally identifiable information. We are in the process of obtaining approval from Mathematica's Institutional Review Board. If required by individual participating state or local governments or facilities, internal review board approval will be obtained before conducting site visits and/or interviews.

Key informant interviews, including both telephone interviews with state demonstration project directors and interviews with facility staff during site visits, will discuss the procedures utilized in implementing the demonstration and results. Responses are not seen as containing private information, but they will be aggregated to the extent possible so individual answers will not be identifiable. Individual responses may be inferred from individual state profiles and case study narratives, however, because of the limited number of respondents interviewed per state and facility (for example, there is only one project director per state). For each respondent, name, professional affiliation, and title will be collected, but Social Security numbers, home contact information, and similar information that can directly identify the respondent will not be collected.

Participants in beneficiary interviews will be advised that their responses will be kept confidential. Respondents will be given this assurance during recruitment (see Attachment E, Beneficiary Interview Consent Form and Recruitment Script) and again immediately before their interview. Further, they will receive assurance that the information being gathered is for evaluation purposes only. Name, contact information, and other identifying information will be requested only as needed to contact the individual for the interview and to deliver the incentive payment. Comments made during the interview will not be linked to individual beneficiaries.

During the informed consent process and prior to the interview, all interview respondents will be asked if they give permission to have the conversation audio recorded solely for the purpose of filling in any gaps in the research notes. Only the research team will have access to the recording. The beneficiary will be informed that they may request to listen to the audiotape. The audiotape will be destroyed after the contents are transcribed no later than 90 days after the interview. If the respondent does not wish to have the interview audiotaped, the interviewer will take notes instead. The transcription and interview notes will be maintained in a secure study-specific electronic folder that only a minimum number of research staff members may access.

To maintain patient confidentiality in the medical record reviews, the evaluation contractor will use a unique numbering system to identify patients in the sample. The contractor number will indicate the state, type of facility (IMD, ER, or general hospital), and a two-digit suffix unique to the patient. IMD patients discharged 30–60 days prior to the site visit will be identified by suffixes between 21 and 29, and IMD patients discharged 30–60 days prior to the demonstration by suffixes between 31 and 39. Patients discharged from an ER 30–60 days prior to the site visit will be identified by suffixes between 41 and 49; patients discharged from an ER 30–60 days prior to the demonstration will be given suffixes between 51 and 59; general hospital patients discharged 30–60 days prior to the site visit will have suffixes between 61 and 69; and general hospital patients' discharged 30–60 days prior to the demonstration will have suffixes between71-79. Site visitors will receive several prenumbered sample labels for each patient sampled. Site visitors will attach a label to the applicable roster next to the patient's name and will enter the number in the record review data collection protocol. The facility points of contact will be asked to keep the labeled rosters for six months after the site visit in case questions arise regarding the record review after the site visit is completed.

Data from both the medical record review and beneficiary interviews will be kept confidential. The evaluation contractor, Mathematica Policy Research, has established data security plans for the handling of all personally identifiable information, including administrative data obtained from CMS, states, and facilities; interview notes, audiotapes, coded interview data, and data processing for the interviews; and medical records abstractions. These plans meet the requirements of U.S. federal government agencies and are continually reviewed for compliance with new government requirements and data collection needs. Such security is based on (1) exacting company policy promulgated by the highest corporate officers in consultation with systems staff and outside consultants, (2) a secure systems infrastructure that is continually monitored and evaluated with respect to security risks, and (3) secure work practices of an informed staff who take all necessary precautions when dealing with confidential data. All employees also sign a general confidentiality pledge, included as Attachment H. During site visits, evaluation researchers will at all times keep notebooks and laptop computers on their persons or in secure, locked locations. Confidential data are kept in study-specific folders that only a minimum number of staff members may access. All typed or electronically coded qualitative data are periodically backed up and preserved on secure media.

Sensitive Questions

Given the nature of the demonstration and its evaluation, beneficiary interview questions of a sensitive nature concerning the individual's psychiatric condition, his or her recent and past psychiatric emergencies, and details of medical treatment, are unavoidable. This information is

at the center of the qualitative data and is necessary to conduct the evaluation. Beneficiaries will be advised of the nature of these questions in advance of the interview and informed that their participation is strictly voluntary. Beneficiaries will also have the option of declining to answer specific questions without opting out of the interview as a whole; incentive payments will not be affected by choosing not to answer particular questions. In the event that a beneficiary becomes upset during the interview, the interviewer will pause and let them collect their thoughts. The interviewer will ask the beneficiary if they are okay and if they would like to continue, or if they would prefer a callback at another time. If the interviewer determines that the beneficiary is a danger to him/herself (i.e., the beneficiary expresses a plan to harm him/herself or others) the interviewer will stop the interview and give the beneficiary the phone number for the crisis hotline. All confidentiality and security procedures described in the prior section will apply to the sensitive information collected. Solicitation of sensitive information will be limited to only that needed for evaluation purposes.

