

CFR 46, followed by an expert panel discussion on the impact of artificial intelligence algorithms on Institutional Review Board considerations for human subjects protections. The day will conclude with discussion of a new SACHRP charge addressing the current system of engagement and the interpretation of HHS support in 45 CFR 46. The second day, July 22, will include discussion of consideration of risks to third parties in research, and continue discussion of topics from the first day's agenda. Other topics may be added; for the full and updated meeting agenda, see <https://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 4:30 p.m. July 22.

The public will have an opportunity to send comment to SACHRP during the meeting's public comment session or to submit written public comment in advance. Persons who wish to provide public comment should review instructions at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html> and respond by midnight July 16th, 2021, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov). Comments are limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by SACHRP.

Dated: June 14, 2021.

**Julia G. Gorey,**

*Executive Director, Secretary's Advisory Committee on Human Research Protections, Office for Human Research Protections.*

[FR Doc. 2021-13362 Filed 6-23-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Appointment of Administrative Dispute Resolution Board Members

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** On December 14, 2020, the Department of Health and Human Services published in the **Federal Register** a final rule ("Rule") establishing the 340B Drug Pricing Program (340B Program) Administrative Dispute Resolution (ADR) Board (hereafter, "the Board"). See 85 FR 80632 (Dec. 14, 2020). According to the Rule, the purpose of the 340B Program's ADR process is to resolve (1) claims by

covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the Public Health Service Act, that a covered entity has violated the prohibitions on diversion or duplicate discounts. The Rule states that Board members from the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) must have relevant expertise and experience in drug pricing or drug distribution. The Rule also states that Board members from the Office of the General Counsel (OGC) must have expertise and experience in handling complex litigation. From the 340B ADR Board, the HRSA Administrator will select three voting members, one from each of the three HHS operating/staff divisions involved (*i.e.*, CMS, HRSA, OGC) to form 340B ADR Panels that will review claims and, pursuant to delegated authority from the Secretary, make certain final agency decisions.

All previous appointments to the Board are revoked. Based on recommendations from OGC, CMS, and HRSA, I hereby appoint the following Board members, who shall serve a term of two years, to be extended for additional terms upon agreement by the member and the head of his or her operating/staff division.

*Sean R. Keveney*, Deputy General Counsel, the Office of the General Counsel, Department of Health and Human Services;

*Andy J. Miller*, National Complex Litigation and Investigations Division Attorney, the Office of the General Counsel, Department of Health and Human Services;

*Glenn Clark*, Public Health Advisor, HIV/AIDS Bureau, Health Resources and Services Administration, Department of Health and Human Services;

*CAPT Christina Meade*, Area Regional Pharmacy Consultant, Office of Regional Operations, Health Resources and Services Administration, Department of Health and Human Services;

*CDR Timothy Lape*, Division of Medicare Health Plans Operations, Medicare Branch, Centers for Medicare & Medicaid Services, Department of Health and Human Services;

*Adele Pietrantonio*, Office of Program Operations and Local Engagement, Division of Drug and Health Plan Operations, Centers for Medicare & Medicaid Services, Department of Health and Human Services;

*Chantelle Britton*, Senior Advisor, Office of Pharmacy Affairs, Health

Resources and Services Administration, Department of Health and Human Services, as *ex-officio*, non-voting member; and

*Julie Zadecky*, Pharmacist, Office of Pharmacy Affairs, Health Resources and Services Administration, Department of Health and Human Services, as *ex-officio*, non-voting member.

Dated: June 21, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021-13461 Filed 6-23-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0955-0003]

### 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](http://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, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0955-0003-30D 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:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

*Type of Collection:* Father Generic ICR revision.

OMB No. 0955-0003—Office of the National Coordinator for Health Information Technology.

*Abstract:* The Office of the National Coordinator for Health Information Technology is seeking a three-year revision of OMB control number 0955-0003 to continue collecting routine customer feedback on agency service delivery. The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. Qualitative

feedback means information that provides useful insights on perceptions and opinions, and is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; provide an early warning of issues with the service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as timeliness, appropriateness, accuracy of information, courtesy, efficiency of

service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency’s services will be unavailable.

*Affected Public:* Individuals, households, professionals, and/or the public/private sector.

*Average estimates for the next three years:*

*Estimated Total Number of Respondents:* 10,000.

*Expected Annual Number of Activities:* 6.

*Average Number of Respondents per Activity:* 1667.

*Frequency of Response:* Once per activity.

*Average Minutes per Response:* 7.

*Total Burden Hours:* 1167.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Individuals, households, professionals, and/or the public/private sector .....	10,000	1	7/60	1167
Total .....	10,000	1	7/60	1167

**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 and request for public comment.

*Name:* National Committee on Vital and Health Statistics (NCVHS), Listening Session to be held by the Subcommittee on Standards.

*Dates and Times:* Wednesday, August 25, 2021: 10:00 a.m.–5:30 p.m. EST.

*Place:* Virtual.

*Status:* Open.

*Purpose:* The purpose of this listening session is to obtain input from representatives of standards development organizations, invited industry stakeholders, and

representatives from federal agencies on a variety of topics pertaining to data standards, harmonization of standards and code sets, new Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs) to enhance the exchange of clinical and administrative data, the state of readiness for certain administrative and clinical standards to be considered for adoption or use as standards under the Health Insurance Portability and Accountability Act (HIPAA),<sup>1</sup> for interoperability, and other subjects beyond HIPAA transactions.

This Notice also includes a Request for Public Comment to solicit input from interested individuals and stakeholders who would like to provide input to the Subcommittee in advance of the August 25, 2021, listening session.

The Subcommittee seeks to understand the extent to which current and emerging standards for exchanging electronic health-related data under HIPAA and other applicable federal legislation and regulatory processes are

meeting the business needs of the health care system. Applicable legislation and regulation include, but are not limited to HIPAA, the final Interoperability and Patient Access Rule promulgated by the Centers for Medicare and Medicaid Services (CMS),<sup>2</sup> the 21st Century Cures Act,<sup>3</sup> the Affordable Care Act of 2010,<sup>4</sup> the Health Information Technology for Economic and Clinical Health Act (HITECH),<sup>5</sup> and Medicare Access and

<sup>2</sup> Centers for Medicare and Medicaid Services, Final Rule: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers,” 85 FR 25510, May 1, 2020, available at <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf>.

<sup>3</sup> Public Law 114–255, 130 STAT. 1033 (Dec. 13, 2016), available at <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>.

<sup>4</sup> Public Law 111–148, 124 Stat. 119 (Mar 13, 2010), available at <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>.

<sup>5</sup> Public Law 111–5, Title XIII, 123 Stat. 115, 226 (Feb. 17, 2009), available at <https://www.govinfo.gov/content/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf>.

<sup>1</sup> Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at <https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf>.