

*Regulations.gov.* An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: June 25, 2019.

**David A. Shive,**

*Chief Information Officer.*

[FR Doc. 2019-14217 Filed 7-2-19; 8:45 am]

**BILLING CODE 6820-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Patient Safety Organizations: Voluntary Relinquishment for QA to QI 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 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 has accepted a notification of voluntary relinquishment from QA to QI LLC, PSO number P0091, of its status as a PSO, and has delisted the PSO accordingly.

**DATES:** The delisting was effective at 12:00 Midnight ET (2400) on June 15, 2019.

**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: [psa@ahrq.hhs.gov](mailto:psa@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 federally approved PSOs.

AHRQ has accepted a notification from QA to QI LLC, to voluntarily relinquish its status as a PSO. Accordingly, QA to QI LLC, P0091, was delisted effective at 12:00 Midnight ET (2400) on June 15, 2019.

QA to QI LLC has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 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 has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO’s 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.*

[FR Doc. 2019-14215 Filed 7-2-19; 8:45 am]

**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Public Health Service Act, Delegation of Authority

Notice is hereby given that I have delegated to the Director, Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC), and the Director, Human Resources Office (HRO), CDC, without authority to redelegate, the authority vested in the Director, CDC/Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), under Section 317F, Title III of the Public Health Service Act, [42 U.S.C. 247b-7, as amended, to carry out a loan repayment program in accordance with Section 317F, guidelines and procedures issued by the Director, CDC/Administrator, ATSDR, CSELS, HRO, and all other applicable federal laws, regulations and policies, in conjunction with the Future Leaders in Infectious and Global Health Threats (FLIGHT) program.

This delegation became effective on June 26, 2019.

**Robert R. Redfield,**

*Director, Centers for Disease Control and Prevention, Administrator, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 2019-14255 Filed 7-2-19; 8:45 am]

**BILLING CODE 4160-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10556]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**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 (the 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 60 days for public comment on the

proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by September 3, 2019.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS-10556 Medical Necessity and Contract Amendments Under Mental Health Parity**

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Contract Amendments Under Mental Health Parity; *Use:* Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions given the choices available to them through their plans and may result in better treatment of their mental health or substance use disorder (MH/SUD) conditions. States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. In states where a Medicaid Managed Care Organization (MCO) is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state will review the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs. *Form Number:* CMS-10556 (OMB control number: 0938-1280); *Frequency:* Once and occasionally; *Affected Public:* Individuals and households, the Private sector, and State, Local, or Tribal Governments; *Number of Respondents:* 47,468,596; *Total Annual Responses:* 285,444; *Total Annual Hours:* 48,057. (For policy questions regarding this collection contact Juliet Kuhn at 410-786-2480.)

Dated: June 27, 2019.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2019-14131 Filed 7-2-19; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-2809]

**Patient Engagement Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (the Committee). The general function of the Committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

**DATES:** The meeting will be held on September 10, 2019, from 8 a.m. to 5:30 p.m.

**ADDRESSES:** Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900; additional information is available online at <https://www.ihg.com/holidayinn/hotels/us/en/gaithersburg/wasrv/hoteldetail>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>.

**FOR FURTHER INFORMATION CONTACT:**

Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002, [letise.williams@fda.hhs.gov](mailto:letise.williams@fda.hhs.gov), 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly