Centers for Medicare & Medicaid Services (CMS) Plan to Enhance Public Access to the Results of CMS-Supported Research

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I. Introduction

The Centers for Medicare & Medicaid Services (CMS) Plan to Enhance Public Access to the Results of CMS-Supported Research (CMS Public Access Plan) establishes CMS Public Access Policy (effective December 31, 2025) and provides an implementation roadmap for how CMS will enhance access to scholarly publications and their associated scientific data. Increasing access to publications and data resulting from published federally funded peer-reviewed research offers many benefits to the scientific community and the public. Additionally, doing so upholds CMS' commitment to open data, transparency of, and access to taxpayer funded research.

The CMS Public Access Plan seeks to address the requirements outlined in the August 25, 2022, Office of Science and Technology Policy (OSTP) Memorandum, "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research". The August 25, 2022, OSTP Memorandum sets forth three broad expectations for public access to federally funded research:

- Accelerated access to scholarly publications;
- Increased access to related scientific data; and
- Enhanced tracking of resulting research products through persistent identifiers (PIDs) and metadata.

The CMS Public Access Plan promotes the following objectives:

- Establish CMS' commitment to public access to scientific research results;
- Facilitate free and easy public search, analysis of and access to peer-reviewed scholarly publications directly arising from research funded wholly or in part by CMS;
- Ensure full public access to publications' metadata without charge;
- Ensure the attributes to authors, journals, and original publishers are maintained;
- Ensure that all intramural researchers (i.e., CMS employees and contractors conducting research on behalf of CMS) as well as extramural researchers (i.e., external researchers or contractors receiving CMS funding through grants or cooperative agreements) develop data management and sharing plans, as appropriate, describing how they will provide for long-term preservation of and access to data from peer-reviewed scientific publications in a digital format; and
- Affirm CMS' commitment to research integrity and supporting the reproducibility of research results.

The CMS Public Access Plan was developed by the CMS Office of Enterprise Data and Analytics with input from across CMS. CMS will review this plan annually to consider stakeholder feedback, technology changes, and operational improvements. This plan will be publicly posted on cms.gov.

II. Background

Promoting public access to CMS data is essential to supporting the agency's strategic mission of serving the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. As the single largest payer for healthcare in the United States, CMS generates an enormous amount of data ranging from administrative claims, plan and health care provider data, compliance data, quality metrics, customer service, beneficiary experience data and beyond. CMS recognizes the immense value in making data available, including increased innovation inside and outside of government, enhanced interoperability, and increased accountability. As such,

CMS has made a longstanding commitment to making more information available to researchers and the public, while still balancing the need to protect the privacy and security of the data.

The primary method CMS utilizes to make data publicly available is through the development of de-identified public use data files and information products. CMS publishes these de-identified data products on a variety of public websites including data.cms.gov, which gives users direct access to data in open, accessible, and machine-readable formats. In general, data can be downloaded, viewed, and analyzed using different interactive tools, and accessed through Application Programming Interfaces (APIs) that let developers connect other applications to data in real time. In addition, researchers can apply to access identifiable data for research purposes.

III.   CMS Public Access Policy

Through this CMS Public Access Plan, CMS seeks to take additional action to ensure the results of the peer-reviewed research it undertakes and financially supports is freely available to the public. Beginning December 31, 2025, the CMS Public Access Policy states:

CMS-funded researchers are required to submit to CMS their final, peer-reviewed manuscripts upon acceptance for publication to be made publicly available at the time of publication via the National Library of Medicine's PubMed Central (PMC) digital archive.

IV.   Scope and Applicability

The CMS Public Access Policy and Plan applies to any manuscript that:
- Is peer-reviewed;
- Is accepted for publication in a journal on or after December 31, 2025; and
- Arises from:
    o   Any direct funding from a CMS grant or cooperative agreement;
    o   Any direct funding from an CMS contract; or
    o   A CMS employee.

The CMS Public Access Policy and Plan applies to the following groups (collectively referred to as CMS-supported researchers):

- All CMS intramural researchers (i.e., CMS employees conducting research or CMS contractors conducting research on behalf of CMS); and
- All extramural researchers (i.e., external researchers or contractors receiving CMS funding through grants or entering into cooperative agreements).

The CMS Public Access Policy and Plan will apply to all peer-reviewed publications funded by CMS, except where such research is administered or performed by a collaborating federal agency with a comparable Public Access Policy, in which case CMS will defer to the collaborating agency's policies on the management of scholarly publications and digital data sets.

Digital scientific data that is outside the scope of this policy include:

- Personally identifiable data (however, CMS will work toward increasing access to research data by creating de-identified public use data files);
- Proprietary or commercially sensitive data;
- Data related to protecting critical infrastructure;

- Other data for which disclosure is limited due to applicable laws, regulations, privacy or security requirements or CMS policies; and
- Per The Office of Management and Budget (OMB) Circular A-110, the following are not considered research data and therefore not subject to this policy: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues.

The CMS Public Access Policy is effective December 31, 2025. Implementation will be prospective and will not apply retroactively to any publication or digital data set arising from an CMS-sponsored grant, cooperative agreement, contract, or intramural research published prior to the effective date of the CMS Public Access Policy. CMS-supported scholarly publications and accompanying scientific data published after the effective date will be subject to the CMS Public Access Policy, including those stemming from preexisting CMS-sponsored grants, cooperative agreement, and contracts.

In accordance with the August 25, 2022, OSTP Memorandum, CMS anticipates making an additional update to this plan with information on CMS' approach to implementing the memo's provisions on Scientific and Research Integrity in Agency Public Access Policies (i.e., persistent digital identifiers). CMS will publish full policy guidance for implementing these provisions by December 31, 2026, with a proposed effective date of December 31, 2027.

V.   Scholarly Publication

The CMS Public Access Policy requires that starting on December 31, 2025, all peer-reviewed scholarly publications resulting from CMS-funding are made freely available, without charge, and publicly accessible by default without any embargo or delay after publication. In lieu of the final peer-reviewed manuscript, CMS will accept the final published article, provided the authors can ensure CMS has the rights to make the published version public. The CMS Public Access Policy and Plan is subject to applicable law; agency mission; agency resource constraints; U.S. national, homeland, and economic security considerations; and the objectives listed in the OSTP memorandum.

Implementation Plan

CMS intends to collaborate with the National Institutes of Health (NIH) and the NIH National Library of Medicine (NLM), to use PMC to make peer-reviewed scholarly publications publicly accessible. CMS will maintain attribution to authors, journals, and original publishers through PMC.

Submission Process

Prior to submitting a manuscript for publication, CMS-supported extramural researchers will be required to notify CMS of their intent to publish as well as their plan for providing free, immediate access to the publication by sending an email to PublicAccessPolicy@cms.hhs.gov. This notification should include their associated CMS project officer, if applicable, and will provide CMS with an additional opportunity to share resources or educate CMS-supported researchers on their obligations and options for complying with the CMS Public Access Policy and Plan. Intramural researchers, including CMS contractors conducting research on CMS' behalf, will submit this notification when they submit their draft publication to the CMS Manuscript Clearance Process.

The CMS Public Access Policy and Plan should not impact an author's selection of a vehicle or venue for publishing their results. CMS is not suggesting that authors must publish in any particular type of journal or journal with any specific type of business model (e.g., subscription model, open access model). However, CMS-supported authors must retain rights to the final peer-reviewed manuscript, regardless

of the pathway to publication, to ensure that their CMS-supported research can be made freely available at no cost and publicly accessible without any embargo or delay after publication.

In addition, each instance of CMS-supported research is subject to the terms and conditions of the relevant contract or agreements governing their engagement with CMS. These contracts or agreements must contain terms that delineate the respective rights and obligations of the Government and the researcher regarding the use, reproduction, and disclosure of that data. CMS will review the terms and conditions of any contracts or agreements entered between CMS and CMS-supported researchers to ensure alignment and compliance with the CMS Public Access Policy and Plan and the overarching objective of increasing public access to scholarly publications and scientific data.

CMS-supported researchers are required to deposit, or have deposited on their behalf, the final peer-reviewed manuscript to CMS via email (PublicAccessPolicy@cms.hhs.gov) at the time of acceptance for publication in a journal. CMS will make the manuscript accessible in PMC via the National Institutes of Health Manuscript Submission (NIHMS) system. In addition, CMS will consider compliant those CMS-supported researchers who choose to publish in journals that already have formal agreements with NLM to submit final published articles to be available in PMC at the time of publication.

In cases where journals have a formal agreement to submit directly to PMC but with an embargo period that extends beyond the date of publication, the CMS-supported researcher will be expected to either ensure the final peer-reviewed manuscript is submitted to PMC upon acceptance for publication, to be made publicly available at the time of publication, or arrange with the journal to deposit the individual published article to PMC without a post-publication embargo. CMS acknowledges that in some cases there may be some PMC processing period prior to release.

Access, Discoverability, and Preservation

The use of PMC will ensure easy search, analysis, and download of peer-reviewed scholarly publications arising from research funded by CMS without charge. The public's ability to locate and access digital data resulting from CMS' federally funded scientific research as well as for publications will be improved with PMC. In addition, NLM maintains multiple backup copies of the PMC database to ensure preservation.

PMC will make access to CMS-supported papers easier while taking appropriate steps to prevent unauthorized mass redistribution. NLM has established sophisticated monitoring systems to detect and prevent potential misuse that are very similar to the processes used by publishers' websites. NLM systems detect and prevent bulk downloading and will immediately cut off any sites, foreign or domestic, that appear to be abusing copyrighted property. Unless publishers have chosen PMC as the sole distributor of the electronic contents of their journals, all articles that are accessible on PMC can also be accessible on publisher websites.

CMS intends to maximize the equitable reach of public access to peer-reviewed scholarly publications including ensuring free online access to peer reviewed scholarly publications via PMC in formats that allow machine readability and enable broad accessibility through assistive devices. Accessibility of articles in PMC depends on the completeness of accessibility information provided in the article submissions. CMS will collaborate with NIH to improve guidance for submitters on how they can supply more accessible content.

Reasonable Costs

CMS will allow funding to be used to cover costs of publication. Publication costs, including article processing charges often associated with open access publishing, may be charged to CMS grants and

contracts with prior approval by CMS. CMS seeks to ensure that costs associated with the publication of findings from CMS-supported research are reasonable and do not serve as an impediment to publishing by researchers from limited-resourced institutions or under-represented groups.

VI.   Scientific Data

Scientific data underlying peer-reviewed scholarly publications resulting from federally funded research will be made freely available and publicly accessible by default at the time of publication, unless subject to legal, privacy, ethical, technical, intellectual property, or security limitations, and/or other restrictions or limitations on data use or disclosure included in a funding agreement or award or set forth in a data use agreement or stipulations set forth by an Institutional Review Board, as described in Section 3(c)(i) of the August 25, 2022, OSTP Memorandum. In addition, scientific data from underlying peer-reviewed scholarly publications will be subject to guidelines established in CMS' data use agreement for researchers. All CMS-funded researchers will be required to submit to CMS a data management and sharing plan for sharing de-identified final research data in a digital format, or state why data sharing is not possible. This plan must be submitted at the start of the CMS-funded research award or project and be emailed to PublicAccessPolicy@cms.hhs.gov.

Scientific data includes the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings. Such scientific data does not include laboratory notebooks, preliminary analyses, case report forms, drafts of scientific papers, plans for future research, peer-reviews, communications with colleagues, or physical objects and materials, such as laboratory specimens, artifacts, or field notes.

CMS remains committed to developing approaches for sharing other federally funded scientific data that are not associated with peer-reviewed scholarly publications. The primary method CMS utilizes to make data publicly available is through the development of de-identified public use data files and information products, which are published on variety of public websites including data.cms.gov.

CMS funded researchers must follow federal laws and OMB policies that govern federal agencies' information management practices and protect certain types of data, to the extent that the scientific data created by, collected by, under the control or direction of, or maintained by the federal researchers is subject to those laws and policies. To the extent feasible and in accordance with all applicable laws and policies; CMS' mission; agency resource constraints; U.S. national, homeland, and economic security; and the objectives listed below, digitally formatted scientific data resulting from unclassified research supported wholly or in part by federal funding should be stored and publicly accessible to search, retrieve, and analyze.

Data management and sharing plans will be evaluated by CMS staff for merit and will be revised as needed based on feedback from CMS while considering the values of long-term preservation, access, and the associated cost, and administrative burden. CMS expects the timely release and sharing of data to be no later than the acceptance for publication of the main findings from the final dataset. The specific time will be influenced by the nature of the data collected. Extramural researchers will work with CMS staff and/or commercial repositories to deposit data upon publication. It may not be feasible to share all data; the costs and benefits of sharing data should be considered in data management planning. CMS will attempt to make intramural research data available to the public by creating de-identified public use data files.

If a CMS-funded grant, cooperative agreement, contract or intramural research project transforms or links datasets, rather than producing a new set of data, the researchers will still be required to submit a

data management and sharing plan. If there are limitations associated with the data sharing agreements for the original data that preclude subsequent sharing, the research applicants must explain these limitations.

Implementation

CMS already shares a significant amount of scientific data with researchers through public data sites like data.cms.gov and through our research data request pathway (www.resdac.org). CMS will continue to explore and develop approaches and timelines for sharing other federally funded scientific data that are not associated with peer-reviewed scholarly publications wherever feasible.

CMS will explore the feasible approaches to accept and manage data submitted by extramural, intramural, and contract researchers, which may include contracting with a commercial repository.

CMS staff will coordinate with the researcher upon notification of funding, prior to the start of the research project, and throughout its life cycle to ensure the current usability, long-run preservation, and access to the data. Data will be made available in a digital format free of charge to the public via the selected repository. CMS will publicize the location of the data to the public on its website and provide a link to the data. Information on how to access all CMS' funded scientific data will be provided on CMS' website with links to the data.

CMS will continue working with OSTP and other federal agencies in developing guidance to researchers that ensures the digital repositories used align, to the extent practicable, with the National Science and Technology Council document entitled "Desirable Characteristics of Data Repositories for Federally Funded Research." To determine how best to develop and sustain repositories for digital scientific data, CMS intends to continue to collaborate with HHS operating divisions and other agencies that support research in related areas.

VII.   Scientific and Research Integrity in Agency Public Access Policies

CMS will take actions to ensure that scientific and research integrity policies are in place to strengthen public trust in federally funded science. By December 31, 2024, CMS plans to submit to OSTP and OMB a second update to the CMS Public Access Plan specifying the approaches taken to implement the provisions in Section 4 of the August 25, 2022, OSTP Memorandum. CMS plans to complete and publish full policy development for plans implementing these provisions by December 31, 2026, with an effective date no later than one year after the publication of the agency plan.

VIII.   Roles and Responsibilities

CMS Director of the Office of Enterprise Data and Analytics (OEDA)

- Assumes CMS-wide authority, control, and management of the CMS Public Access Policy.
- Manages the implementation of the CMS Public Access Policy and Plan and ensures compliance with the CMS Public Access Policy.
- Coordinates with CMS' Office of Acquisition and Grants Management (OAGM) to ensure the requirements of this policy are included as terms and conditions of funding for grants, contracts, and cooperative agreements.
- Develops practical funding strategies to ensure the successful implementation of this policy.
- Coordinates the collaboration and cooperation of public access and data sharing with other federal agencies.

Grant, Cooperative Agreement, and Contract Awardees and their institutions that receive CMS funding to conduct research:

- Ensure that researchers and authors are aware of and comply with the CMS Public Access Policy and Plan.
- Ensure all terms and conditions of awards are met.
- Submit data management and sharing plan with grant, cooperative agreement, and contract applications.
- Include reasonable cost for public access to publications and data in digital format as a component of grant, cooperative agreements, and research contract applications.

Authors who receive CMS funding to conduct research:

- Work with the publisher before any publication rights are transferred to ensure that all conditions of the CMS Public Access Policy and Plan can be and are met.

CMS will provide guidance to awardees and training, education, and workforce development for its employees about the new requirements related to scientific data management, analysis, storage, preservation, and stewardship in advance of the implementation date. This guidance and training will describe any required changes to the conditions of awards and a publicly available timeline for the implementation of the policy. CMS will also use public websites and internal mechanisms to disseminate information and solicit feedback before and after the implementation date. The capability for CMS and the science communities it supports to help one another through ongoing dialogue is expected to be a key part of a successful policy implementation.

CMS will require periodic reporting on compliance with the approved data management and sharing plans as part of the terms and conditions of award and will develop mechanisms to monitor such compliance. The data management and sharing plan currently undergoes objective review and approval by CMS' grant and technical peer review groups to assess its merits. CMS will continue to require all data management and sharing plans to be consistent with applicable laws and regulations governing the privacy and confidentiality of individual human data. The CMS Public Access Policy and Plan recognizes proprietary interests, business confidential information, and intellectual property rights and avoids significant negative impact on intellectual property rights, innovation, and U.S. competitiveness of research grants and cooperative agreements and appropriate contracts.

IX.   Metrics, Compliance, and Evaluation

CMS will include public access requirements in all grant and contract solicitations. All research proposals will be required to include a data management and sharing plan as part of the overall research proposal. Researchers will be expected to follow the approved data management and sharing plan, to the best of their ability. Failure to do so will negatively influence future funding opportunities. CMS will monitor all CMS-funded researchers to verify compliance with the CMS Public Access Policy and Plan. Grant final reports will be used to confirm compliance with the CMS Public Access Policy and Plan. Contract progress reports will also be monitored for compliance.

Prior to funding new grant and contract awards, CMS will confirm awardees are in compliance with the CMS Public Access Policy and Plan. CMS will not make grant or contract awards in cases of non-compliance. CMS may delay processing of non-competing continuation awards that are not in compliance with the CMS Public Access Policy and Plan.

CMS will report to OSTP as needed on the status of the public access plans and policy implementation, including relevant statistics collected by the agency, such as number of publications resulting from agency-supported research grants, contracts, and cooperative agreements.

CMS' expectations for data sharing are and will continue to be communicated to intramural and extramural researchers through guidance documents and outreach activities, including through the notice of grant award or the contract award. CMS will continue to monitor and take steps to ensure compliance with the terms and conditions of the award.

X.   Interagency Coordination

CMS will continue interagency coordination through the following steps:

- Full participation on the OSTP organized interagency public access work group.
- Full participation on the United States Department of Health and Human Services (HHS) interagency public access work group.
- Full participation on the government-wide public access publications and data work groups facilitated by OSTP.
- Full participation in the National Science and Technology Council (NSTC) Subcommittee on Open Science.
- Coordinating with NIH in the use of PMC and adherence to all established PMC requirements.

XI.   Inquiries

Please direct all inquiries to: PublicAccessPolicy@cms.hhs.gov.