Department of Health and Human Services Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005

The Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act), and the implementing regulations at 42 CFR Part 3, provide for the disclosure of information relating to patient safety events by health care providers to entities known as "patient safety organizations" (PSOs). The statute attaches privilege and confidentiality protections to this information, termed "patient safety work product" (PSWP), to encourage providers to assemble and report this information without fear of liability, and provides for the certification and listing of PSOs, which receive this information and analyze these patient safety events so as to improve patient safety and the quality of care.

The Agency for Healthcare Research and Quality (AHRQ), within the Department of Health and Human Services (HHS), is responsible for certifying and listing entities as PSOs based on their meeting certain criteria, with continued listing contingent upon their continuing to meet such criteria. AHRQ may also certify and list "component PSOs," which are "component organizations." A "[c]omponent organization means an entity that: (1) [i]s a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization); or (2) [i]s owned, managed, or controlled by one or more legally separate parent organizations." 42 CFR 3.20. The Office for Civil Rights (OCR) within HHS is responsible for interpretation, administration and enforcement of the confidentiality protections and disclosure permissions of the Patient Safety Act and Rule.

The purpose of this Guidance is to address questions that have arisen regarding the obligations of PSOs where they or the organization of which they are a part are legally obligated under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., and its implementing regulations to report certain information to the Food and Drug Administration (FDA) and to provide FDA with access to its records, including access during an inspection of its facilities. For example, FDA-regulated device manufacturers who are subject to FDA medical device reporting requirements may seek listing for a component PSO. See 21 U.S.C. § 360i(a) and 21 CFR Part 803. This Guidance applies to all entities that seek to be or are PSOs or component PSOs (collectively, "PSOs") that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations ("FDA-regulated reporting entities") or are organizationally related to such FDA-regulated reporting entities (e.g., parent organizations, subsidiaries, sibling organizations). This Guidance provides: 1) clarification regarding the Patient Safety Act statutory and regulatory provisions that provide for disclosure pursuant to the Patient Safety Act, and 2) provides the circumstances under which a conflict of interest may prevent the listing (or require the delisting) of a component PSO and the steps the Department is taking to prevent and address such conflicts. This Guidance should be used by currently listed PSOs and entities seeking to be listed as PSOs that are, or are

organizationally related to, FDA-regulated reporting entities, and will be used by AHRQ in making listing and delisting decisions.

Provisions Providing for FDA Reporting and Access to PSWP

In enacting the Patient Safety Act, Congress protected PSWP as privileged and confidential, and also recognized that exceptions to these protections are warranted in some limited circumstances such that the disclosing of PSWP would be permitted. In regard to the FDA, the Patient Safety Act 1) permits providers to disclose PSWP to the FDA with respect to a product or activity regulated by the FDA (the "FDA Exception"), and 2) permits any person or entity to disclose to the FDA PSWP necessary to meet required reporting obligations to the FDA ("the FDA Rule of Construction"). These provisions recognize that the Patient Safety Act works in concert with FDA laws in pursuit of their common goal of promoting and protecting patient safety. The FDA Rule of Construction ensures that PSOs that are FDA-regulated reporting entities and PSOs that are organizationally related to FDA-regulated reporting entities cannot avoid their mandatory reporting obligations to the FDA under the FDCA and its implementing regulations, and otherwise permits the effective operation of the FDA reporting system.

The FDA Exception

The confidentiality requirements of the Patient Safety Act do not apply to or prohibit a "[d]isclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration." 42 U.S.C. § 299b-22(c)(2)(D). The final rule implementing the Patient Safety Act regulation at 42 CFR 3.206(b)(7)(i) provides that the confidentiality provisions shall not apply to or prohibit: "Disclosure by a provider of patient safety work product concerning an FDA-regulated product or activity to the FDA, an entity required to report to the FDA concerning the quality, safety, or effectiveness of an FDA-regulated product or activity, or a contractor acting on behalf of FDA or such entity for these purposes." Subsection (b)(7)(ii) provides that: "Any person permitted to receive patient safety work product pursuant to paragraph (b)(7)(i) of this section may only further disclose such patient safety work product for the purpose of evaluating the quality, safety, or effectiveness of that product or activity to another such person or the disclosing provider."[1]

