

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.*

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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.*

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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