COUNCIL OF MEDICAL SPECIALTY SOCIETIES

July 12, 2026

Russell Vought
Director
Office of Management and Budget
Executive Office of the President
725 17th Street NW
Washington, DC 20503

Submitted electronically via regulations.gov

Re: Regulation for Federal Financial Assistance (OMB-2026-0034)

Dear Director Vought:

The Council of Medical Specialty Societies (CMSS) writes to share the concerns of the medical specialty community regarding the proposed Regulation for Federal Financial Assistance (OMB-2026-0034). CMSS is the collective voice of American medical specialty societies. CMSS includes 58 member societies that represent nearly 1 million physicians across medicine, including those who lead federally funded biomedical research, deliver newly discovered treatments, and teach the next generation of physicians and scientists.

As medical societies, we support OMB's stated goals of transparency, accountability, and reduced administrative burden. But several provisions in this proposal would work against those goals, including measures that would weaken scientific peer review, introduce uncertainty into multi-year research awards, and raise the cost of sharing new discoveries with other researchers and patients. This proposed rule would also weaken American innovation and could lead to American scientific talent leaving the country for better opportunities abroad. The true impact of this rule will be felt across the full breadth of medicine, not in any one specialty.

We are also concerned that the proposal opens the door to politicizing public health and scientific decision-making. Federal agencies already have the authority to reallocate resources as priorities shift. This rule allows arbitrary decisions about individual grants, outside existing programmatic oversight, that risk conflicting with congressional intent.

We request that OMB delay finalization of this rule and use the additional time to address the concerns below, which our member societies have identified as most consequential for biomedical research and, ultimately, for patient care.

Scientific merit review must remain the basis for funding decisions

Peer review has driven American leadership in biomedical research for decades. Study sections and council review place scientific judgment, not political judgment, at the center of funding decisions. The proposed changes to *§ 200.205* would make peer review recommendations advisory rather than determinative and would direct political appointees to weigh, rather than defer to, the conclusions of scientific reviewers. Our member societies believe this change would erode confidence in the review process, discourage talented investigators from applying for federal funding, and make it harder to recruit qualified peer reviewers.

This problem starts even before a proposal reaches review. *§ 200.202* would require federal programs to be designed to align with "current administration policies and priorities," a term the rule never defines. Research programs run for years and often outlast the administration that funded them. Tying program design to whatever priorities are in effect at a given moment means a program's goals and the standards used to judge it could shift mid-course. We ask OMB to withdraw this requirement and instead strengthen the evidence and performance measures agencies already use to evaluate whether a program is well-designed.

We are similarly concerned about the proposal's preference for spreading awards to a wider set of recipients rather than "a select group of repeat recipients." The most consequential findings in medicine, from long-running cohort studies to multi-decade research programs, come from sustained investment in investigators and institutions that have proven their work merits continued support. Diversifying who receives federal funding is a worthwhile goal, but it should not come at the cost of defunding successful, ongoing science. The training pipeline that produces new independent investigators runs through these established programs; disrupting them narrows opportunity rather than expands it.

The proposal also conditions funding on undefined "Gold Standard Science" benchmarks. We share the Administration's interest in reproducible, transparent, and rigorous research. But a standard applied across every federal agency and every field of medicine needs a clear, workable definition developed with input from the research community, not left to the discretion of individual reviewers. As written, the term invites inconsistent application and provides institutions with no reliable way to know what compliance requires.

International research collaboration needs a risk-based approach, not a blanket restriction

§ 200.220 would bar the use of federal funds for collaboration with covered foreign countries or entities unless a statute or an agency head expressly authorizes it, with no finding required that a specific collaboration involves sensitive technology, protected data, or any other identifiable security risk. Related provisions under *§ 200.202* would apply a similar domestic-first presumption to research and development program design.

Medicine does not stop at the border, and neither does the evidence base on which it depends. Results of rare disease studies often only reach statistical significance when patient populations are pooled across countries. Genomic discoveries, from the gene mutation linked to ALS to major Alzheimer's risk loci, have come from data-sharing among American, European, and other international consortia that no

single country's population could have produced alone. A blanket restriction, applied without regard for whether a given collaboration involves sensitive technology or data, would cut off this kind of work along with any genuine security risks.