Burden Estimates (Hours & Wages)

Table 2, below, shows the estimated burden hours and costs for the respondents' time to participate in this evaluation. All 12 states will be visited twice. Each site visit will consist of a visit to each participating IMD and, for each IMD, to one ER that refers patients to the IMD and one general hospital that boards patients with psychiatric emergencies in nonpsychiatric general medical units when no psychiatric beds are available. On average, site-visit teams will conduct four 60-minute interviews each day at each facility, with one respondent per interview. Site-visit teams will also conduct medical record reviews of 10 medical records at each IMD, referring ER, and general hospital they visit. In addition to the site visits, estimates are provided for the associated project director and beneficiary telephone interviews, site-visit planning time, assistance with gathering documents to be reviewed, and submitting and assisting the evaluation contractor to understand needed state and facility administrative data.

The total burden for this evaluation is estimated to be 2,613 hours, and the total cost burden is estimated to be $111,706.

Burden hour estimates are based on prior experience of the evaluation contractor with evaluations of a similar nature. Throughout the information collection process, the contractor will monitor the length of the interviews, comments received from participants and field interviewers, and the number of individuals who refuse to be interviewed. If this information indicates that the burden on participants is so great as to undermine the collection of high quality data, procedures will be revised accordingly. For example, the number of questions asked during interviews may be reduced. If procedures require revision, the CMS will seek OMB approval to implement specific changes.

Table 2. Estimated Total Burden Hours and Cost Over Three Year

Data Collection Activity/ Respondent Type	Number of States and/or Facilities	Number of Respondents per State and/or Facility	Frequency of Response[1]	Number of Responses	Average Burden Per Response in Hours	Total Burden Hours	Average Hourly Wage	Total Cost Burden
Site Visit Planning—Facility Administrator	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	2	324	$84.88	$27,501
Site Visit Interview—Facility Administrator	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	1	162	$84.88	$13,751
Site Visit Interview—Psychiatrist	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	1	162	$83.73	$13,564
Site Visit Interview—Counselor (e.g., social worker, psychologist)	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	1	162	$32.78	$5,310
Site Visit Interview—Registered Nurse	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	1	162	$33.23	$5,383
Medical records assistance—Registered Nurse	81 (27 IMDs, 27 general hospitals, and 27 ERs)	1	2	162	3	486	$33.23	$16,150
Obtaining beneficiary consent to be called by evaluation staff —Social Worker	27 IMDs	25	2	1350	0.2	270	$20.50	$5,535
Telephone Interview—Beneficiary	27 IMDs	5	2	270	1	270	$7.25	$1,958
Telephone Interview—Project Director	12 states	1	2	24	1	24	$55.04	$1,321
Assistance gathering site documents—Administrative Assistant	39 (12 states plus 27 IMDs)	1	2	78	0.5	39	$15.87	$619
Facilitation of administrative data requests—Project Director	12 states	1	1	12	2	24	$55.04	$1,321
Ad-hoc email/phone communication to answer questions about MSIS data—Data Analyst	12 states	1	1	12	2	24	$36.54	$877
Assistance in extracting, sending, and answering questions about state or facility administrative data on IMD admissions and ER boarding—Data Analyst	12 states	1	3[2]	36	14	504	$36.54	$18,416

Data Collection Activity/ Respondent Type	Number of States and/or Facilities	Number of Respondents per State and/or Facility	Frequency of Response[1]	Number of Responses	Average Burden Per Response in Hours	Total Burden Hours	Average Hourly Wage	Total Cost Burden
Totals	**93 (12 states, 27 IMDs, 27 general hospitals, and 27 ERs)**			**2,754**		**2,613**		**$111,706**

[1]The individuals interviewed during the second round of site visits may differ from those interviewed during the first round, but categories of respondents will remain the same. Estimates for conversations regarding MSIS data, which will occur on an ad-hoc basis, are for the total number of hours needed over the course of the three-year evaluation.

