Sara Luckhaupt at *sluckhaupt@cdc.gov* or (513) 841–4123 for information about how to register for the meeting.

ADDRESSES: Oral comments given at the meeting will be recorded and included in the NIOSH–187 docket. You may submit comments, identified by docket number NIOSH–187, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226.
- *Facsimile:* (513) 533–8285.
- *E-mail: nioshdocket@cdc.gov.*

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at *http://www.cdc.gov/niosh/docket,* and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

Background: The NHSN is an Internet-based surveillance system established in 2005 by the CDC Division of Healthcare Quality Promotion (DHQP) that includes both patient safety and healthcare personnel health and safety modules. The proposed enhancement to the NHSN will electronically link and integrate a wide variety of ongoing occupational health surveillance activities and facilitate more accurate and timely prevention strategies, while meeting necessary confidentiality and security requirements.

This project focuses on surveillance and prevention of four occupational health outcomes among healthcare workers: (1) Traumatic injuries in the workplace (specifically: (a) musculoskeletal disorders due to patient handling and working in awkward postures, (b) slips, trips, and falls, and (c) workplace violence); (2) dermatitis due to workplace exposures; (3) work-related asthma; and (4) airborne transmission of tuberculosis in the workplace. Once these enhancements to NHSN are successfully implemented, additional occupational health metrics can be added to the system to address emerging problems such as pandemic influenza.

The success of this project will depend on the participation of healthcare facilities in the surveillance system. Because the stakeholders themselves will be the central users of our proposed additions to NHSN, they will be extensively involved in every stage of this project—including initial development, implementation, and evaluation of the new module and event forms. This meeting will provide an opportunity for stakeholders to contribute to the initial development of the data collection forms.

FOR FURTHER INFORMATION CONTACT: Ahmed Gomaa, Robert A. Taft Laboratories, MS–R17, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 841–4337, or Sara Luckhaupt, same address, telephone (513) 841–4123.

References: National Healthcare Safety Network (NHSN)—*http://www.cdc.gov/nhsn/index.html.*

Healthcare Personnel Safety Component—*http://www.cdc.gov/nhsn/hps.html.*

Dated: September 14, 2009.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–22656 Filed 9–18–09; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: A Compliance Self-Assessment Guide

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—Patient Safety Organizations: A Compliance Self-Assessment Guide.

SUMMARY: AHRQ is announcing the availability of a document entitled: ''Patient Safety Organizations: A Compliance Self-Assessment Guide.'' The Patient Safety and Quality Improvement Act of 2005, Public Law 109–41, 42 U.S.C. 299–b21—b–26 (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) (42 CFR part 3) authorizes AHRQ, on behalf of the Secretary of HHS, to: list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing; and request additional information and conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ developed the sample questions in this guide to encourage each PSO to take a thorough and systematic approach to compliance. The guide recognizes that each PSO's approach to compliance may be different based upon the specific mission it has chosen, the specific activities and expertise it offers to healthcare providers, and its size and mode of operation. Thus, these questions are merely illustrative; some questions will not be applicable or even appropriate for every PSO. The guide does not establish new standards or requirements beyond those that are established by the Patient Safety Rule.

DATES: Availability of resource.

ADDRESSES: ''Patient Safety Organizations: A Compliance Self-Assessment Guide'' can be accessed electronically at the following HHS Web site: *http://www.pso.ahrg.qov/index.html.*

FOR FURTHER INFORMATION CONTACT: Diane Cousins, RPh., Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427 1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; E-mail: *pso@ahrq.hhs.qov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act establishes a framework by which healthcare providers can report information voluntarily to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events and quality concerns. A PSO is an entity listed by the Secretary of HHS, which has a primary focus to conduct activities to improve patient safety and the quality of healthcare delivery.

The requirements governing PSOs are set forth in subpart B of the Patient Safety Rule. These include: the requirements that an entity must meet to become, and remain listed, as a PSO; the procedures and processes for assessing an entity's eligibility; the processes for ensuring a PSO's compliance with the requirements of the Patient Safety Rule, and for correcting deficiencies in a PSO's compliance; and the process by which a PSO can voluntarily relinquish its listing or, in the case of a PSO that does not correct one or more deficiencies, the process for delisting a PSO for cause. Within the framework established by the Patient Safety Act, PSOs are a source of expert advice for providers, and PSOs enable providers to take advantage of the potential for significant aggregation of patient safety

events within the protections of the Patient Safety Act and Patient Safety Rule. As a result, healthcare providers, and those committed to improving the safety and quality of patient care, have a strong interest in the integrity of PSOs and their ability to carry out this statutory mission.