The preamble to the final rule implementing the Patient Safety Act responded to a number of comments on the FDA Exception. The following comment and HHS response are relevant here. The comment, as indicated in the regulation at 73 Federal Register 70732, 70782 (November 21, 2008), states: "Comment: Five commenters asked that the

[1] We also note that the Patient Safety Act does not interfere with or affect providers voluntarily sharing non-PSWP with the FDA, which can include analyses of adverse events that were not assembled or developed for reporting to a PSO or information that exists separately from a patient safety evaluation system (PSES). PSES is defined in the Patient Safety Act's regulation as "the collection, management, or analysis of information for reporting to or by a PSO." 42 CFR 3.20.

final rule allow PSOs as well as providers to disclose or report patient safety work product to the FDA or to an entity that is required to report to the FDA." HHS' response was as follows: "We do not modify the *provision* as there is no statutory authority to allow PSOs to report patient safety work product to the FDA or to an entity required to report to the FDA. However, the statute does permit providers to report patient safety work product to the FDA or to an entity required to report to the FDA." (emphasis added)

The response to the comment was intended to explain that the FDA Exception set forth in 42 U.S.C. § 299b-22(c)(2)(D) only pertains to disclosure by a provider, not by any other entity. To avoid any misinterpretation of the response to the comment, this Guidance clarifies that the response is limited to the scope of 42 U.S.C. § 299b-22(c)(2)(D), as reflected in 42 CFR 3.206(b)(7). Also, to avoid any misinterpretation of the response to the comment, this Guidance clarifies that, independent of the FDA Exception, the FDA Rule of Construction operates to permit the disclosure of PSWP to the FDA to meet required reporting obligations. Thus, there is statutory authority (i.e., the FDA Rule of Construction) that allows PSOs to report PSWP to the FDA. The FDA Rule of Construction is discussed in more detail below.

The FDA Rule of Construction

The Patient Safety Act includes a provision at 42 U.S.C. § 299b-22(g)(6), the "FDA Rule of Construction," which states that "[n]othing in this *section* shall be construed . . . to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration." (emphasis added) The Patient Safety Act added sections 921 to 926 to the Public Health Service Act. The "*section*" that is referenced in the FDA Rule of Construction is section 922 of the Public Health Service Act, 42 U.S.C. § 299b-22, which includes all of the Patient Safety Act's privilege and confidentiality protections and exceptions. Thus, the privilege and confidentiality protections in the Patient Safety Act cannot be construed to limit, alter, or affect any requirement for reporting information to the FDA regarding the safety of an FDA-regulated product or activity.

FDA-regulated entities generally have mandatory adverse event reporting responsibilities under the FDCA and its implementing regulations. One example of such FDA mandatory reporting requirements is device manufacturers' medical device reporting (MDR) responsibilities. See 21 CFR Part 803. If a device manufacturer has a component PSO, the device manufacturer must have access to certain complaint/adverse event information the PSO receives as PSWP in order to fully comply with its MDR responsibilities under the FDCA. Under the FDCA and its implementing regulations, device manufacturers are required to establish and maintain MDR event files and complaint files, and must also establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. See 21 CFR 803.18 and 21 CFR 820.198. In addition, certain records, including complaint files, must be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to FDA employees designated to perform

inspections, and MDR event files must be clearly identified and must be maintained to facilitate timely access. See 21 CFR 803.18 and 21 CFR 820.180. A device manufacturer must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify MDR event files. 21 CFR 803.18(b)(2).

This Guidance clarifies that the FDA Rule of Construction is to be read broadly to permit PSOs that are, or are organizationally related to, FDA-regulated reporting entities to report to the FDA, including where such reports contain PSWP collected or developed by the FDA-regulated reporting entity or a PSO organizationally related to the FDA-regulated reporting entity. This Guidance clarifies that the reporting requirements referenced in the FDA Rule of Construction encompasses the steps FDA may take under the FDCA, including FDA inspection, to ensure FDA-regulated reporting entities are making all required reports under the FDCA and are adequately evaluating and investigating adverse events/complaints. Thus, FDA may inspect facilities and any adverse event/complaint files, including files containing PSWP that are held by PSOs that are FDA-regulated reporting entities or a PSO that is organizationally related to an FDA-regulated reporting entity. In addition, under the FDA Rule of Construction, the FDA-regulated reporting entity may have access to all complaint and adverse event files related to its products, including files containing PSWP that it creates or receives as a PSO or that is created or received by a PSO organizationally related to the FDA-regulated reporting entity.