We support safeguards for collaborations that involve identifiable risk. We ask that OMB avoid a categorical bar that treats all international collaboration as suspect, regardless of its content. A risk-based approach, one that targets sensitive information and controlled technology while preserving legitimate scientific partnerships, would protect national security without asking American researchers to sit out of the international collaborations their own fields depend on.

Termination authority needs clear standards and due process

Sections *§ 200.340* through *§ 200.343* would let agencies terminate awards when a project no longer serves "agency priorities" or the "national interest," undefined terms that could shift with each change in leadership, and would narrow existing rights to notice, hearing, and appeal. Medical research often takes years to produce results. Clinical trials enroll patients on the understanding that the study will be completed. Investigators build labs and hire staff on the strength of a multi-year award. Broad, loosely defined termination authority puts patients, trainees, and research infrastructure at risk, and it will make investigators more cautious about pursuing the ambitious, long-horizon research that produces the biggest gains for patients.

This is not a hypothetical risk. Between February and April 2025, NIH terminated 694 grants worth roughly $1.8 billion, cutting off 383 active clinical trials that had already enrolled more than 74,000 patients. Courts later found those terminations unlawful and ordered funding restored, but the reversal came too late for studies that had already stopped enrolling, lost staff, and left gaps in data that cannot be recovered. A broader, less defined termination authority makes a repeat of that outcome more likely, not less.

We also ask OMB to clarify that any final rule will not apply to competitive renewals or recompetes where peer review has already begun under the current framework. Changing the standard mid-cycle, after applicants and review panels have already invested time under the existing rules, is fundamentally unfair to everyone who followed the process in good faith and ultimately harms patients.

Fixed amount awards and subaward flexibility should be preserved

Fixed-amount awards and subawards let institutions focus on scientific performance rather than transaction-level accounting. They are especially important for training grants, fellowships, and multi-site clinical trial networks. Eliminating or narrowing them, as proposed under *§§ 200.201 and 200.333*, would shift administrative and financial risk onto research institutions, particularly smaller and community-based partners with the least capacity to absorb it. Similarly, expanded subrecipient oversight requirements under *§§ 200.331–200.332* should be scaled to actual risk. Reputational or subjective criteria are not a sound basis for oversight decisions that affect research collaborations across institutions.

Risk and eligibility criteria should stay tied to the award itself

§ 200.206 would allow agencies to weigh an applicant's membership in or affiliation with organizations engaged in disfavored activities when assessing risk. Physicians often join these organizations as their professional homes to access cutting-edge education, research, and publications. They do not join organizations for any single position statement, and it does not make sense to hold them responsible for conduct they had no part in, including conduct that occurred after they left the organization. This is not a fair way to assess risk. *§ 200.300* raises a related concern by extending eligibility restrictions to an institution's separately funded, non-federal activities. A federal award should be evaluated on how the federal funds are used, not on unrelated programs that a university or health system funds independently. Reaching into institutional activity that has no connection to the award turns a grant compliance rule into open-ended institutional oversight and creates uncertainty far beyond the research the award supports. We ask OMB to confine eligibility and risk review to the conduct and activities of the federal award itself.

§ 200.300 also directs agencies to ensure that federal funds do not support diversity, equity, and inclusion activities. In research, this limits researchers' ability to consider standard patient-level risk variables, such as rurality, insurance coverage, and access to care, that they rely on to understand why health outcomes differ across communities. These critical analyses often identify modifiable risks that drive population outcome gaps. Stripping these data from federally funded research would make studies across many fields of medicine less useful, not more objective. We ask OMB to ensure that this provision does not apply to standard research variables used to understand and address inconsistencies in access and outcomes.