[2]Assistance will be requested on a schedule to be worked out individually with each state and facility from which data are needed. Average burden per response is an estimate of time needed for this assistance during each of the three years of the evaluation.

Average hourly wages were drawn from the May 2011 National Occupational Employment and Wage Estimates, United States, as reported by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm, accessed February 18, 2013). Psychiatrist, social worker, registered nurse, and administrative assistant rates are the average wages for these positions, respectively. Facility administrator rates were estimated based on wages for chief executive officers; the rate for counselors was based on the average of wages for social workers and psychologists, for project directors it was based on general and operations managers, and for data analysts, it was based on computer programmer wages. The majority of Medicaid beneficiaries to be interviewed are likely to be unemployed; therefore, the beneficiary rate is based on the federal minimum wage.

Capital Costs

There are no capital costs.

Cost to Federal Government

Table 3 shows the total and annualized cost for this evaluation. The total cost to the federal government of the entire evaluation contract is $5,468,458 (including a base period and three option periods); the annualized cost is $1,367,114 per year. These costs will be incurred from September 2012 through September 2016.

Table 3. Estimated Total and Annualized Cost for Four-Year Evaluation Contract

Cost Component	Total Cost	Annualized Cost
Evaluation Design	$231,159	$57,790
Data Collection and Analysis	$4,381,091	$1,095,273
Synthesis of Project Findings	$178,379	$44,595
Management and Oversight	$677,828	$169,457
Total	$5,468,458	$1,367,115

Changes to Burden

Based on changes made as a result of the pilot test, the burden estimate has increased since the 60-day *Federal Register* notice was published, by a total of 567 hours, from a total of 2,046 hours to 2,613 hours. Correspondingly, the estimated cost burden has increased by a total of $17,656, from a total of $94,050 to $111,706. The increase results from three sources.

The largest increase is due to the pilot test's demonstration of the need for facility staff to assist the evaluation contractor in finding information in the medical records. To reflect this need, we have added 2.5 hours of staff time to assist with the medical record reviews at each of the 81 facilities that we visit in each of the two rounds of site visits, for a total increase in burden of 405 hours, at a cost of $13,458.

A further increase in burden is due to the pilot test's demonstration of the need to obtain additional informed consents for beneficiary interviews from IMD staff. We originally asked for only 10 consents in hopes of interviewing 5 beneficiaries from each IMD. Difficulties in reaching many of the beneficiaries in the pilot test, however, revealed the need to obtain additional consents in order to complete five interviews. Therefore, we will now ask staff of each

of the 27 IMDs to obtain 25 consents for each of the two rounds of site visits. The IMD visited during the pilot test indicated that obtaining the consents was easy to do and that obtaining 25 consents would not be a burden to them. The additional consents will require a total of 162 additional burden hours, at a cost of $3,321.

The remaining $877 increase in the burden costs is due to correction of a calculation error in the original submission.

Publication/Tabulation Dates

CMS expects the site visits to begin in the spring of 2014, pending OMB clearance. CMS's evaluation contractor will synthesize the interview data for inclusion in annual reports as well as a final evaluation report. These reports will integrate qualitative data from the site visits with quantitative data. The reports will be released to the public only after they have been cleared for release by CMS. The evaluation contractor will also develop interactive webinar presentations for key stakeholders that present cross-cutting analyses of integrated quantitative and qualitative data and provide opportunities for discussion. Webinars will only be scheduled and conducted upon approval from CMS. Table 4 presents the anticipated data collection, analysis, and reporting schedule.