Upon disclosure to the FDA pursuant to the Rule of Construction (whether through the FDA-regulated reporting entity or directly to the FDA), PSWP will no longer be considered privileged or confidential. Based on this Guidance, PSWP received by the FDA under the FDA Rule of Construction is not subject to continued protection under the Patient Safety Act, and therefore can be used by the FDA for enforcement purposes to ensure the safety of FDA-regulated products or activities. For example, FDA may seek civil money penalties for violations of the FDCA, including violations of adverse event reporting requirements, or injunctions to prevent unsafe products from being placed in the marketplace.

In conclusion, the Patient Safety Act's mandate that nothing in the Act's privilege and confidentiality provisions shall be construed to "affect any requirement for reporting" to the FDA prevents the use of PSOs by FDA-regulated reporting entities to avoid their obligations to the FDA and otherwise permits the effective operation of the FDA patient safety system created by Congress.

Conflict of Interest

The Patient Safety Act establishes criteria for the certification and listing of PSOs. Entities that wish to be component PSOs must meet these criteria as well as additional requirements if they are to be (and remain) component PSOs. One of these additional requirements is the requirement that "the mission of the [component PSO] does not create a conflict of interest with the rest of the organization." 42 U.S.C. § 299b-24(b)(2)(C). This Guidance addresses two points: first, as discussed above, for an FDA-regulated

reporting entity, there is no inherent conflict between its obligations to FDA under the FDCA and its obligations under the Patient Safety Act; and second, how to avoid any potential conflict of interest.

Generally the mission of a component PSO that is a part of an FDA-regulated reporting entity does not create a "conflict of interest" with the rest of the organization. For example, a key mission of a component PSO is maintaining the confidentiality of PSWP under the Patient Safety Act. There is no conflict of interest between a component PSO and the rest of the organization that is subject to FDA reporting requirements because disclosure is permitted by the FDA Rule of Construction.

However, a "conflict of interest" between the component PSO and the FDA-regulated reporting entity may arise where the FDA-regulated reporting entity (or its component PSO) does not comply with its FDA reporting obligations. A "conflict of interest" arises where a component PSO misuses its status as a component PSO and its Patient Safety Act confidentiality mission as a basis for preventing the FDA-regulated reporting entity or component from meeting its legally-required FDA reporting obligations. Thus, an entity whose parent organization is an FDA-regulated reporting entity will not be eligible to be certified and listed as a component PSO unless the entity agrees to disclose PSWP to its parent and FDA, when required under the FDCA and its implementing regulations, and provide FDA with access as required by law and as discussed in this Guidance. In addition, if it is determined that a component PSO does not make such disclosures or provide such access to the FDA, this would be a basis for delisting that component PSO. In these situations, there is a "conflict of interest" under the Patient Safety Act in that the component PSO would be acting in conflict with the responsibilities of the FDA-regulated reporting entity of which it is a part to comply with its reporting obligations under the FDCA and its implementing regulations.

Preventing and Addressing "Conflicts of Interest"

In order to ensure the integrity and effectiveness of both the Patient Safety Act and the FDA reporting regimes, HHS believes it should deny component PSO certification and listing to entities that cannot adequately ensure that such certification and listing would not create a "conflict of interest" between the component PSO and the FDA-regulated reporting entity of which it is part, and by delisting PSOs that, through their actions, create a "conflict of interest."

AHRQ is responsible for certifying and listing PSOs, including component PSOs, and for delisting such entities when necessary. AHRQ currently requires entities that seek to be component PSOs to sign an attestation that the statements on the application form, and any submitted attachments or supplements, are true, complete and correct to the best of the authorizing official's knowledge. Included on the application is an opportunity for the applicant entity to check "yes" or "no" to question number 18: "Will the component entity ensure that the pursuit of its mission will not create a conflict of interest with the rest of its parent organization(s)?" The application form also indicates that if the answer is "no" for any of the questions, additional clarification may be sought before the

Secretary makes a determination regarding initial listing. In addition, the form indicates that applicants must promptly notify HHS if any changes take place that would render any attestation inaccurate or incomplete.