Restricting publication and conference costs will slow the translation of research into patient care

Publishing results and presenting them at scientific meetings are critical steps in the clinical research process. They are how new findings get tested, replicated, and adopted into clinical practice. The proposed restrictions on publication costs under *§ 200.461* and on conference costs under *§ 200.432* would make it harder for investigators to meet existing public access requirements and would fall hardest on early-career researchers and trainees, who rely most heavily on grant support to attend meetings and publish their work. Requiring advance, itemized approval for conference attendance is also impractical: abstract acceptances and speaking invitations routinely arrive after an award is already underway.

Most of our specialty society members publish peer-reviewed medical journals. The OMB proposal misunderstands what a subscription or an article processing charge pays for. The grant revenue funds peer review administration, editorial oversight, integrity screening, statistical review, indexing, digital preservation, accessibility compliance, and cybersecurity, the infrastructure that makes a journal article trustworthy rather than just published. Restricting direct and indirect cost recovery under *§§ 200.413, 200.414, and 200.454*, alongside publication costs under *§ 200.461*, would press on both the subscription and the open-access sides of scholarly publishing at once. For nonprofit society publishers, that revenue is reinvested in physician education and patient care resources, so the effects of these cuts would not stop at the journal's masthead.

A related proposal under *§ 200.421* would make nearly all advertising and public relations costs unallowable. Communicating research findings to the public and the press is critical in ensuring federally funded discoveries reach the people they are meant to help. We ask OMB to preserve the allowability of costs that support public communication of research results.

Rather than eliminate these costs, we encourage OMB to consider a narrower fix: a standing exception to any prior-approval requirement for conferences, memberships, and subscriptions tied to a recognized medical specialty, research, or patient organization with an obvious connection to the funded work. That approach would preserve the accountability OMB seeks without requiring investigators to obtain case-by-case approval for routine, clearly relevant professional activity.

Centralizing the Uniform Guidance will reduce the flexibility research agencies need

Converting the Uniform Guidance from government-wide guidance into a binding, centrally administered regulation would limit NIH and other research agencies' ability to adapt their own policies to new scientific opportunities and emerging public health needs. Medical research does not move at the pace of centralized rulemaking. Agencies need the latitude to respond to their own scientific portfolios, and interagency research initiatives need agencies to retain enough flexibility to coordinate with one another.

The burden-reduction goal will not be met as the rule is currently written

OMB's aim of reducing recipient burden is one we support without reservation. But new documentation requirements, expanded oversight, broader termination authority, and undefined compliance standards will add administrative work, not remove it. Institutions will spend more time on legal review, compliance monitoring, and justification of routine research activities, not less. We encourage OMB to weigh each burden-reduction measure in the proposal against the new compliance obligations it introduces elsewhere in the same rule.

Conclusion

CMSS and our member societies want the same outcome OMB does: a federal research enterprise that is transparent, accountable, and efficient. We do not believe this rule, as proposed, will achieve these goals. We ask OMB to:

- Preserve scientific peer review, not political appointee review, as the primary and binding basis for research funding decisions;
- Withdraw the requirement that program design and award decisions align with undefined "administration policies and priorities," and clearly define any "Gold Standard Science" standard with stakeholder input from the research community before applying it;
- Restore clear, disclosed standards and meaningful notice, hearing, and appeal rights before any award is terminated, and apply any new standard prospectively rather than to pending applications and renewals already under review;
- Confine risk and eligibility review to the conduct and activities the federal award itself funds;

- Replace the blanket restriction on international collaboration with a risk-based standard tied to sensitive technology, controlled information, or protected data;
- Preserve fixed amount awards, subawards, and reasonable subrecipient oversight scaled to actual risk; and
- Retain conference, membership, publication, and public communication costs as allowable, reasonable expenses of disseminating federally funded research.

At a minimum, we seek continued engagement with OMB about these proposed changes and opportunities to achieve shared goals for the benefit of our members and their patients. We ask that you work with the research and medical communities to develop a final rule that protects scientific merit review, provides recipients with clear and stable standards, and preserves the flexibility that has made American biomedical research the world's strongest for generations.

Thank you for the opportunity to comment. We welcome the chance to discuss these concerns further and to serve as a resource as OMB considers next steps. Please contact me directly with any questions at hburstin@cmss.org.

Respectfully submitted,

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