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Center for Quality Improvement and Patient Safety
Attention: Patient Safety Act NPRM Comments
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

RE: Patient Safety and Quality Improvement Proposed Rule

Dear Administrator:

The American Medical Association (AMA) appreciates the opportunity to submit comments regarding the U.S. Department of Health and Human Services (HHS) proposed rule on Patient Safety and Quality Improvement, 42 CFR Part 3 (February 12, 2008) (Agency for Healthcare Research and Quality and the Office for Civil Rights, HHS, RIN 0919—AA01). The AMA applauds the efforts of HHS and the Agency for Healthcare Research and Quality (AHRQ) for capturing in the proposed rule the intent of the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41). The AMA strongly supports the establishment of a federal framework for physicians, hospitals, and other health care professionals and entities to voluntarily report "patient safety work product" to patient safety organizations (PSOs) on a privileged and confidential basis. The proposed rule provides further guidance for the establishment of a patient safety evaluation system that will set the stage for enhancing patient safety activities across the spectrum of health care delivery settings. HHS and AHRQ will play a vital role in ensuring that the integrity of PSOs is maintained and in creating a culture whereby innovative, provider-driven initiatives are developed to advance patient safety.

Subpart A—General Provisions

§3.20 Definitions

Disclosure—The regulations should further clarify the meaning of "disclosure" and "use." The proposed regulations use these terms interchangeably. The proposed regulations recognize only disclosure as the sharing or transfer of patient safety work product (PSWP) outside of the legal entity. Disclosure is defined as the "release, transfer, provision of

access to, or divulging in any other manner of patient safety work product by a person holding the patient safety work product to another."

Uses of PSWP, as extrapolated from the Patient Safety and Quality Improvement Act (Patient Safety Act) and the proposed regulations, should be allowed for the following purposes:

- pursuing efforts, including potential utility, to improve patient safety and quality of health care delivery;
- developing information to improve patient safety and quality of health care delivery (e.g., recommendations, protocols, information on best practices);
- encouraging a culture of safety;
- providing feedback to effectively minimize patient risk;
- assisting to effectively minimize patient risk;
- utilizing qualified staff;
- pursuing activities relating to the operation of a patient safety evaluation system (PSES); and
- pursuing activities related to feedback to participants in a patient safety evaluation system.

Parent Organization—The term controlling interest ("owns a provider entity or a component organization") to define a parent organization is appropriate. We recommend that the regulations clearly indicate that the requirement to identify the parent organization(s) of a component PSO in and of itself does not impose any legal responsibilities, obligations, or liabilities on the component PSO's parent organization(s). For conflicts of interest discussion, please review comments provided in §3.102(c).

Patient Safety Evaluation System (PSES)—The PSES allows for the collection, management, or analysis of information for reporting to or by a PSO. The AMA agrees with AHRQ's recommendation to allow flexibility in system designs, functions, and documentation capabilities. We recommend that AHRQ provide technical guidance on the structuring of a PSES. Although the Secretary will not require a PSES to be documented, the Secretary should strongly encourage providers and PSOs to ensure that the structure and functions of a PSES are clearly known and understood by those who are engaged in or who want to engage in reporting PSWP. This is best accomplished through documentation. Also, encouraging documentation will help preserve the integrity of a PSO's certification by the Secretary and the confidentiality and legal protections of PSWP provided under the statute, thus reducing the threat of a legal challenge that could disrupt reporting.

Patient Safety Work Product (PSWP)—Congress intended that the Patient Safety Act cover a broad spectrum of data gathering and analytic efforts in order to identify causal

factors or relationships that might impact patient safety, quality, and outcomes. Therefore, the definition for PSWP should be as broad as other definitions of work product in existing federal and case law such as *U.S. vs. Weber Aircraft*, which includes impressions, personal recollections, riders, theories, strategies, charts, and other materials that are relevant to the work of safety and quality improvement that the reporter provides. The reporter should be able to offer their own charts, riders, graphs, theories, strategies, reports, records, memos, analysis, oral and written statements, thought process, and conceptual impressions without concerns that the reporter's personal submissions will be discoverable or admissible. In addition, reporting PSWP to a PSO should not waive state peer review protections.

