

21 CFR part; guidance; or FDA form	Topic	OMB control No.
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910-0073

Dated: December 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-27433 Filed 12-18-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0955-new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 18, 2019.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0955-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this 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.

Title of the Collection: National Survey of Health Information Exchange Organizations (HIO)

Abstract: Electronic health information exchange (HIE) is one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the \$30 billion federal investment in electronic health records (EHRs) results in higher-quality, lower-cost care. The ability of providers to share data electronically is a core goal of HITECH and a central feature of a high-performing healthcare delivery system. Greater EHR adoption without data flowing between systems substantially limits quality and efficiency gains as well as reduces the value of the health IT investment.

There is growing consensus that achieving broad-based HIE is one of the most difficult components of HITECH. This is because successful HIE at scale involves coordination between many stakeholders, including but not limited to federal and state policymakers, healthcare delivery organizations, EHR and HIE vendors, and specific organizations supporting HIE, such as health information organizations (HIOs) and health information service providers (HISPs). Further, the issues requiring coordination are diverse, spanning technical standards, consent regulations, business models and incentives, workflow integration, trust and governance, and information privacy and security.

Three HIE issues have proven particularly challenging: Implementation of and use of standards, information blocking, and sustainability. The ultimate goal of our project is to administer a survey instrument to HIOs in order to generate the most current national statistics and associated actionable insights on electronic health information exchange to inform policy efforts.

Need and Proposed Use of the Information: Collecting timely, national data from HIOs in the three domains of standards, information blocking, and sustainability is valuable to inform both HIE-specific policy efforts as well as broader health system reform efforts.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
HIO Survey	200	1	20/60	67
Total	67

Terry Clark,

Assistant Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018-27469 Filed 12-18-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

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