This Guidance clarifies that, in determining whether the component entity is able to avoid a "conflict of interest," an affirmative answer to the attestation under question 18 by an entity applying to be a component PSO that is part of an FDA-regulated reporting entity has particular meaning. It signifies that the component PSO agrees that it must comply with all FDA reporting responsibilities, including 1) disclosing relevant PSWP held by the component PSO to the FDA-regulated reporting entity and to the FDA, and providing FDA with access to such PSWP (held at the PSO); and 2) having the component PSO disclose relevant PSWP to the FDA-regulated reporting entity of which it is part in order to ensure that such entity meets its FDA reporting requirements. The PSWP that is relevant depends upon the specific FDA requirements relating to the entity. For example, FDA-regulated manufacturers are subject to mandatory MDR responsibilities pertaining to device-related adverse events as provided in 21 CFR Part 803.

This Guidance also clarifies that AHRQ may seek additional information as needed for determining whether an applicant meets the PSO and component PSO criteria. The Patient Safety Act regulation provides, at 42 CFR 3.102(a)(1)(vii), that entities seeking to be PSOs or component PSOs, must "[p]rovide other information that the Secretary [of HHS] determines to be necessary to make the requested listing." For example, AHRQ may request additional information from entities that apply to be component PSOs and may be part of an organization that has FDA reporting responsibilities.

AHRQ may also request additional information from any entities that currently are component PSOs whose organization includes an FDA-regulated reporting entity so as to better understand whether they can meet or are meeting their mandatory FDA reporting requirements and to determine whether there is a "conflict of interest." [2] AHRQ will also be asking currently listed component PSOs and entities seeking to be component PSOs to identify whether they are organizationally related to an FDA-regulated reporting entity.

AHRQ will also be asking component PSOs of FDA-regulated reporting entities to provide timely notification to currently reporting providers and prospective reporting providers that the PSO will disclose certain information to the FDA-regulated reporting entity of which it is part and that FDA will have access to certain adverse event information received by the PSO as outlined in this Guidance. In addition, AHRQ will be asking that such notification be included in any contracts that component PSOs have

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[2] We also note that the Patient Safety Act regulation, at 42 CFR 3.110, "Assessment of PSO compliance," states: "The Secretary may request information or conduct announced or unannounced reviews of, or site visits to, PSOs, to assess or verify PSO compliance with the requirements of this subpart and for these purposes will be allowed to inspect the physical or virtual sites maintained or controlled by the PSO. The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records deemed necessary and requested by the Secretary to implement the provisions of this subpart. Such PSO records may include patient safety work product in accordance with § 3.206(d) of this part."

with providers. Finally, after seeking any needed verification from component PSOs, and as an aid to providers, AHRQ plans to identify on its website those component PSOs that it learns are subject to FDA reporting requirements.

Additional Actions to Be Taken By AHRQ

PSOs, and entities that seek to be PSOs, are reminded that an entity that is a unit or division of a legal entity, or that is owned, managed or controlled by one or more legally separate parent organizations, and that seeks to be a PSO, must apply as a component PSO. Thus, an entity that would be operating as a PSO and that is part of a larger organization that engages in FDA-regulated reporting activities, or that has a parent organization that engages in FDA-regulated reporting activities must seek listing as a component PSO. In addition, under 42 U.S.C. 299b-24(b)(1)(A), a PSO's mission and primary activity must be to conduct activities to improve patient safety and the quality of health care delivery. Seeking listing as a component PSO helps to ensure that entities with multiple missions and activities (such as FDA-regulated reporting activities) are in compliance with this statutory requirement. Given the issues identified in this Guidance, AHRQ will also be engaging in additional inquiry of applicants and PSOs to determine whether the entity is organizationally related to an FDA-regulated reporting entity such that it should be listed as a component PSO (i.e., it is a unit or division of a legal entity, or is owned, managed or controlled by one or more legally separate parent organizations). If the entity should be listed as a component PSO, AHRQ will work with the entity to pursue such appropriate listing.