The final rule should clarify that it is permissible for providers and PSOs to analyze data from existing databases and sources that reside outside PSOs, and that the deliberations relating to such analysis, the analysis itself, and materials developed by a provider or PSO based on such deliberations and analysis, be defined as PSWP. Analysis of existing data would assist in defining a safety event and discovering information that would enhance patient safety. Although the existing data described above would not be deemed PSWP, the reports, charts, riders, graphs, theories, or strategies developed from analysis of this existing data would be deemed new PSWP and therefore fully protected.

The timeframe allowed for assembling, collecting, deliberating, developing, analyzing, and reporting, etc. PSWP should be reasonable. This timeframe should be contingent upon multiple factors, including but not limited to, the complexity of the facts and circumstances surrounding the analysis of a medical error or other event. Information collected during this time period should be considered PSWP. As the Institute of Medicine (IOM) stated in its 1999 report, "To Err is Human," the most effective legal protections cover the "entire chain of custody of the information from the initial generation to its ultimate use." In addition, there should be a presumption of good faith and intent with respect to determining the earliest date from which a provider could collect information for reporting to a PSO for the purpose of creating PSWP. The final regulations should further recognize that not all information collected within a PSES is reported to a PSO, but nonetheless should be considered PSWP given that the information is part of the deliberations or analysis. For example, information collected for the purpose of reporting to a PSO may be transcribed from raw, handwritten notes to a computer-based data set prior to reporting to the PSO. The final rule should clarify that the original notes would be considered protected PSWP because they "identify or constitute the deliberations or analysis of…a patient safety evaluation system."

Moreover, retrospective analysis of events should be deemed PSWP including but not limited to the following circumstances:

- Historical perspective of events previously reported: All the components of the safety event did not manifest at the time of the report; it may take time to successfully connect the dots and fully realize the context, consequences,

importance, magnitude, or scope of an event (e.g., reporter learns more about the event as consequences or outcomes become known);

- Historical perspective of events previously unreported: Not all safety events or errors are recognized as events or errors when they first occur or if their occurrence is rare; it may take another event to successfully connect the dots (e.g., reporter suddenly recognizes that this event and past events are the same or similar and should be reported and, therefore, reports past events that share same or similar characteristics of condition(s), time, modality, processes, equipment, location, staffing, level of staff expertise, infrastructure, or other); and
- Acts of God or other superseding causes that prevent reporting (e.g., Hurricane Katrina, floods, fire, explosions, or physical damage to care setting; reporter inability to report at time of event due to illness or injury).

It is important to keep in mind that the physician's ethical and legal obligations to protect patient privacy and adhere to standards of confidentiality has never precluded the role of the physician as a teacher who imparts knowledge and skills and techniques to colleagues, and as a student who constantly seeks to keep abreast of new medical knowledge. Physicians have a duty to share their knowledge and skills. There should be no tension in the Patient Safety Act that prohibits physicians and other health care professionals in any instance from discussing information with other health care professionals that may be PSWP and reported to a PSO that is critical to safe patient care and preventing or ameliorating harm. The final rule should clarify that a permissible disclosure of PSWP includes discussions among physicians and/or other providers as part of a PSES.

Provider—The Secretary should have the authority to expand the definition of provider. However, HHS' recommendation to expand the definition of provider to include "a corporate parent organization for one or more entities licensed or otherwise authorized to provide health care services under state law" is problematic. Prohibited entities such as health insurance issuers (including Health Maintenance Organizations), regulatory, and accrediting entities could qualify under this expanded definition. The definition should include specific exclusions.

The term "reporter" is used throughout the proposed regulations (i.e., see § 3.206(b)(2)—Equitable Relief for Reporters) but is not expressly defined in the statute or the regulations. We recommend that the regulations provide a definition for a reporter (i.e., an individual who or entity that submits information to a PSO or within a PSES). The contract between the provider and the PSO should include a provision that the PSO agrees to not disclose the reporter's identity to the contracting provider unless the PSO has received permission from the reporter for such a disclosure.

Subpart B—PSO Requirements and Agency Procedures

This subpart outlines the certification and notification requirements that PSOs must meet, the actions that the Secretary may and will take relating to PSOs, the requirements that PSOs must meet for the security of PSWP, the processes governing correction of PSO deficiencies, revocation, voluntary relinquishment, and related administrative authorities and implementation responsibilities.

§3.101 HIPAA Privacy Rule

The AMA recommends that the regulations specify that a PSO should notify the organizational source of an impermissible use or disclosure of PSWP, or that the information reported may not meet the definition of PSWP (e.g., the reporting of an event that is prima facie criminal). The value of a well-structured PSES is to prevent reporting of information that is not PSWP. In the event of impermissible disclosure, the final regulations should encourage PSOs to notify the reporter that the information submitted is not PSWP.

§3.102(a) Eligibility and Process for Initial and Continued Listing as a PSO

We agree that HHS should establish a streamlined certification process that minimizes barriers to entry for eligible entities that seek to be initially or continually listed as PSOs. We also agree with HHS' assessment that exceptions for eligibility should include entities that conduct regulatory oversight of health care providers. As indicated in the proposed regulations, public and private entities that conduct regulatory oversight of health care providers, including accreditation and licensure, should be prohibited from seeking eligibility as a PSO.

The proposed rule would allow a component of a regulatory entity to seek listing as a PSO. Such component, as with components of non-regulatory entities, would be required to establish and maintain a strong firewall between a component PSO and its parent regulatory entity with respect to its activities as a PSO, including adequate safeguards for PSWP. Providers would have access to the name of the parent regulatory entity, and such information would be publicly available.

We believe that the intent of the statute is to establish an environment that assures providers that information they voluntarily report to PSOs will be used to promote and improve patient safety, not for regulatory or punitive purposes. While we recognize that the reporting system created by the Patient Safety Act is completely voluntary, if a component of a regulatory entity cannot establish such an environment, then it should not be certified as a PSO. As pointed out in the proposed rule, some regulatory entities that cannot themselves become PSOs could nonetheless try to circumvent the firewalls required between the parent organization and component. Also, they could attempt to compel providers to report to their component PSO over other PSOs. Even the perception that such

activity by a regulatory entity is possible could be enough to completely undermine the intent of the law.

Therefore, we urge HHS to take additional measures to ensure that a component of any regulatory entity meets the criteria to be listed as a PSO. Components of regulatory entities should be required to explicitly identify their parent organization as a regulator, specify the scope of the parent organization's regulatory authority, and submit attestations from contracting provider(s) that such providers are informed of the nature and scope of the parent organization's regulatory authority and have not been compelled or otherwise influenced to report to the component PSO. Further, HHS should prohibit any "individual" or "unit" access to PSWP under section 3.102(c)(1)(ii) if the individual or unit is part of the parent regulatory entity.

Health insurance issuers and components of health insurance issuers, including but not limited to Health Maintenance Organizations and health purchasers, should also be prohibited from seeking eligibility as a PSO. The AMA recommends that HHS clearly define health insurance issuers and components of health insurance issuers in the regulations.

In addition to meeting certification requirements, there should be assurances that entities seeking initial or continued listing as a PSO are financially viable to perform patient safety activities.

§3.102(b)(2) Minimum Contracts Requirement

To encourage use, the AMA recommends that the regulations not impose contract requirements that specify specific time periods and/or specific tasks. The regulations should clearly indicate that health care providers and PSOs have the ability to enter customized agreements on patient safety topics and activities. However, contracts between health care providers and PSOs, at a minimum, should contain all safeguards, including but not limited to, privacy and confidentiality requirements that are outlined in the Patient Safety Act and should also address legal remedies for any breach. Also, the final rule should clarify that providers cannot be compelled to or prevented from reporting to a PSO under an employment or other contract.

