AHRQ REQUEST FOR EXPEDITED OMB REVIEW OF A PATIENT SAFETY ORGANIZATION ATTESTATION FORM: Guidance to PSOs with Mandatory FDA-Reporting Obligations

Summary of Request

The Agency for Healthcare Research and Quality (AHRQ) is requesting expedited review and approval by OMB of a form that will require attestations from approximately 80 existing Patient Safety Organizations (PSOs) and approximately 15 entities expected to seek listing by AHRQ as a PSO in 2011. The Department of Health and Human Services (HHS) issued Guidance on December 30, 2010, describing how a PSO that has, or is organizationally related to an entity with, mandatory FDA-reporting obligations, can meet those responsibilities. AHRQ has been advised that attestations are necessary to provide AHRQ with a legal basis for taking action against a PSO that has but does not meet its mandatory FDA-reporting obligations or fails to permit FDA access to its facilities or to FDA-reportable information held by the PSO. AHRQ intends to include these attestations in its existing initial and continued listing PSO forms which will be submitted to OMB next month (approval for existing forms expires August 2011). However, without approval of this interim form, AHRQ would only be able to seek attestations from an existing PSO until its three-year period of listing is about to expire and the PSO seeks continued listing; thus, AHRQ could not enforce the Guidance fully until this three-year cycle is complete. Therefore, approval of this request will enable AHRQ to obtain attestations from all existing PSOs in a timely manner and obtain attestations from all entities seeking listing in 2011. AHRQ intends to discontinue use of this form after OMB approves the revisions proposed to existing initial and continued listing forms and all existing PSOs have submitted the required attestations.

The Patient Safety Act

The Patient Safety Act encourages providers to participate in voluntary initiatives to improve the safety and quality of patient care by providing strong confidentiality and privilege protections for patient safety information that is developed when a health care provider works with a PSO. The protections apply when providers work with an entity listed by AHRQ as a PSO; listing is based upon submission of attestations by an entity that it meets specific statutory and regulatory criteria set forth in the Patient Safety Rule. An entity can seek PSO listing at any time and listing is for three-year, renewable periods. The Rule provides little discretion for AHRQ to deny an application for initial listing.

The ability to disclose protected information (known as patient safety work product, PSWP) is quite limited. The implementing regulation (Rule) states that disclosures can only be made if there is a specific permission (exception) to disclose PSWP. In most circumstances, the information remains confidential and privileged following a permissible disclosure.

Guidance Regarding Compliance With Mandatory FDA-Reporting Obligations

AHRQ has received applications for PSO listing from subsidiaries of medical device manufacturers regulated by the Food and Drug Administration (FDA). These applications raised a number of questions, including: (1) whether a PSO with FDA-reporting responsibilities could meet its responsibilities to disclose required information to its parent organization (manufacturer) or FDA in light of the restrictions

on disclosure of PSWP that is received or developed by a PSO; and, (2) whether AHRQ could take action to delist a PSO that has, but fails to meet, such FDA-reporting obligations. The policy concern is that close organizational ties between a PSO and an entity with mandatory FDA-reporting obligations could divert the reporting of information to a PSO that should have been reported to the manufacturer or the FDA. In doing so, the information would become PSWP, thereby compromising the ability of the FDA to receive (directly or through required reports by entities such as manufacturers) important safety and quality information and, thereby, limit FDA's ability to take appropriate enforcement action.

The HHS Guidance just issued clarifies how such entities can provide manufacturers or FDA with reportable information, how FDA can inspect such PSOs to verify that required reporting has occurred, and that FDA can take appropriate enforcement action with the information. The basis for this clarification is an FDA-related "rule of construction" in the Patient Safety Act that states that nothing in the section of the Act that states the privilege and confidentiality protections "…shall be construed…to limit, alter, or affect any requirement for reporting to the Food and Drug Administration…." Because this FDA-related "rule of construction" was not discussed in the Rule, the HHS Office of General Counsel determined that HHS needed to issue Guidance, advised AHRQ to seek attestation from existing and prospective PSOs, and recommended amending the Rule to include reference to the Guidance.

Rationale for Expedited Approval

To facilitate timely enforcement of the Guidance, AHRQ proposes a two-step process for seeking attestations. First, AHRQ is seeking expedited approval of this interim form that would allow AHRQ to seek attestations from all existing (80+) PSOs and entities seeking listing during the first three-quarters of 2011. Second, AHRQ will seek OMB approval to modify the existing PSO forms, including incorporating these attestations into the initial and continued listing forms, as part of AHRQ's Paperwork Reduction Act (PRA) submission to OMB next month (approval of all existing PSO forms expires August 2011).

Approval of this request is expected to provide greater assurance that FDA will receive required safety and quality reports on FDA-regulated products and activities, by ensuring that AHRQ can de-list a PSO that fails to meet its obligations. The alternative, reliance solely upon modifying existing forms, would delay AHRQ's ability to seek attestations from each existing PSO until its three-year period of listing is about to expire and it seeks continued listing. Therefore, use of this interim form will greatly reduce the time needed to obtain attestations from all existing PSOs and, thereby enhance AHRQ's ability to take action if a PSO subject to the Guidance does not meet its obligations.