

RESPONSE TO OMB QUESTIONS OF AUGUST 30, 2007

(1) Confidentiality

The Healthcare Research and Quality Act of 1999 will in fact protect AHRQ from FOIA requests for information collected as part of the pilot testing of MEADERS.

(2) Rationale for practice/site IDs

A critical factor in assuring that MEADERS contributes to improvements in patient safety and quality of care within practices is the ability of the system to provide periodic feedback that summarizes the individual practice's error reporting and compares it to the de-identified aggregate data from the other pilot practice sites. Since individual reports are otherwise de-identified, a practice/site ID on every report is necessary in order to allow the system to link that report to a specific practice when feedback is being generated. When MEADERS underwent beta-testing (see page 3 of the application), the request to provide a practice/site ID did not appear to affect the willingness of clinicians to report observed events.

It should be noted that the identity of the individual reporter within the practice is protected. Even when reports are forwarded to MedWatch, FDA must ask the practice to identify the individual reporter as part of its follow-up procedures.

(3) Assessment of the usefulness of MEADERS

In response to OMB's concern, we will conduct a series of focus groups to gather additional qualitative information on the usefulness of MEADERS in terms of improving patient safety. Four focus groups, each involving 8-10 clinicians/staff from participating practices in each of the PBRNs, will be scheduled at the completion of the pilot testing. (Total participants = 32-40 individual clinicians/staff). A brief description of this process has been added to the text of the application, with corresponding changes made to the estimated cost burden table (see tracked changes). In addition, a more detailed description of the proposed process and focus group guide are included as a separate attachment (FOCUS GROUP).

(4) Follow-up survey

The requested changes to the follow-up survey have been made. Please see tracked changes in Attachment #2.