§3.102(b)(2) Collecting Data in a Standardized Manner

The AMA agrees that the Secretary should provide ongoing recommendations to PSOs on formats and definitions in order to facilitate aggregating PSWP. Facilitating reporting of patient safety events will lead to improvements in patient safety. To ensure that information is collected that is required to support improvement, it is critical to have standardized formats for use in data collection. In addition, using this standardized format will conserve resources by not having every PSO create their own formats.

The common formats and standards should be developed and tested by those involved in the delivery of health care services. Ongoing refinement of the formats and definitions should not negate the value of previously reported information. The Secretary's process for developing and maintaining recommended common formats and definitions, through its Patient Safety Work Group, should be a transparent consensus process that includes representatives of national physician and other health professional specialty organizations, experts from aviation, and others who have experience in safety events reporting formats. This Patient Safety Work Group should be required to meet on a regular basis in order to develop and update common formats and definitions. We look forward to reviewing and commenting on the common formats that are expected to be published in July/August 2008.

§3.102(c) Additional Certifications Required of Component Organizations

The regulation calls for three additional statutory certification requirements for a component PSO which are the following: secure maintenance of documents and information separate from the rest of the parent organization(s); avoid unauthorized disclosures of PSWP to the parent organization(s); and ensure that the mission of the component PSO does not create a conflict of interest with the rest of the parent organization(s).

The component PSO and parent organization should maintain a substantial firewall to ensure compliance with the privilege and confidentiality requirements of the Patient Safety Act. A component PSO should only be allowed to contract with a unit or individual of its parent organization(s) for clearly defined and limited staff services involving the PSO. As pointed out in the proposed rule, employees of the component PSO "must not engage in work for the rest of the organization(s) if such work could be informed or influenced by the individual's knowledge of identifiable PSWP." There should be no direct conflict between the PSWP functions and the non-PSWP functions. The degree and manner of activities and potential conflicts of interest should be carefully considered. For example, many units of parent organizations may have regulatory or oversight duties that immediately or ultimately affect providers, and thus may likely pose a conflict of interest (e.g., investor-owned hospitals; legal relationships providers may have with parent or its subsidiaries, etc.). Moreover, any information exchanged between PSOs and their subcontractors should not waive the confidentiality of PSWP. Please review additional comments noted above in §3.102(a).

§3.102(d) Required Notifications

The AMA agrees that in order for a PSO to meet its statutory obligation of entering at least two bona fide contracts that meet the requirements of proposed §3.102(b)(2), PSOs should be allowed to notify the Secretary of their compliance within a reasonable time frame; 45 calendar days before the last day of the period that is 24 months after the date of its initial listing and 45 day calendar days prior to the last day of every 24-month period.

§3.102(d)(1) Notification Regarding PSO Compliance with the Minimum Contract Requirement

The AMA agrees that a PSO be provided with adequate time (i.e., period of correction extends until midnight of the last day of the applicable 24-month assessment period for the PSO) to respond to a preliminary finding of alleged deficiency.

§3.102(d)(2) Notification Regarding PSO's Relationships with its Contracting Providers

The AMA agrees with the proposed time frame for the Secretary to receive the disclosure statement regarding its relationship(s) with any contracting provider(s); within 45 calendar days of the PSO's determination that the PSO's relationship with a contracting provider warrants disclosure. We are concerned about the unintended consequences of disclosure of the PSO's relationship with its contracting providers to the public (e.g., disclosing names of physicians undermines the privacy and confidentiality protections outlined in the Patient Safety Act). The NPRM did not fully address the issue of disclosure. We recommend that AHRQ foster the development of well-defined, minimum standards for disclosures so that providers can make informed decisions regarding contractual relationships with PSOs.

The attestation provided by the PSO should include reason(s) (e.g., data breach, insolvency, no reports, etc.) for any delisting. The Secretary should have discretion in releasing identities of workforce members, staff, or private parties. For example, a data breach may be attributable to substandard security rather than individuals disclosing protected information; financial difficulties, or insolvency may be attributed solely to the entity.

