ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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July 13th, 2026

Office of Federal Financial Management
The Office of Management and Budget
725 17th St. NW
Washington, DC 20503

Submitted electronically via www.regulations.gov

Re: Docket No. OMB-2026-0034; Regulation for Federal Financial Assistance

To Whom It May Concern:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to the proposed rule to revise the Guidance for Federal Financial Assistance; Public Docket OMB-2026-0034.

AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Our membership includes professionals from academic medicine, hospital-based and private clinical laboratories, government, and the in-vitro diagnostics industry.

AMP is concerned that several provisions of the proposed rule could significantly impede the clinical research and healthcare infrastructure that supports the development, validation and implementation of molecular diagnostic testing. Such changes may adversely affect scientific innovation, medical progress and patient access to diagnostics that are patients the foundation for precision cancer care, for understanding rare diseases and developing innovative therapies, preparing for infectious disease response efforts, and much more**. Accordingly, AMP respectfully urges the Office of Management and Budget (OMB) to withdraw the proposed rule, or at a minimum, delay its finalization and engage stakeholders across the scientific, clinical and patient communities to evaluate potential unintended consequences and identify alternative approaches to improving federal grant management.** Doing so would allow robust discussion and sufficient time to implement reforms without compromising research processes and the clinical infrastructure that are vital to innovation, medical progress, and patient care.

Below are AMP's comments on specific areas of the proposed rule that would most impact our members' work.

Subpart E: Cost Principles

The rule's proposals to limit funding support for scientific publications, journal subscriptions, and attendance at scientific conferences would hinder the ability of researchers to disseminate discoveries, learn about emerging advances, and establish highly productive collaborations. AMP urges OMB to retain publications, conference travel, and society membership dues as allowable expenses.

More detailed comments are included below by section.

[§200.432] Conferences

Scientific conferences are an invaluable mechanism for researchers to exchange information and engage in meaningful dialogue about their respective fields of study. Further, it's an opportunity for practicing clinicians to obtain continuing medical education, collaborate to translate research findings to clinical care, and generally improve the quality of care provided to their patients. AMP's Annual Meeting and Expo convenes thousands of molecular diagnostic professionals to share study findings, establish meaningful collaborations, and mentor the next generation of molecular pathologists and doctoral scientists. Conferences also create a space to foster collaborative interactions between patients and those who are working from a research and clinical perspective to address a disease. The proposal would eliminate the use of grant funds to attend conferences related to the scientific work of the grant as a routine, allowable cost. Instead, the grantee would be required to seek and obtain express permission from agency political personnel to use grant funds in this manner and further, would have to note this use of the funds in the initial terms and conditions of the award.

This new requirement will harm the way that scientists and advocates have historically engaged for several reasons. It would require awardees to know, at the time of the award, which conferences they (and anyone supported by the grant) plan to attend over the multi-year project period. Developments in molecular diagnostics are occurring at a rapid pace, which means opportunities for information dissemination can and do emerge during the life cycle of the grant. Requiring investigators to identify conference participation at the time of award may limit their ability to respond to emerging scientific developments and collaborative opportunities that arise during the course of a multi-year research project. Such flexibility is particularly important in rapidly evolving fields such as molecular diagnostics and genomics. The new policy also will limit the dissemination of federally funded research findings because it presents a barrier to attendance at scientific conferences to present, share, and discuss relevant research ideas, methods, and findings. Additional layers of administrative review may create delays and uncertainty that reduce participation in scientific meetings and impede timely dissemination of federally funded research findings.

Any actions that slow and jeopardize communication among the research community could have the unintended consequence of slowing research advances and delaying the translation of those findings into clinical care. In the case of AMP, this means potential delays in bringing innovative, cutting edge, molecular diagnostics into the clinic to better inform care in oncology, infectious disease, rare disease, and more.

§200.454 Memberships, Subscriptions, and Professional Activity Costs

AMP has concerns about the rule's prohibition on society membership dues as an allowable grant expense, a change that is particularly problematic when coupled under the proposed rule with new restrictions on use of grant money to assist with certain publication and conference expenses. Scientific societies are the organizations that publish the journals in which federally funded findings appear, organize the conferences at which those findings are presented, and train the peer reviewers who evaluate the quality of that work. Prohibiting investigators from using grant funds to support membership in the organizations that sustain these functions, which are critical to advancing science, may yield limited budgetary savings while weakening important elements of the scientific infrastructure that support peer review, professional education, publication, and research dissemination.

§200.461 Publication and Printing Costs

AMP is particularly concerned about the proposed prohibition on open-access publication expenses, including article processing charges (APCs) as an allowable grant expense. . Investigators must often comply with these charges under the NIH public access mandate, so prohibiting use of grant funds to publish the science funded by said grant creates a significant tension with existing federal public-access requirements that encourage or require dissemination of federally funded research findings. AMP, through the *Journal of Molecular Diagnostics,* fulfills this role by communicating research advances in translation and validation of molecular discoveries in medicine into the clinical diagnostic setting. Scholarly publishers like AMP also protect the integrity of the scientific record and support global dissemination of information that ultimately benefits the public.

[§200.205] Federal Agency Review of Merit of Proposals

The rule's proposal to change the award-approval process so that all federal discretionary awards must be reviewed by senior political appointees marks a fundamental change in how research funding decisions are made, how opportunities are developed, how proposals are evaluated, and how priorities are established. The proposal instructs senior political appointees to apply specific criteria when approving grants that align with Presidential policy priorities. While AMP recognizes the Administration's interest in ensuring alignment between federal spending and policy priorities, scientific merit review by subject-matter experts has long served as the cornerstone of federal biomedical research funding. The proposed expansion of political review raises concerns regarding predictability, continuity, and confidence in the research funding process. This uncertainty may have a dramatic and negative effect on biomedical research and ultimately patient care, especially projects that are long-term and longitudinal in nature. Because the rule proposes converting the Uniform Guidance to federal regulation, it would extend into future administrations, institutionalizing an additional layer of non-scientific review that could reduce the stability and long-term planning necessary for major biomedical research initiatives.

Under the proposed changes, an incoming administration could alter and even halt research projects underway if they do not align with stated priorities, wasting federal taxpayer dollars already invested in these projects and slowing medical progress. Consider the Human Genome Project, which began in 1990 and concluded in 2003. This landmark, long-term research study funded by NIH spanned three Administrations, Democratic and Republican, and relied on a steady commitment from multiple Congresses with ever-changing leadership. Without the Human Genome Project, the field of molecular diagnostics would not be where it is today, driving precision medicine that saves and improves lives and transforming the way we treat myriad conditions, from cancer to rare diseases. Had the project fallen victim to shifting priorities between administrations, modern medicine would lack the foundational blueprint of DNA, and the costs to society would be incalculable.

The federal government has provided billions of dollars in funding to accelerate the development, validation, and clinical deployment of molecular diagnostic assays and laboratory tests. This financial support spans biomarker identification and characterization, early-stage technology innovation, assay validation, and improvements to diagnostic platforms. These programs are built around the expectation that funding decisions are made in a timely manner and reflect scientific merit as evaluated by independent experts. Replacing that standard with political appointee approval, without any required justification for overriding a peer-review panel, could have the unintended consequence of destabilizing the research enterprise, putting existing long-term projects like NIH All of Us at risk and squandering years of federal investment that builds on decades of work and new technologies. Altering the historically objective approach to scientific review also sidesteps traditional and transparent scientific metrics that could weaken the American public's confidence in the U.S. research enterprise.

Further, permitting political review without requiring public disclosure of the rationale for funding denials is inconsistent with OMB's stated objective of enhancing transparency. AMP believes that transparency in decision-making is fundamental to good governance, public accountability, and maintaining confidence in the integrity of the federal funding process.

For the research pipeline to successfully keep pace with clinical needs, funding decisions also must be timely. The additional layer of review by political appointees risks unnecessary delays in grant decisions and funding distribution. This year marks the second year in a row that the number of grants awarded by NIH has precipitously declined (17%), leaving researchers and clinicians with the challenge of keeping operations afloat while they wait for the dollars to be distributed. Further, granting this level of discretion to political appointees could undermine federal funding priorities and lead to grant implementation that is inconsistent with Congressional intent. Under its Article I authorities, Congress appropriates federal funds; the Executive Branch is to administer federal programs based on the laws passed by Congress. This proposed rule would both lock in threats of pocket rescission and further delay agency funding and grant opportunities.