Table 4. Schedule of Proposed Data Collection, Analysis, and Reporting

Task	Dates
Qualitative Data Collection and Analysis	
Round 1 Site Visits*	
Review state documents prior to round 1 site visits	Jan.—March 2014
Plan round 1 site visits in collaboration with states and IMDs	Jan.—March 2014
Conduct state calls prior to round 1 site visits	Jan.—Feb. 2014
Conduct round 1 site visits	March–June 2014
Conduct beneficiary interviews after round 1 site visits	April–July 2014
Analyze qualitative data from round 1 site visits	April–July 2014
Round 2 Site Visits	
Review state documents prior to round 2 site visits	Jan.—March 2015
Plan round 2 site visits in collaboration with states and IMDs	Jan.—March 2015
Conduct state calls prior to round 2 site visits	Jan.—Feb. 2015
Conduct round 2 site visits	March—June 2015
Conduct beneficiary interviews after round 2 site visits	April–July 2015
Analyze qualitative data from round 2 site visits	April–July 2015
Quantitative Data Collection and Analysis	
Process Medicaid and Medicare data	Mar. 2013–Nov. 2015
Obtain and process state data	Sept. 2013–Nov. 2015
Analyze demonstration year 1 data	Mar.–May 2014
Analyze demonstration year 2 data	Mar.–May 2015
Analyze demonstration year 3 data	Mar.–May 2016
Evaluation Reports	
First annual report	Aug. 29, 2014
Second annual report	Aug. 28, 2015
Final report	Sept. 2, 2016
Webinar presentations	Sept. 2014–Aug. 2016

*The first round of site visits will not begin until the data collection has been approved in accordance with the Paperwork Reduction Act.

Data described in this clearance package will be analyzed to address the research questions described in Section 1. The first round of site visits and interviews will focus on admission, stabilization, and discharge-planning procedures before and after the demonstration. The second round of site visits will take place a few months before the end of the demonstration to allow the evaluation contractor to gather detailed information on lessons learned, changes in quality of care, and sustainability. Administrative data submitted by the states and facilities will be used to supplement Medicaid and Medicare data in analyses of inpatient admissions, emergency services, and costs.

As noted above, notes from all interviews and document reviews will be typed, uploaded to Atlas.ti, and coded according to a specified scheme. Analysis of the site visit and interview data will emphasize policies and procedures that are critical to the implementation of the demonstration, including psychiatric EMC determination, admissions, stabilization assessment, stabilization, and discharge planning. The analysis will include identification of themes within and across states. Throughout the process of gathering, reviewing, and analyzing qualitative data, quotations will be noted that capture a point of view or an experience particularly well. For each project, findings from the implementation analysis will be used to interpret findings about outcomes and to help establish a basis for causal inference. In brief, the interview data collected under this clearance package, when combined with impact analyses using quantitative administrative data, will fully address the critical aspects of the demonstration, as mandated by the ACA.

Expiration Date

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

PART B

SUPPORTING STATEMENT

COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Respondent Universe and Sampling Methods

The information collected under this request is not based on probability samples and may not be generalizable beyond the states included in the demonstration. Interview subjects and medical records to be reviewed are selected purposively and fall into the following categories:

- State demonstration project directors (one telephone call for each of the universe of 12 states). Calls with the project directors will provide an efficient means for collecting information on each state's Medicaid program, mental health delivery system, implementation procedures, and demonstration successes and challenges. As the individuals most involved in project design and oversight, state project directors will provide insight into the implementation of demonstration projects and relevant contextual factors, and may identify lessons and implications as to the broad application and sustainability of projects.
- Key informants from each facility to which site visits are made (up to four in-person interviews at each facility during site visits). Site visits will be made to all 27 IMDs participating in the demonstration, as well as to one ER that refers patients to each IMD and, for each IMD, one general hospital that admits patients with psychiatric EMCs to nonpsychiatric general medical units (that is, scatter beds) when beds in the IMD are not available. ERs and general hospitals will be selected on the basis of a review of state demonstration operational plans and conversations with state project directors and IMD staff about recommended facilities. Priority will be given to facilities that are active participants in the demonstration and that have the largest expected impact on or from the demonstration. For example, if the majority of demonstration referrals to an IMD are made from one particular ER, that ER would be solicited for the site visit; likewise, general hospitals with particularly high use of scatter beds prior to the demonstration would be prioritized because the demonstration aims to alleviate the need for scatter bed use. Because of the need to understand how the demonstration affects the use of scatter beds, general hospitals selected may or may not operate acute inpatient psychiatric units. The demonstration does not alter Medicaid reimbursement for care provided in general hospital psychiatric units, nor does it aim to divert patients from them or change the care they provide; therefore, we do not expect to see significant changes in these units as a result of the demonstration. Funds will be available to provide incentives on an as-needed basis to encourage selected facilities to participate in the site visits. Interview respondents at each selected facility will include administrators and direct care staff from each site who are involved in facility operations or who provide direct care to demonstration participants and can provide information on factors associated with implementation and outcomes. Administrators may include the chief executive officer, chief nursing officer, or other senior managers. Direct care providers may include psychiatrists, registered nurses, and counselors such as social workers and psychologists. Administrators and direct care providers are important interviewees because they will provide insight into changes in access to and quality of care due to the demonstration.

- Beneficiaries (five receiving inpatient services from each IMD through the demonstration, to be interviewed by telephone following their discharge from the hospital). Beneficiary interviews will be essential to understanding patients' experiences with the admission and discharge process—for example, the amount of time spent waiting for admission, their level of involvement in discharge planning, and how waiting time and participation in discharge planning compare with previous hospitalizations for psychiatric emergencies. Beneficiary viewpoints are critical to understanding if and how quality of care improves as a result of the demonstration. IMD staff will be asked to solicit demonstration participants as they are being discharged, to procure their consent to be contacted by the evaluation team. All demonstration participants who are discharged 21 days before the date of the site visit will be asked to participate until 25 have agreed. Patients will be asked whether they would be willing to speak with a member of the evaluation team about their admission and discharge experiences; if they agree to speak with the evaluation team, the IMD staff member will document contact information for each patient and obtain signed consent. The consent form will include a discussion of the use of an audio recording during the interview. The IMD staff will inform patients that they will be selected randomly for an interview; that is, signing the consent form does not guarantee that he or she will be called for an interview. Due to logistical complexities, patients discharged to forensic facilities will not be interviewed. For patients assigned legal guardians for decision-making purposes, IMD staff will solicit consent and contact information from both the guardian and the patient. IMD staff will inform patients that, if selected, they will receive a $20 check from the evaluation staff for participating in the interview. Across all states, the demonstration is expected to enroll hundreds to thousands of participants. The 270 beneficiaries selected for interviews over two rounds of site visits will be selected on the basis of proximity of their discharge dates to the timing of the site visit. Provision of incentives will help to encourage participants with a range of experiences to participate, thereby helping to reduce the potential for bias if only patients with negative experiences were to respond. Patients with more positive relationships with the IMD staff soliciting their participation may be more likely to agree to participate. Due to logistics regarding locating and connecting with individuals for interviews, patients with more positive discharge experiences (such as those discharged to stable homes in the community rather than to forensic units, homeless shelters, or other types of institutional care) may be more likely to participate. Despite these potential sources of bias, the beneficiary interviews provide an important cross-validation of information about implementation procedures provided by medical record reviews and participating facility and demonstration staff, each of which is subject to its own unique biases.
- Medical records review (10 medical records reviewed at each of 27 IMDs, 27 EDs, and 27 general hospitals during site visits). Medical records review will cross-validate and provide a more detailed understanding of stabilization assessment and discharge-planning procedures, interventions administered to achieve stabilization, length of time spent in the ER, procedures for determining and documenting the existence of qualifying psychiatric EMCs, and inpatient referral procedures. Medical records are important for determining whether the demonstration was implemented as intended,

and will facilitate identification of operational lessons learned. Sampling procedures for medical records to be reviewed are described in detail in Attachment C.

Procedures for the Collection of Information

CMS's evaluation contractor will use a systematic qualitative data collection approach that will draw from multiple sources including telephone interviews, document review, beneficiary telephone interviews, and site visits, including in-person interviews and medical records review.

CMS's evaluation contractor will conduct two rounds of site visits during the evaluation period. Pending clearance, the first round will take place about 24 months after the start of the demonstration (spring 2014 through summer 2014) and will focus on admission, stabilization, and discharge-planning procedures before and after the demonstration. The timing of the visits will ensure that states have sufficient time to respond to unforeseen implementation challenges, and that project procedures operate consistently. The second round will take place a few months before the end of the demonstration (spring 2015 through summer 2015) to allow the evaluation contractor to gather detailed information on lessons learned, changes in access and quality of care, and sustainability. The length of each visit will vary based on the number of IMDs involved in each state's demonstration project. Table 5 details the proposed site visit structure and plans for data collection at each facility.

Table 5. Site Visit Structure and Data Collection

State/Number of Participating IMDs	Days On Site	Site Visit Structure and Data Collection
Alabama (4) California (4) Maryland (3) Missouri (3) Washington (3) Illinois (2) Maine (2) West Virginia (2) Connecticut (1) District of Columbia (1) North Carolina (1) Rhode Island (1)	6 5 3 3	Structure: The evaluation team will spend one day at each participating IMD, one day at the IMD's primary ER referral source, and one day at a general hospital that admits patients experiencing a psychiatric emergency to a nonpsychiatric unit when beds are not available in a psychiatric unit or IMD. Because of the need to understand how the demonstration effects the use of scatter beds, the general hospital selected may or may not operate an acute inpatient psychiatric unit. Key Informant Interviews: On average, teams will conduct four 60-minute interviews at each facility. Medical Record Reviews: Teams will review 10 medical records at each facility: IMD, the IMD's primary ER referral source, and the general hospital that admits patients experiencing a psychiatric emergency when beds are not available in a psychiatric unit or IMD.

Note: A four-person team will conduct site visits that involve more than one participating IMD. A two-person team will conduct site visits to states with only one participating IMD.

- State project directors will be interviewed by telephone prior to each round of site visits. One-hour interviews will focus on identifying any changes in the state's role in administering the demonstration and the associated costs, evolving contextual factors affecting psychiatric emergency and inpatient care in the state, and implementation facilitators and challenges. The evaluation team will also review with each project director the state-specific logic model they developed based on information gathered from document review during the evaluation design phase. The

evaluation team will use a standardized set of questions to guide conversations (Attachment B).

- Direct care staff and administrators from IMDs, ERs, and general hospitals will be interviewed in person once during each round of site visits. Each interview will last 60 minutes. Semistructured interview guides will indicate the type of information to be collected but will allow for flexibility across sites in terms of respondents, topics, and questions asked; this flexibility is critically important given the significant variation in demonstration projects across states. Attachment B includes a list of the interview questions to be asked of direct care providers and administrators from IMDs, ERs, and general hospitals.
- Beneficiary telephone interviews will be conducted with five demonstration participants discharged from each IMD after each round of site visits, for a total of 135 interviews. Attachment E details the interview questions for beneficiaries and includes the consent form for beneficiaries and the script IMD staff will use to invite beneficiaries to participate in the interviews.
- Ten medical records will be selected at each facility (IMD, ER, and general hospital), using purposive sampling. Attachment C details the sampling procedures. This technique will enable site visitors to identify records for patients with a wide range of characteristics of interest, such as high-risk behaviors requiring chemical or physical restraint, medical comorbidities, or frequent admissions. Direct care staff at each facility will be asked to assist site visitors in finding information needed for the evaluation within the medical records; this should take approximately 3 hours for staff at each facility. Using a structured tool (Attachment D), the evaluation contractor will abstract from:
  - IMD records, information on stabilization assessment procedures, discharge-planning procedures, and interventions administered
  - ER records, information on length of time in the ER, EMTALA status determination, interventions administered, and inpatient referral procedures
  - General hospital records, information on interventions administered, stabilization assessment procedures, and discharge-planning procedures.

To ensure effective coordination with respondents, the evaluation contractor will use a systematic approach to communicating and coordinating with IMDs, ERs, and general hospitals. Table 6 details the sequence of events. Approximately three months before the scheduled site visit, the contractor will send an email to the demonstration project director and point of contact for each IMD. The email will describe site-visit activities, identify the approximate time frame for the visit, and request a date for a planning meeting via telephone to discuss the logistics of the site visit and all pre-visit activities. During the planning meeting with the IMD point of contact, the evaluation contractor will discuss the schedule for the site visit to the IMD (for example, length of interviews with four key informants and time needed for an overview of medical records) and identify a point of contact for a referring ER and a general hospital that boards patients with psychiatric emergencies in nonpsychiatric general medical units when no beds are available in IMDs. The contractor will inform the IMD contact that, on the first day of

the site visit, the review team will request two lists of patients from which medical records will be selected for review.

After the planning meetings with the IMDs are completed, the evaluation contractor will contact the points of contact at the ERs and general hospitals to discuss site-visit activities and to schedule interviews with four staff members and time for medical record reviews. For example, the contractor will ask the ER contacts to provide the team with lists of patients from which medical records will be selected for review.

Table 6. Site-Visit Planning Protocol

Weeks Before Site Visit	Scheduling Activity	Purpose of Activity
12	Send email to demonstration project directors and IMD points of contact (POC)	• Provide overview of site-visit activities • Propose site-visit dates • Propose planning meeting telephone call date(s) with IMD POC(s) during week 10
11	Send follow-up email to demonstration project directors and IMD POCs	• Confirm site-visit dates • Confirm IMD POC planning meeting call dates and times
9–10	Call IMD POCs to plan site visit	• Review site-visit logistics • Discuss site-visit activities and schedule, including staff interviews and medical record reviews • Request two patient rosters for medical record reviews • Request assistance from IMD staff for beneficiary recruitment for interviews • Request IMD documents • Identify and obtain contact information for ER and general hospital POCs
9	Send email to ER and general hospital POCs	• Provide overview of site-visit activities • Propose site-visit planning meeting telephone call date(s) and time(s)
9	Send follow-up email to ER and general hospital POCs	• Confirm telephone meeting dates and times
7–8	Call ER and general hospital POCs to plan site visit	• Review site visit logistics • Discuss site visit activities and schedule, including staff interviews and medical record reviews • Request two patient rosters from ER POC • Request one patient roster from general hospital POC
1–2	Follow up by telephone with IMD, ER, and general hospital POCs	• Confirm any information that might have changed • Provide site-visit team's names and contact information • Remind POCs about rosters needed from their location • Review site-visit logistics one final time

Quality Control Procedures. Customized, comprehensive training is vital for uniform, consistently high quality qualitative data collection. The evaluation contractor will conduct two training sessions in association with each round of telephone interviews and site visits.

The training sessions will review the semistructured interview guides, the medical record review tool, the beneficiary interview guide, and the data coding scheme. The site-visit teams will practice using the medical record review tool, role-play interviews, and discuss how to respond to unexpected events while on site. The training will promote reliability in use of the protocols and will ensure that each contractor staff member shares a common understanding of the goals of the site visits.

After the first site visit, contractor staff will meet to discuss any changes required to the interview guides or medical record review tool, with revisions made as needed. Further, contractor staff will meet after the site visit to review findings and to identify any information that requires further calls with the site. Once all site visits are complete, the evaluation contractor will train teams to code qualitative data using Atlas.ti software. The contractor will follow a thematic coding scheme to be developed by the qualitative research experts (Attachment I).

The site visit team's lead will ensure quality and consistency of data collection during the site visits by conducting reliability assessments to ensure consistent implementation of the review procedures and accuracy of data collection across team members. At the end of the site visit, the team's lead will review all data collection protocols for missing or inconsistent data.

Methods to Maximize Response Rates and Deal with Nonresponse

The interview and medical record data collection is not based on probability samples and is not meant to represent anyone other than the respondents. Therefore, a response rate does not apply to these activities. However, in selecting states to participate in the demonstration, CMS stipulated that states cooperate fully in the cross-state demonstration evaluation. Given this, and the evaluation contractor's experience conducting other process evaluations, CMS expects a high level of participation from state demonstration personnel and facility administrators and direct care providers. A $300,000 incentive pool has also been established for distribution among states and facilities to assist the evaluation contractor in obtaining and understanding administrative databases and conducting site visits. Incentive payments will be offered on a state-by-state, as-needed basis to ensure necessary cooperation. It is likely for example, that cooperation from facilities not participating in the demonstration from whom staff time, facility access, or data are needed may be enhanced through such incentive payments; such may be the case, for example, for ERs and general hospitals to which site visits will be made or from whom boarding time data are solicited. The incentive payment to be provided to each state and facility will vary, depending on the specific types of data requested, the exact number of states and facilities from which data are requested, and the specific amount of burden entailed for each of the respondents to provide the needed data, given variations in their systems. To further ensure the cooperation of respondents, contractor staff will attempt to minimize individual burden and develop interview schedules that respect site constraints and pressures.

- Minimize individual burden. Willingness of respondents to participate in in-person interviews may hinge on the time these meetings require. To minimize the burden, guides are designed to gather information that is as complete as possible in as little time as possible. The evaluation contractor has developed separate discussion guides for each respondent type so that respondents are not asked about activities or issues

that are not applicable to them. In addition, interviewers will meet with interview respondents in person in their own offices or at a location of their choice. Telephone interviews with facility staff will be scheduled at a time that is convenient for the respondent, and respondents will be provided with the interview questions in advance to allow them to prepare if they so desire.

- Develop interview schedules that respect site constraints and pressures. The contractor will work with each site to determine logistics and a schedule for the in-person interviews. The schedule will avoid conflict with other activities and allow individuals to find time in their calendars to spend with contractor staff.

Although CMS expects a high degree of participation from all respondent types, direct care providers may be less readily available for in-person interviews than other respondent types. The evaluation contractor will offer additional accommodations to this respondent type to increase the likelihood of their participation. They will offer to meet with direct care providers outside of clinical hours, restrict the interview to 30 minutes if 60 minutes is not acceptable, and conduct the interview by telephone if the respondent says that would be more convenient.

