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

April 2024

The Centers for Medicare & Medicaid Services (CMS) Plan to Enhance Public Access to the Results of CMS-Supported Research (CMS Public Access Plan) describes how CMS will take steps to ensure CMS-supported research and their associated scientific data will become more open and available to the public.

### What is the CMS Public Access Plan?

The CMS Public Access Plan establishes the CMS Public Access Policy (effective December 31, 2025) and provides a roadmap for how CMS will enhance access to scholarly publications and their associated scientific data and will ensure these research products are useful and accessible to the public. 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".

Key objectives of the CMS Public Access Plan include elimination of any "embargo" period before the public gains free access to journal articles or final accepted manuscripts resulting from CMS funding; increased access to scientific data displayed in or underlying publications and expanded access to scientific data not displayed in publications, in accordance with all applicable laws, regulations, and policies; and broad adoption of persistent identifiers (PIDs) for research outputs, organizations, awards and contracts, and people.

### Who qualifies as a CMS-supported researcher?

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:
  - 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).

### When will new requirements of the CMS Public Access Plan go into effect?

The CMS Public Access Policy is effective December 31, 2025. Implementation will be prospective and will not apply to any publication or related scientific data arising from an CMS-sponsored grant, cooperative agreement, contract, or intramural research funded prior to the effective date of the CMS Public Access Policy.

In accordance with the August 25, 2022, OSTP Memorandum, CMS anticipates making an additional update to the CMS Public Access 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.

# How will CMS implement the Plan's requirements for providing access to journal articles authored by CMS-supported researchers?

The CMS Public Access Policy requires that as of December 31, 2025, all peer-reviewed scholarly publications resulting from CMS-funded research are made freely available and publicly accessible by default without any embargo or delay after publication. Prior to submitting a manuscript for publication, CMS-supported 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 <a href="mailto:PublicAccessPolicy@cms.hhs.gov">PublicAccessPolicy@cms.hhs.gov</a>. CMS will require authors to submit or have submitted for them the final peer-reviewed accepted journal manuscripts to PubMed Central (PMC).

#### What is PubMed Central?

More information about the U.S. National Institutes of Health's National Library of Medicine's (NIH/NLM) PubMed Central (PMC) is available at <a href="http://www.ncbi.nlm.nih.gov/pmc/about/faq.html">http://www.ncbi.nlm.nih.gov/pmc/about/faq.html</a>.

# How will CMS implement the Plan's requirements for increasing access to scientific data resulting from CMS funding?

CMS will develop additional guidance for CMS-supported researcher data management and sharing plans to address the sharing of de-identified final research data in digital form or to state why sharing is not possible. This guidance will instruct CMS-supported researchers to submit data management and sharing plans that describe how data displayed in or underlying publications will be accessible at the time of publication and provide timelines and approaches for providing access to data not displayed in publications.

Will there be additional funding provided to pay for public access to publications and data? Reasonable publication fees and data management expenses are allowable costs of an award or contract and can be included in proposed budget requests.

#### How will CMS implement the Plan's requirements for persistent identifiers (PIDs)?

In accordance with the 2022 OSTP Memorandum, CMS anticipates making an additional update to the CMS Public Access 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). Agencies are expected to publish full policy guidance for implementing these provisions by December 31, 2026, with a proposed effective date of December 31, 2027.

### **FAQS for CMS-Supported Researchers**

#### What is an accepted manuscript?

An accepted manuscript, also known as the final peer-reviewed accepted manuscript, is the version of the article that has been accepted for publication by a publisher and includes changes made during the peer-review process. It includes the same content as the published version but does not include the publisher's copyediting, stylistic or formatting edits that will constitute the final "version of record" that appears in a scholarly journal (i.e., it is not a "reprint" or a downloaded PDF of the published article).

My paper is based on research only partially funded by CMS. Is the paper required to be submitted? Yes, the CMS Public Access Policy applies to any manuscript that arises from any amount of direct funding from the CMS.

### How can I address copyright and retain my rights?

Before you sign a publication agreement or similar copyright transfer agreement, the agreement must allow for the manuscript to be shared with the public through PubMed Central (PMC), in accordance with the CMS Public Access Policy.

Whose approval do I need to submit my final peer-reviewed manuscript to PubMed Central? Authors own the original copyrights to materials they write. Consistent with individual arrangements with authors' employing institutions, authors often transfer some or all of these rights to the publisher when the journal agrees to publish their paper. Some publishers may ask authors to transfer these rights when the paper is first submitted to the journal.

Authors should work with the publisher before any rights are transferred to ensure that all conditions of the CMS Public Access Policy can be met. Government works are not subject to copyright protection in the United States.

# What should authors ensure is included in a copyright agreement between an author or institution and a publisher to comply with the plan?

Individual copyright arrangements can take many forms, and authors and their institutions should continue to manage such arrangements as they have in the past. Institutions and investigators may wish to develop particular copyright agreement terms in consultation with their legal counsel or other applicable official at their institution, as appropriate. The language should allow for the author to retain the right to provide a copy of the final peer-reviewed manuscript to CMS upon acceptance for journal publication, for public archiving in PMC as soon as possible. Authors may want to check if their institution or professional society has developed specific model language for this purpose, as well.