[§200.218] Prohibition of Using Federal Awards to Promote or Support Theories of Disparate-impact Liability

AMP is concerned that the proposed language may create uncertainty regarding federally funded research involving population health, genetic variation, health outcomes, and demographic factors. Molecular diagnostics and precision medicine depend upon understanding biological diversity across patient populations. Policies that discourage or create ambiguity around such research could unintentionally limit the generation of evidence needed to develop and validate diagnostics and therapies that perform effectively across diverse patient populations.

This move could be harmful to enrollment in clinical trials needed to test and market new diagnostic tests and treatments. It is often challenging to recruit participants, particularly for studies involving small patient populations or focused on rare diseases. Ensuring that clinical trial populations reflect the diversity and heterogeneity of the disease or condition under study is critical to generating scientifically valid evidence and developing diagnostics and therapies that perform effectively across the intended patient population. This prohibition could make it more difficult to recruit and retain participants, limiting the representativeness of clinical trial populations and ultimately impeding scientific progress and innovation in precision medicine.

[200.220] Prohibition of Using Federal Funds for Covered Foreign Collaborations

The rule proposes to add a section creating a broad, and potentially ambiguous, prohibition from using federal funds to support collaborations, agreements, programs or other activities with “covered foreign countries or entities” that meet specific criteria. AMP appreciates the need to foster research here in the U.S. to protect American innovation and national security. However, the broad nature of this provision could disrupt productive, international partnerships that are important contributors to continued U.S. leadership in biomedical research and molecular diagnostics. Accelerating precision medicine, including oncology, and infectious disease tracking requires collaboration through global databases, AI-driven platforms, and clinical networks that extend beyond national borders. Extensive and highly structured international collaboration through standardization and training initiatives supported by the international groups such as the International Federation of Clinical Chemistry and

Laboratory Medicine (IFCC)[1] is paramount to ensuring patient access to biomarker testing, streamlining laboratory workflows, and standardizing genomic interpretation.

§200.340] Termination and Suspension

The proposed rule would significantly expand an agency's discretion to terminate federal awards for broadly defined reasons unrelated to legal or contractual deficiencies, such as noncompliance or other violations. Specifically, it would authorize agencies to terminate an award at any time to reconsider "whether a particular Federal award effectively serves the Federal Government's interest in carrying out public purposes or objectives authorized by law."

Broad discretionary termination authority may create uncertainty for institutions conducting long-term research programs and clinical studies, particularly where significant investments of time, infrastructure, and patient participation have already occurred. The premature termination of federally funded clinical trials could leave participants without access to investigational treatments, result in the loss of years of scientific progress, waste millions of dollars in federal investments, and delay the development of innovative molecular diagnostics and other medical advances on which patients and healthcare providers depend.

Federal agencies already possess the authority to terminate awards for cause, including instances of noncompliance or material violations of award terms. The proposed rule, however, would permit termination on far broader grounds while eliminating important procedural safeguards, including a recipient's ability to object to, request a hearing on, or otherwise appeal certain termination decisions. This increased uncertainty could have a chilling effect on researchers and institutions considering long-term, federally funded clinical trials and other high-risk, high-impact research, ultimately discouraging investment in projects that are essential to advancing medical innovation and improving patient outcomes.

AMP appreciates the opportunity to comment on the proposed revisions to the Uniform Guidance. While we support efforts to strengthen accountability and stewardship of federal resources, several provisions of the proposed rule may unintentionally undermine the biomedical research ecosystem that drives scientific discovery, clinical innovation, and improved patient outcomes.

AMP respectfully urges OMB to reconsider these provisions and engage stakeholders from the research, healthcare, patient advocacy, and scientific communities before finalizing the rule. A collaborative approach will better ensure that reforms to federal grant administration achieve their intended objectives while preserving the research infrastructure necessary to advance medicine and maintain U.S. scientific leadership.

Thank you for your consideration of these comments. Please contact Samantha Pettersen at spettersen@amp.org if AMP can provide additional information or serve as a resource as OMB evaluates stakeholder feedback.

Sincerely,

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President, Association for Molecular Pathology

[1] https://ifcc.org/ifcc-scientific-division/sd-committees/c-md/molecular-diagnostic-network-laboratories/