§3.104(c) Actions Regarding Required Disclosures by PSOs of Relationships with Contracting Providers

The Patient Safety Work Group that will develop common formats should also be responsible for determining the required content for the PSO disclosure statement. We caution against the unintended consequences of disclosure of the PSO's relationship with its contracting providers to the public (e.g., disclosing names of physicians undermines the privacy and confidentiality protections outlined in the Patient Safety Act).

§3.104(d) Maintaining a List of PSOs

We recommend that the PSO Web site include, at a minimum, the following information in accordance with section 924(d) of the Public Health Service Act, 42 U.S.C. 299b–24(d):

1) contact information for each PSO;
2) the effective date and time of listing of the PSO;
3) a copy of each certification form and disclosure statement that the Secretary receives from the entity;

4) information on whether the PSO has certified that it has met the two contract requirement in each 24-month assessment period; and
5) if applicable, a copy of the Secretary's findings regarding any disclosure statements filed by each PSO, including whether any conditions have been placed on the listing of the entity as a PSO and other information that the Secretary is authorized to make available to the to public.

In addition, we recommend that the PSO Web site include the actual names of the subsidiary, the parent organization, and their affiliates. The PSO should also identify the parent company's business objectives and whether the parent company is a profit/non-profit organization. Furthermore, the PSO should identify all of the states where the parent company conducts business.

§3.104(e) Three-Year Period of Listing

We agree that the regulations should require the Secretary to provide a written notice of imminent expiration to a PSO no later than 45 calendar days before the date on which the PSO's three-year period of listing expires, if the Secretary has not received a certification seeking continued listing. Information regarding the PSO's imminent expiration should also be posted on the PSO Web site so that health care providers have adequate notice to make alternative arrangements. The Secretary should also require that PSOs facing imminent expiration be required to notify all affected providers who have reported to them.

§3.106 Security Requirements

The regulations should require PSOs to implement adequate measures for the security of PSWP including security management, separation of systems, security control and monitoring, and security assessment. PSOs should be provided with sufficient flexibility to develop standards. Data security and maintenance of data security are essential to ensuring the protection of PSWP.

§3.108(a) and (a)(2) Correction of Deficiencies, Revocation and Voluntary Relinquishment

The regulations should clearly indicate that PSOs have the right, including a procedural right, to appeal alleged deficiencies, regardless of how "egregious" the alleged conduct is. We request that HHS provide a definition for conduct that is so serious that it cannot be corrected. The Secretary should also consider whether the PSO has acted in good faith in correcting and remedying an alleged deficiency. The PSO should be given an automatic right to appeal a proposed and final revocation and/or delisting. The PSO should be provided adequate time to provide a written appeal. The proposed rule indicates that a PSO has 30 calendar days from receipt of notice of a proposed revocation and/or delisting to respond to such notice. We recommend that the time frame be extended to 45 calendar

days to allow adequate time to appeal such notice. In addition, PSOs should be given an opportunity to take appropriate action to correct an alleged deficiency.

§3.108(b)(2) Required Notification of Providers and Status of Data

With respect to the required notification of providers of a revocation, we believe that the 15 calendar days required notice time period to inform the Secretary that the PSO has taken reasonable steps to notify each provider is adequate. The PSO should also be responsible for notifying all affected providers and reporters within 15 calendar days from notice of revocation and should provide a list of affected providers and reporters to the Secretary within the same time period. Furthermore, the Secretary must ensure that information on affected providers and reporters is kept confidential.

§3.108(b)(3) Disposition of Patient Safety Work Product and Data

We recommend that the timeframe and process to complete disposition of the PSWP held by a PSO, which has been revoked for cause, be similar to the timeframe and process imposed under the HIPAA Privacy Rule.

§3.108(c)(2) Notification of Voluntary Relinquishment

There should be a 30-day window for providers to report data to a PSO after the PSO has been delisted regardless of whether the delisting was voluntary or involuntary. The intent of the Patient Safety Act is to provide protections for PSWP. The provider may send information to a PSO not realizing that the PSO was subject to revocation and/or delisting or had already been revoked or delisted. Thus, the information should be deemed PSWP and confidential. The PSO should be responsible for notifying the provider of its revocation and/or delisting and the appropriate disposition of PSWP in its possession.

