

must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record.² Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov, we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 12, 2019. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <https://www.ftc.gov/site-information/privacy-policy>.

Heather Hipsley,

Deputy General Counsel.

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BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment for Healthcare Quality Support, LLC (P0050); Premier Patient Safety Organization (P0054); QA STATS LLC (P0140); Securus Medica, LLC (P0053); Vascular Study Group Patient Safety Organization, LLC (P0080); and Washington State Patient Safety Organization (P0060)

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 Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (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 and Quality Improvement Act of 2005 (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 accepted a notification of proposed voluntary relinquishment from Healthcare Quality Support, LLC (P0050); Premier Patient Safety Organization (P0054); QA STATS LLC (P0140); Securus Medica, LLC (P0053); Vascular Study Group Patient Safety Organization, LLC (P0080); and Washington State Patient Safety Organization (P0060), of their PSO status and delisted the PSOs accordingly, but did not previously publish notices of their delisting in the **Federal Register**.

DATES: The delistings were effective at 12:00 Midnight ET (2400) on

- February 9, 2011—Healthcare Quality Support, LLC (P0050)
- February 9, 2011—Premier Patient Safety Organization (P0054)
- January 7, 2015—QA STATS LLC (P0140)
- March 2, 2011—Securus Medica, LLC (P0053)
- February 15, 2011—Vascular Study Group Patient Safety Organization, LLC (P0080)
- March 2, 2011—Washington State Patient Safety Organization (P0060)

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/listed>.

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; 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.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b–21 to 299b–26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for

the aggregation and analysis of patient safety events.

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 a 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 PSOs.

AHRQ accepted requests to voluntarily relinquish their PSO status from Healthcare Quality Support, LLC (P0050); Premier Patient Safety Organization (P0054), a component entity of the Premier Incorporated; QA STATS LLC (P0140); Securus Medica, LLC (P0053); Vascular Study Group Patient Safety Organization, LLC (P0080), a component entity of the M2S, Inc.; and Washington State Patient Safety Organization (P0060), a component entity of the Washington State Hospital Association. Accordingly, Healthcare Quality Support, LLC (P0050—February 9, 2011), Premier Patient Safety Organization (P0054—February 9, 2011), QA STATS LLC (P0140—January 7, 2015), Securus Medica, LLC (P0053—March 2, 2011), Vascular Study Group Patient Safety Organization, LLC (P0080—February 15, 2011) and Washington State Patient Safety Organization (P0060—March 2, 2011) PSOs, were delisted effective at 12:00 Midnight ET (2400) on the dates noted above. Notices of these delistings were not previously published in the **Federal Register**.

Healthcare Quality Support, LLC (P0050), Premier Patient Safety Organization (P0054), QA STATS LLC (P0140), Securus Medica, LLC (P0053), Vascular Study Group Patient Safety Organization, LLC (P0080) and Washington State Patient Safety Organization (P0060) had patient safety work product (PSWP) in their possession. The PSOs were required to meet the requirements of section

² See FTC Rule 4.9(c).

3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO had 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that was currently in the PSOs' possession.

More information on PSOs can be obtained through AHRQ's PSO website at <http://www.pso.ahrq.gov>.

Virginia L. Mackay-Smith,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection

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

ACTION: Notice of availability—new common formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats or formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the availability of the Common Formats for Nursing Home Version 1.0

DATES: Ongoing public input.

ADDRESSES: The *Common Formats for Nursing Home Version 1.0* can be accessed electronically at the following website: https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background on Common Formats Development

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-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 70731-70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, and analyze confidential and privileged information regarding the quality and safety of health care delivery. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

Aggregation of these data enables PSOs and others to identify and address underlying causal factors of patient safety and quality issues. The Patient Safety Act provides for the development of standardized reporting formats using common language and definitions to ensure that health care quality and patient safety data collected by PSOs and other entities are comparable. The Common Formats facilitate aggregation of comparable data at local, PSO, regional and national levels. In addition, the formats are intended to enhance the reporting of information that is standardized both clinically and electronically.

AHRQ has developed Common Formats for three settings of care—acute care hospitals, nursing homes, and community pharmacies—for use by health care providers and PSOs. AHRQ-listed PSOs are required to collect patient safety work product in a standardized manner to the extent practical and appropriate; this is a requirement the PSO can meet by collecting such information using Common Formats. Additionally, providers and other organizations not working with an AHRQ-listed PSO can use the Common Formats in their work to improve quality and safety; however, they cannot benefit from the federal confidentiality and privilege protections of the Patient Safety Act.

Since February 2005, AHRQ has convened the Federal Patient Safety Work Group (PSWG) to assist AHRQ in developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS as well as the Departments of Defense and Veterans Affairs. The PSWG helps assure the consistency of definitions/formats with those of relevant government agencies. In addition, AHRQ has solicited comments from the private and public sectors regarding proposed versions of the Common Formats through a contract, since 2008, with the National Quality Forum (NQF), which is a non-profit organization focused on health care quality. After

receiving comments, the NQF solicits review of the formats by its Common Formats Expert Panel. Subsequently, NQF provides this input to AHRQ who then uses it to refine the Common Formats.

The *Common Formats Nursing Home Version 1.0* include five modules: Generic, falls, medication, pressure injury and device. AHRQ developed other elements of the Common Formats for Event Reporting—Nursing Homes including aggregate reports, data elements and algorithms, and technical specifications. All elements of the Common Formats for Event Reporting—Nursing Home will be posted at the PSOPPC website: https://www.psoppc.org/psoppc_web.

AHRQ is specifically interested in receiving feedback in order to guide the improvement of the formats. Information on how to comment on the *Common Formats for Nursing Home Version 1.0* is available at: http://www.qualityforum.org/Project_Pages/Common_Formats_for_Patient_Safety_Data.aspx.

Additional information about the Common Formats can be obtained through AHRQ's PSO website: <https://www.pso.ahrq.gov/>.

Virginia L. Mackay-Smith,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-19-0041]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled "National Amyotrophic Lateral Sclerosis (ALS) Registry" to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 24, 2019 to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection