information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 20, 2014.

Richard Kronick,

Director.

[FR Doc. 2014–20423 Filed 8–28–14; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Patient Safety Services, LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of NHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from Patient Safety Services, LLC of its status as a PSO, and has delisted the PSO accordingly.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on July 30, 2014.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.AHRQ.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, 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; Email: *pso@AHRQ.hhs.qov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when the PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Patient Safety Services, LLC, PSO number P0129, to voluntarily relinquish its status as a PSO. Accordingly, Patient Safety Services, LLC was delisted effective at 12:00 Midnight ET (2400) on July 30, 2014.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov/index.html.*

Dated: August 20, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–20424 Filed 8–28–14; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Health Information Exchange

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

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Health Information Exchange, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before September 29, 2014.

ADDRESSES: Online submissions: *http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/.* Please select the study for which you are submitting information from the list to upload your documents. Email submissions: *SIPS@epc-src.org.*

Print Submissions

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Health Information Exchange.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Health Information Exchange, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1943.*

This notice is to notify the public that the EHC Program would find the following information on Health Information Exchange helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.
- For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EHC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EHC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC Program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/ioin-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1943.*

The Key Questions

The draft Key Questions (KQs) developed during Topic Refinement were available for public comment from February 6 to February 26, 2014. The comments did not lead to significant changes but were helpful in identifying additional factors of interest in KQ 4 and KQ 5, and for clarifying the wording of the questions.

Based on the public comments and subsequent discussions with AHRQ, the following changes of note were made to the KQs:

- KQ 4: Added ''provider type'' to KQ 4b. Added an additional sub question of ''Do level of use and primary uses vary by data source?''
- KQ 5: Added an additional sub question of ''How does usability vary by health care settings or systems?''

The revised KQs are as follows:

KQ 1: Is health information exchange (HIE) effective in improving clinical (e.g. mortality and morbidity), economic (e.g., costs and resource use, the value proposition for HIE) and population (e.g., syndromic surveillance) outcomes?

- Does effectiveness vary by type of HIE?
- Does effectiveness vary by health care settings and systems?
- Does effectiveness vary by IT system characteristics?
- What evidence exists that the lack of HIE leads to poorer outcomes?

KQ 2: What harms have resulted from HIE? (e.g., violations of privacy, errors in diagnosis or treatment from too much, too little or inaccurate information, or patient or provider concerns about HIE)?

- Do harms vary by type of HIE?
- Do harms vary by health care settings and systems?
- Do harms vary by the IT system characteristics?

KQ 3: Is HIE effective in improving intermediate outcomes such as patient and provider experience, perceptions or behavior; health care processes; or the availability, completeness, or accuracy of information?

- Does effectiveness in improving intermediate outcomes vary by type of HIE?
- Does effectiveness in improving intermediate outcomes vary by health care settings and systems?
- Does effectiveness in improving intermediate outcomes vary by IT system characteristics?
- What evidence exists that the lack of HIE leads to poorer intermediate outcomes?

KQ 4: What is the current level of use and primary uses of HIE?

- Do level of use and primary uses vary by type of HIE?
- Do level of use and primary uses vary by health care settings and systems, or provider type?
- Do level of use and primary uses vary by IT system characteristics?
- Do level of use and primary uses vary by data source?

KQ 5: How does the usability of HIE impact effectiveness or harms for individuals and organizations?

- How usable are various types of HIE?
- What specific usability factors impact the effectiveness or harms from HIE?
- How does usability vary by health care settings or systems?

KQ 6: What facilitators and barriers impact implementation of HIE?

- Do facilitators and barriers that impact implementation vary by type of HIE?
- Do facilitators and barriers that impact implementation vary by health care settings and systems?
- Do facilitators and barriers that impact implementation vary by IT system characteristics?

KQ 7: What facilitators and barriers impact use of HIE?

- Do facilitators and barriers that impact use vary by type of HIE?

• Do facilitators and barriers that impact use vary by health care settings and systems?
• Do facilitators and barriers that impact use vary by IT system characteristics?

KQ 8: What factors influence sustainability of HIE?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Setting)

Populations

Any individual or group of health care providers, patients, managers, health care institutions, or regional organizations.

Intervention

Heath Information Exchange (HIE). HIE is defined as the electronic sharing of clinical information among users such as health care providers, patients, administrators or policy makers across the boundaries of health care institutions, health data repositories, States and others, typically not within a single organization or among affiliated providers, while protecting the integrity, privacy, and security of the information.

Comparators

• Time period prior to HIE implementation
• Locations (geographic or organizational without HIE)
• Situations in which HIE is not available, akin to ''usual care'' in a clinical study
• Comparisons across types of HIE
• Comparisons of the characteristics of the different settings, health care system, and IT systems in which HIE is used

Outcomes (specified for each Key Question)

KQ 1: Effectiveness is defined in terms of clinical outcomes (e.g., mortality and morbidity), economic outcomes (e.g., costs and resource use, the value proposition for HIE) and population outcomes (e.g., syndromic surveillance for the identification of trends or clusters).

KQ 2: Harms include unintended negative consequence or adverse events experienced by individuals, institutions, or organizations. Harms from HIE may include negative outcomes or the risk of negative outcomes resulting from information that is wrong, not provided in a timely manner, or in formats that inhibit its identification, comprehension, and use. Harms also may result from too much information as well as lack of information. Harms can also include negative impacts on attitudes (e.g., patients not trusting the privacy will be protected, clinicians' concerns about legal liability).

KQ 3: Intermediate outcomes include outcomes such as provider and patient experience and perceptions; changes in provider behavior and health care processes; and changes in the availability, completeness, or accuracy of information.

KQ 4: Level of use is the rate of HIE use by individuals, health care institutions, or regional organizations.

KQ 5: Usability focuses on the function of the HIE in terms of the interaction between users and HIE and their ability to navigate and accomplish tasks.

KQ 6: Implementation of HIE is defined as the realization of an HIE project such that the exchange of data is operational.

KQ 7: Use is the incorporation of the HIE into the workflow and decisions of patients, providers or organizations.

KQ 8: Sustainability is long-term maintenance, and improvement or expansion of HIE, after the implementation period.

Timing

No minimum duration of time lapsed from implementation of HIE to the measurement of outcomes.

Settings

Any aspect of the setting in which health information is exchanged for the purpose of improving health or health care decisions that is hypothesized to impact effectiveness, use, usability or sustainability. This may include the type(s) of clinical environments (e.g., ambulatory care, hospital, nursing home, etc.), payment/reimbursement model(s) (e.g., fee-for-service, managed care setting, risk/value-based model such as an accountable care organization, etc.), and legislative requirements (e.g., participation in HIE required to participate in Medicaid).

Dated: August 20, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–20425 Filed 8–28–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10147, CMS–2540–10, CMS–265–11, CMS–10106 and CMS–10537]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *September 29, 2014.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*