

CHIP Reauthorization Act of 2015 (MACRA).⁶

Building on recent work of both NCVHS and the Office of the National Coordinator for Health Information Technology (ONC), the Subcommittee is gathering input to inform phase 1 of its two-year project *Standardization of Information for Burden Reduction and Post-Pandemic America*. This work involves assessing the current landscape of standards development and regulatory adoption processes and identifying opportunities for improving coordination of standards development, adoption, implementation, and conformity across disparate health-related data systems. NCVHS may use the information to inform recommendations to HHS. These recommendations may include an updated framework for standards adoption and implementation that takes into consideration public health, wellness, social services, clinical and claims information and newer technologies that promote interoperability across the health care system.

In conjunction with the August 25th listening session, the Subcommittee is including in this notice a Request for Public Comment to obtain written input from any interested stakeholders including: Trading partners and consumers; payers; providers; patients; standards organizations; advocacy groups; data exchanges; health information technology developers; and other data producers and data consumers including long term and post-acute care providers; public health agencies; population health registries; and operators of public and private sector claims and encounter data reporting systems. The Committee has developed specific questions to ensure comments address key issues under consideration by the Committee. Those questions are outlined here and available at: <https://ncvhs.hhs.gov/Request-for-Public-Comment-Standards-Subcommittee-August-Listening-Session>.

(1) How can data sharing be improved between patients, providers, payers, public health system, and other actors in health care? What are the barriers to these improvements?

(2) Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to HHS for adoption to support interoperability, burden reduction and administrative

simplification? Some examples might include new information sharing in health care, such as data or semantics for social determinants of health, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.

(3) How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?

(4) What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?

Please submit comments to NCVHSmail@cdc.gov by close of business Friday, July 30, 2021.

The Subcommittee will consider information from the invited panelists as well as all timely submitted written comments from the public in its development of a landscape assessment and potential recommendations.

There will be a public comment period. The meeting times and topics are subject to change. Please refer to the NCVHS website posted agenda for any updates.

Contact Person for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458-4715, email NCVHSmail@cdc.gov. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website <https://ncvhs.hhs.gov/>. Further information, including an agenda and instructions to access the broadcast of the meeting, will be posted as soon as the information is available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488-3210 as soon as possible.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0260]

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 July 26, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-0260 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: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Type of Collection: Extension with change.

OMB No. 0990-0260 Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB

⁶Public Law 114-10, 129 Stat. 87 (April 16, 2015), available at <https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>.

Review/IRB Recordkeeping/Informed Consent/Consent Documentation, OMB No. 0990–0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a

Common Rule department or agency has (1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: Assess whether the institution is following the established procedures; ensure that Federal funds are not expended for

unapproved human subjects research; and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: Institutions, institutional review boards and investigators.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.103(b)(5), .113 [Pre-2018 Requirements]/.108(a)(4), .113 [2018 Requirements]—Incident Reporting, Suspension or Termination of IRB approval Reporting	5,200	1	5,200	1	5,200
Total			5,200		5,200

TABLE 2—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total	6,000		96,000		1,152,000

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Common rule provision	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
.109(d) [Pre-2018 and 2018 Requirements]—Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.46.116(a) and (b) (Pre-2018 Requirements)/.46.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent	6,000	25	150,000	0.5	75,000
.46.116(h)—[2018 Requirements]—Posting clinical trial consent form	100	3	300	0.5	150
.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent	6,000	25	150,000	0.5	75,000
.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived	6,000	10	60,000	1	60,000
Total			510,300		285,150

Sherrette A. Funn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Notice of Meeting and Request for Public Comment

Pursuant to the Federal Advisory Committee Act, the Department of

Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Hearing of the Subcommittee on Privacy, Confidentiality and Security

DATES: Wednesday July 14, 2021: 9:30 a.m.–5:30 p.m. EST.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for

Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website, <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

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