AHRQ administers the provisions of the Patient Safety Rule relating to listing and operation of PSOs, which are the focus of this guide. The HHS Office for Civil Rights is responsible for enforcing the confidentiality protections of the Patient Safety Act and Patient Safety Rule.

For an entity to be listed, and remain listed, as a PSO, the Patient Safety Rule relies primarily upon a system of attestations. An entity seeking listing for a three-year period as a PSO must submit to AHRQ a form, Certification for Initial Listing, to attest that it meets the Patient Safety Rule's eligibility and listing requirements at the time the entity submits its certifications. During its period of listing, a PSO must submit a form, Two Bona Fide Contract Requirement, every two years attesting that it has at least two contracts with different providers. If the PSO has other relationships, specified in section 3.102(d)(2), with any contracting provider, it must also submit the form, PSO Disclosure Statement, regarding its relationships with the provider and attest to the completeness and accuracy of its disclosures. Finally, a PSO must submit the form, Certification for Continued Listing, to seek continued listing for an additional three-year period and attest that it meets the requirements for continued listing. This process places the burden for understanding and complying with the Patient Safety Rule on the PSO.

The Patient Safety Rule also authorizes AHRQ to assess or verify PSO compliance with the rule's requirements at any time through requests for information or by conducting announced or unannounced reviews of, or site visits to, PSOs (section 3.110). In addition to routine compliance reviews, AHRQ may also conduct site visits or request additional information if, for example, AHRQ becomes aware that a PSO is not in compliance with the requirements of the statute or the Patient Safety Rule.

The Patient Safety Rule provides PSOs latitude in complying with its requirements. In part, this reflects a recognition that PSOs will vary in terms of size, complexity, and sophistication and, over time, PSOs will vary significantly in the breadth and scope of their activities. For example, PSOs can be local, regional, or national in orientation; they can focus narrowly or broadly in terms of the clinical or analytic services they offer providers; they can target their services toward one type of healthcare facility or multiple healthcare settings; and, they are likely to vary in the sophistication and complexity of information technology employed.

Each PSO will need to develop its approach to compliance by taking into account the specific mission it has chosen for itself, the specific activities and expertise it offers to healthcare providers, and its size and mode of operation. As a consequence, AHRQ developed this self-assessment guide recognizing that individual PSOs are likely to approach compliance from different perspectives. Thus, the guide does not propose a uniform approach to compliance, Instead, the guide presents sample questions—some of which may not be applicable or appropriate to a specific PSO—to encourage each PSO to take a comprehensive and systematic approach to compliance that best meets its circumstances.

The questions in the guide do not establish new standards or requirements; they are only presented for an illustrative purpose. If there is any inadvertent discrepancy between the text of the guide and the Patient Safety Rule, PSOs should consider the text of the rule as authoritative.

More information on the ''Patient Safety Organizations: A Compliance Self Assessment Guide'' and PSOs can be obtained through AHRQ's PSO Web site: *http://www.pso.ahrq.gov/index.html.*

Dated: September 11, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–22594 Filed 9–18–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0441]

Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools; Notice of Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER), in collaboration with FDA's Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), and Center for Devices and Radiological Health (CDRH), is announcing a public hearing to discuss issues related to the promotion of FDA-regulated medical products (including prescription drugs for humans and animals, prescription biologics, and medical devices) using the Internet and social media tools. FDA is seeking participation in the public hearing and written comments from all interested parties, including, but not limited to, consumers, patients, caregivers, health care professionals, patient groups, Internet vendors, advertising agencies, and the regulated industry. This meeting and the written comments are intended to help guide FDA in making policy decisions on the promotion of human and animal prescription drugs and biologics and medical devices using the Internet and social media tools. FDA is seeking input on a number of specific questions but is interested in any other pertinent information participants in the hearing would like to share.

Dates and Times: The public hearing will be held on November 12 and 13, 2009, from 8 a.m. to 5 p.m. each day. Submit written or electronic registration by close of business on October 9, 2009. Written and electronic comments will be accepted until February 28, 2010.

Location: The public hearing will be held at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594, 202–314–6305; Metro: L'Enfant Plaza station on the yellow, green, orange, and blue lines; see: *http://ntsb.gov/events/newlocation.htm.* (FDA has verified the Web site address, but FDA is not responsible for any changes to the Web site after this document publishes in the **Federal Register**.)

ADDRESSES: Submit written registration and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic registration and electronic comments, identified with the docket number found in brackets in the heading of this document, to *http://www.regulations.gov*.

Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the hearing (see section VI of this document).

Registration to Attend and/or to Participate in the Meeting: Seating at the hearing is limited. People interested in attending should submit written or electronic registration as specified above