To encourage participation of beneficiaries in the interviews, an incentive payment of $20 in the form of a check will be paid for each interview. This will help to encourage patients with a range of experiences to participate, thereby helping to reduce potential biases if only patients with negative experiences were to respond. IMD staff will be asked to solicit agreement from patients for them to be contacted by the evaluation team as well as their contact information, immediately prior to discharge. Obtaining contact information at this point will greatly facilitate the ability to locate discharged demonstration participants; being asked by hospital staff with whom they are familiar might encourage participation. IMD staff will be asked to obtain consent to be contacted from 25 patients discharged within 21 days of the site visit; of these 25, only 5 will be randomly selected to be interviewed. Beneficiaries who cannot be located or who chose not to be interviewed when contacted by the evaluation team will be replaced from among the remaining pool of those providing initial consent at discharge. The proximity of the interviews to the respondents' hospital discharge dates will facilitate the evaluation team's ability to locate potential participants and the respondents' ability to recall details of their recent hospitalization experiences. Interview respondents may choose not to answer specific questions without consequences; the interview notes will record such decisions.

Test of Procedures or Methods to Be Undertaken

The evaluation contractor pilot tested the protocols by conducting a site visit and associated interviews for the Connecticut demonstration project from May 20-22, 2013. Connecticut was selected because of its proximity to the evaluation contractor's offices and because only one IMD is participating in the state's demonstration project, which simplified logistical arrangements and allowed the visit and interviews to be completed on an expedited schedule without violating the PRA.

CMS's objectives during the pilot test were to assess whether (1) planned procedures allow collection of the information needed in the allotted time, (2) respondents can readily understand and answer the interview questions, (3) interviews flow sensibly from topic to topic, and (4) the questions seem to yield thoughtful, candid responses. The pre-tests were also useful for

identifying interviewer training needs and considering refinements to site-visit planning procedures (for example, how best to identify facilities to visit, individuals to interview, and medical records to review). Pilot testing also helped confirm the burden estimates.

The site visit protocols attached to this supporting statement (Attachments B - E) directly reflect the pretest results. Below, we summarize changes made in response to lessons learned during the pilot test.

- The medical record review protocol for the IMD took longer than anticipated. To eliminate redundancy and reduce burden on staff, the contractor removed several items and subquestions from the medical record review protocols and simplified and reworded others.
- Facility staff had lists of medical records prepared for site visits as requested, and staff noted that preparing these lists required little effort. Procedures for sampling these records were simplified to reduce burden on facility staff. Rather than asking staff to recall patient characteristics, the evaluation team will now utilize readily available information on diagnostic codes and length of stay to select participants. In addition, the evaluation contractor initially planned to review two open medical records for patients in the IMD but some information for patients currently receiving treatment at the IMD in the pilot site was maintained on the unit rather in the medical records office. To minimize burden on staff working on the unit, the evaluation contractor will now review only closed medical records during the site visit.
- The point of contact for the pilot site reported that requesting IMD staff to recruit beneficiaries to participate in interviews was feasible and that the process was straightforward and did not require much time. The IMD gave the evaluation contractor 12 signed consent forms, even though only 10 were requested. Subsequent to the site visit, however, the contractor had difficulty contacting many of the beneficiaries who provided consent. To obtain enough consents to ensure that that the desired sample size can be achieved, therefore, the contractor will now ask IMDs to gather at least 25 consents.
- The interview questions were generally understood by respondents, but the majority of respondents were not aware that the state is participating in the MEPD. Therefore, questions that refer to changes since the demonstration began were reworded using the date of implementation as the reference point for changes. Respondents did not generally have difficulty answering the interview questions, but some clarifying modifications were made to the interview protocols.

Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

CMS contracted with Mathematic Policy Research to design and conduct the evaluation of the MEPD. Table 7 identifies the individuals at Mathematica involved in designing, overseeing, and analyzing the data.

Mathematica also consulted with a technical expert panel on the methods and data collection procedures used in this project. Attachment G identifies members of the technical expert panel.

Table 7. Individuals Consulted on Statistical Aspects of the Design

Name	Project Role	Email	Phone
Project Management			
Crystal Blyler	Project Director	cblyler@mathematica-mpr.com	(202) 250-3502
Quantitative Team			
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Qualitative Team			
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