thresholds for certain data items to reduce reporting burden. The comment period expired June 29, 2018.

Detailed Discussion of Public Comments

The Federal Reserve received one comment from a banking association. The commenter noted several inconsistencies on the FR Y–9C report form and one inconsistency on the instructions when compared to the Call Report pertaining to Schedule HC–Q Memoranda items 4.b and 4.d, column A and Schedule HC–S Column G instructions and requested clarification on the proper reporting. The draft report form was inadvertently updated to reflect the removal of items 4.b and 4.d and a line item reference on the instructions for Schedule HC–S Column G was also inadvertently struck through. The Board has revised these items so that both the report form and instructions align with the Call Report. Additionally, the commenter noted an inconsistency between the caption on the report form and the caption on the instructions pertaining to *Equity investments without readily determinable fair values* on Schedule HC–F line item 4 on the FR Y–9C report. The Board has updated the instructions so that the report form and instructions align.

The revisions will be implemented as proposed, with the modifications described above, effective for the June 30, 2018, report date.

Board of Governors of the Federal Reserve System, July 25, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16265 Filed 7–30–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Diagnostic Quality Assurance

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

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule 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. 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 Diagnostic Quality Assurance of its status as a PSO, and has delisted the PSO accordingly. Diagnostic Quality Assurance, PSO number P0170, submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

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 1, 2018.

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

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, 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 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, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), 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 Diagnostic Quality Assurance, a component entity of Quality Star, LLC, to voluntarily relinquish its status as a PSO. Accordingly, Diagnostic Quality Assurance was delisted effective at 12:00 Midnight ET (2400) on July 1, 2018. AHRQ notes that that Diagnostic Quality Assurance submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on April 10, 2018.

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

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–16327 Filed 7–30–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and