§3.108(c)(5) Non-Applicability of Certain Procedures and Requirements

In cases of explicit or implied voluntary relinquishment, PSOs should have an opportunity to appeal or challenge their removal from the listing. PSOs should be required to post procedures for transferring information and have adequate time to establish new relationships for transition purposes.

§3.110 Assessment of PSO Compliance

We agree that the Secretary's inspection authority to ensure that PSOs are meeting their statutory obligations does not extend to health care providers. As indicated by AHRQ, AHRQ's regulatory authority in accordance with the Patient Safety Act only extends to PSOs; AHRQ will not regulate providers that work with PSOs.

Subpart C—Confidentiality and Privilege Protections of PSWP

§3.204(c) Implementation and Enforcement of the Patient Safety Act

In order to implement and enforce the Patient Safety Act, an exception should be narrowly drawn to permit the Secretary to perform enforcement and operational duties against a PSO. PSWP must be protected and the risk of improper disclosure of PSWP must be minimized. We strongly urge the Secretary to use judicious restraint with respect to requesting disclosure of PSWP for compliance and enforcement activities in order to preserve the integrity of the reporting system, to prevent being viewed as overly regulatory, and to maintain focus on the intent of the law—encouraging an environment for reporting information to improve patient safety. Therefore, the full authority of the Secretary's enforcement power should be reserved for the most egregious breaches and failures and that those working with the Secretary in this activity should protect PSWP, regardless of the breach or failure, and be mindful that these types of incidences have the potential to erode trust in the reporting system.

§3.206(b) Exceptions to Confidentiality

We request that the Secretary provide a definition and examples of redisclosures. Rather than focusing solely on negative implications of limiting redisclosures, we ask the Secretary to consider the consequences of redisclosures and unrestricted redisclosures. Redisclosures can be compared to "hand-offs," an informal term for a whole series of activities that need to take place when an individual transitions in care from one setting to another, from one clinician to another (Carolyn Clancy, MD, "Consumer Insider Medical Handoffs," April 25, 2007). Robust systems are needed to prevent dangers inherent to multiple hand-offs such as loss of information and diffusion of responsibility (Tejal K. Gandhi, MD, MPH; Ann Intern Med 2005; 142: 352-358). Similarly, redisclosures of confidential, protected information (i.e., PSWP) may involve multiple transfers through systems that are not equally robust, thus providing opportunity for breaches in confidentiality or unauthorized disclosures. Additionally, redisclosures, like hand-offs, are subject to diffusion of responsibility, information loss, misuse of information, and unauthorized disclosure.

§3.206(b)(2) Equitable Relief for Reporters

The AMA agrees that the regulations should specify that a protective order is required for disclosure, as authorized by the regulations, where an employee seeks redress for adverse employment actions for good faith reporting of information to a PSO directly or to a health care provider with the intended disclosure to a PSO. Even though the reporter is afforded discretion to disclose the relevant PSWP to seek and obtain equitable relief, all subsequent holders receiving the PSWP from the reporter should be bound by the continued privilege and confidentiality protections.

§3.206(b)(3) Authorized by Identified Providers

Although HIPAA is intended to protect patients from consequences of impermissible use and disclosure of protected health information (e.g. discrimination), the intent of the Patient Safety Act is to apply the HIPAA Privacy Rule to providers and protect them from consequences of misuse (e.g., defamation and loss of economic opportunity).

The Patient Safety Act does not specify the form of the authorization by a provider to come within this disclosure exception or a timeframe for record keeping. We agree with the proposal that an authorization be in writing, be signed by the authorizing provider, and give adequate notice to the provider of the nature and scope of each disclosure authorized. The content of the authorization should explicitly inform the provider as to the nature and scope of the identifiable patient safety work product to be disclosed to ensure the provider is making a knowing authorization.

§3.206(b)(4) Patient Safety Activities—Disclosure between a Provider and a PSO

The AMA agrees that PSOs should be allowed to reciprocally disclose PSWP back to health care providers with respect to patient safety activities. This information exchange is necessary to ensure that the goal of the Patient Safety Act is met—advancing patient safety improvements. PSOs should also be permitted to disclose PSWP to other PSOs with respect to patient safety activities in accordance with the Patient Safety Act. Any information exchanged between PSOs and their subcontractors does not waive the confidentiality of PSWP.

Compliance with the HIPAA Privacy Rule

The exchange of PSWP for patient safety activities among providers and PSOs in accordance with the Patient Safety Act is critical for improving patient safety. The HIPAA Privacy Rule definition for health care operations should contain a specific reference to patient safety activities conducted pursuant to the Patient Safety Act.

§3.206(b)(5) and (6) Disclosure of Non-Identifiable PSWP

The risks of disclosing identifiable PSWP must be carefully considered. Identifiable information about a nondisclosing provider should **not** be released. De-identification of identifiable PSWP is a complex undertaking. Adequate safeguards must be in place to ensure that identifiable information is not released. We urge AHRQ to establish a work group to further evaluate the proposed standards and approaches identified in the regulations.

§3.206(b)(7) To the Food and Drug Administration (FDA)

Because Congress did not expressly include disclosure to FDA-regulated entities, we request that AHRQ provide examples that would cause disclosures under this provision.

§3.206(b)(8) Voluntary Disclosure to an Accrediting Body

We caution against promoting voluntary disclosures to an accrediting body, given the potential for unintended consequences of such disclosures. The Patient Safety Act includes provisions that limit the actions an accrediting body may take to seek PSWP. We also request that the regulations provide a definition for accrediting bodies.

§3.206(b)(9) Business Operations

The AMA recommends that the regulations allow for disclosures of PSWP for business operations purposes by a health care provider or a PSO to associated professionals such as attorneys, accountants, etc. The regulations should clearly specify that business operations disclosures do not waive privilege of PSWP and therefore PSWP cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception. Any additional business operation disclosures should comply with the HIPAA Privacy Rule and confidentiality requirements. Thus, the business operations exception should be broad enough to cover all activities and functions listed as "health care operations" under HIPAA. In addition, the Secretary should only use the rule-making process for the adoption of business operations exceptions from confidentiality requirements since the rule-making process allows the opportunity for public comments.

§3.206(b)(10) Disclosure to Law Enforcement

The regulations should clearly specify that business operations disclosures do not waive privileges of PSWP and therefore PSWP cannot be subpoenaed, ordered, or entered into evidence in a criminal or civil proceeding through this exception.

§3.206(c) Safe Harbor

The regulations create a safe harbor for provider(s) and responsible person(s) when a member of its workforce discloses PSWP that does not include information that assesses the quality of care of an identifiable provider, or describes or pertains to one or more actions or failures to act by an identifiable provider. The AMA recommends that this safe harbor also be extended to PSOs.

§3.210 Required Disclosure of PSWP to the Secretary

Disclosure of PSWP should be limited to only what is needed for the investigation and enforcement activities or what is needed in seeking and imposing civil money penalties in accordance with the Patient Safety Act. The PSWP should be kept confidential.

Subpart D—Enforcement Program

We agree that PSOs should be encouraged but not required to post on their web sites narrative statements regarding their capabilities.

§ 3.408—Factors Considered in Determining the Amount of a Civil Money Penalty

We agree with the use of detailed, multiple factors outlined in the proposed regulations for calculating civil money penalties. The list of factors should not be expanded to include self-report disclosures given that self-report disclosures may be viewed as an additional reporting obligation.

In conclusion, we look forward to reviewing additional regulations that will be issued for comment regarding the common format to be used by PSOs and network of patient safety databases. Improving patient safety and health care quality is a long-standing and ongoing high priority for the AMA. We applaud you for your leadership on this critical health care issue and we are committed to working with you and our partners in patient safety initiatives to achieve a meaningful long-term approach to improve patient safety in the delivery of quality health care in our nation. If you have any questions or need additional information, please do not hesitate to contact Carol Vargo, Assistant Director, Federal Affairs, at 202-789-7492 or by email at Carol.Vargo@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA