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July 10, 2026

RE: OMB-2026-0034

The Honorable Russ Vought
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Regulation for Federal Financial Assistance, 91 FR 32198

The Society for Academic Emergency Medicine (SAEM) appreciates the opportunity to comment on the Office of Management and Budget's (OMB) proposed revisions to regulations governing federal financial assistance.

SAEM represents over 11,000 emergency physicians, researchers, educators, and trainees dedicated to advancing the science and practice of emergency care in the United States. Emergency departments (ED) are a pillar of the U.S. health care system, accounting for over 155 million visits per year, or one visit for every 2 Americans. Our members lead federally funded research that improves medical outcomes for patients with acute illness and injury, strengthens disaster preparedness, advances public health, and improves the efficiency and effectiveness of care provided in this country.

Our members are deeply concerned that several provisions of the proposed revisions could unintentionally undermine the United States' current global leadership in biomedical research and innovation. We respectfully urge OMB to revise the proposal to better preserve scientific independence, protect research participants, and avoid disruptions to federally funded research directly benefiting our patients and communities. In that regard, we make the following recommendations:

[200.205 – Federal Agency Review of Merit of Proposals]

SAEM shares OMB's belief that federal awards should be merit-based and produce real results that advance science and improve the lives of our citizens. We urge OMB to preserve independent peer review by qualified experts as the basis for evaluating the scientific and technical merit of research proposals.

Independent peer review is a cornerstone of American scientific preeminence. In emergency care, peer-reviewed federal research has driven major advances in modern practice, including in trauma systems, stroke care, cardiac arrest resuscitation, sepsis management, overdose treatment, disaster preparedness,

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and emergency care delivery. This progress resulted from federal dollars directed to the strongest proposals on the basis of their scientific merits, the same process that sustains US leadership in biomedical science and most reliably secures the rigor and reproducibility that the proposed rule rightly seeks.

The evaluation of scientific and technical quality requires relevant scientific, clinical, and methodological expertise and should remain free from shifting political biases. As drafted, § 200.205 threatens that independence by adding a pre-issuance review by senior appointees to evaluate compliance with policy priorities. Federal agencies currently set research priorities, establish guidelines, and ensure that awards comply with law. These additional appointee reviews will add costs and delays, reduce transparency in grant decisions, and work against the administration's stated goal of rigorous, reproducible science and a strong return for the taxpayer. Adding these reviews conflicts with the administration's Executive Order 14303 defining "Gold Standard Science" to include science "subject to unbiased peer review" and directs that, "reproducibility, rigor, and unbiased peer review must be maintained."

We urge OMB to:

1. Preserve independent peer review by qualified experts as the primary basis for determining the scientific and technical merit of research proposals;
2. Keep any review for legal compliance or agency priorities separate from, and not a substitute for, the scientific-merit determination; and
3. Advance the rule's rigor and reproducibility goals by strengthening expert review, not by reducing it to an advisory role.

[200.206—Federal Agency Review of Risk Posed by Applicants]

SAEM agrees that agencies should confirm that an applicant can competently complete the work before federal funds are committed to a research proposal. The existing factors for this, financial stability, management systems, past performance, and audit findings, are sound measures of that ability, and we support them as currently applied. However, several newly proposed factors would undermine the rule's impact.

Penalizing an applicant for "non-replicable studies" punishes the ordinary trial and error of legitimate science. Non-replication is how science self-corrects, and no investigator should face a funding penalty for honestly and ethically conducting and reporting a study that a subsequent effort did not reproduce. This revision directly contradicts the administration's own Executive Order 14303, which defines "Gold Standard Science" as "structured for falsifiability of hypotheses" and "accepting of negative results as positive outcomes." Without clarification, this factor would discourage precisely the high-impact research the rule seeks to promote.

Other proposed new factors lack sufficient clarity and may create uncertainty about applicants' disqualifying characteristics. Activities "inconsistent with" civil-rights or religious-liberty laws, and affiliations that "undermine public safety or national security," are not adequately defined in the proposed revisions. Prospective investigators will be unable to determine which contacts or associations might render them ineligible for awards. This ambiguity in the existing language undermines OMB's own commitment to provide recipients with clear and straightforward notice of the terms governing their awards. And because these factors also drive the conditions imposed

under § 200.208 and subrecipient oversight, the uncertainty spreads well beyond the initial application.

We urge OMB to:

1. Retain the existing financial, management, performance, and audit factors, and confirm that this provision does not authorize additional audits, progress reports, or other new administrative burdens;
2. Remove "non-replicable studies," and limit any integrity factor to formally adjudicated research misconduct, namely fabrication, falsification, or plagiarism, consistent with Executive Order 14303; and
3. Remove the civil-rights, religious-liberty, and affiliation factors, or require an actual legal finding of a violation rather than the "publicly available" information standard the proposal allows.

[200.340 —Termination and Suspension]

SAEM recognizes the government's responsibility to steward taxpayer resources and ensure that federal awards continue to serve their authorized purposes. We write to address a specific gap: as proposed, § 200.340 adapts contract-style termination and stop-work tools to federal awards without accounting for the ethical obligations that attach to research involving human subjects.

Emergency medicine researchers frequently conduct clinical trials involving critically ill or injured patients, including studies performed under emergency research regulations and Exception From Informed Consent (EFIC) provisions. The abrupt termination of funding may place enrolled participants at risk, disrupt follow-up, compromise data integrity, and waste public resources already invested in the research. The harm is not limited to clinical trials. Interrupting a longitudinal surveillance, cohort, or epidemiologic study creates a permanent gap in prospectively collected data that cannot be reconstructed, degrading the disease surveillance communities and agencies rely on to detect outbreaks and allocate resources. Furthermore, abrupt termination without cause violates the ethical principles underpinning the informed consent of enrolled subjects.

In addition, the proposed rule grants broad authority to suspend or terminate awards based on standards that may be difficult for grant recipients to interpret consistently. Such uncertainty may discourage investigators from pursuing innovative or high-impact research and could jeopardize ongoing studies that have already received scientific review and federal approval. When ongoing studies are terminated before completion, this not only devalues the contribution of patients and subjects, but it also could place patients at risk of harm of not completing therapies.

We urge OMB to:

1. Provide that, for awards involving enrolled human participants, any discretionary termination or temporary suspension takes effect only after a defined wind-down period sufficient to ensure participant safety, complete protocol-required follow-up, and preserve research data;
2. Guarantee funding for the orderly closeout of human-subjects research, including required safety monitoring, follow-up, and data preservation, rather than leaving these costs to

- case-by-case agency discretion, consistent with the FAR's allowance for reasonable termination expenses; and
3. Require, before any stop-work order applies to an active clinical trial, notification of the responsible Institutional Review Board and a participant-safety plan addressing continuity of care for enrolled patients.

[200.218—Prohibition of Using Federal Awards To Promote or Support Theories of Disparate-Impact Liability]

Emergency departments, under the Emergency Medical Treatment and Labor Act (EMTALA), serve all Americans regardless of ability to pay and frequently care for populations disproportionately affected by injury, illness, substance use disorders, mental health conditions, and barriers to healthcare access. We support the administration's efforts to defend civil rights laws and prohibit discrimination in federally funded research. However, the proposed revision risks limiting important scientific inquiry by conflating the identification of differences in outcomes with the presumption of discriminatory practices in research studies.

Evaluating how diseases, treatments, technologies, and health systems affect different populations is critical to improving care for all patients and all Americans, as identifying variation allows researchers and clinicians to develop interventions that are more effective and broadly applicable. The presence of restrictions on the use of terminology related to studying disparate impacts in various populations may inadvertently discourage investigators from conducting appropriate research in certain groups, even if in compliance with federal research priorities. Such limitations could impede discovery, obscure meaningful differences in health outcomes, and ultimately undermine efforts to improve care across the entire population.

For example, one key difference to study is in how Medicare beneficiaries utilize the emergency department compared to the general population. Medicare beneficiaries account for the vast majority of Americans aged 65 and older. Given their advanced age on average relative to the U.S. population, they are more likely to visit the ED, incur higher health expenditures per visit, more likely to be admitted to the hospital, and more likely to be repeat visitors.¹ The uncertainty posed by this proposed rule could have a chilling effect on research to improve the cost and quality of care delivery for the Medicare population.

Another example is the different ways urban and rural populations utilize the emergency department.² Rural patients are more likely to utilize the emergency department for primary care services than their urban counterparts, indicating challenges to accessing primary care and increasingly fragmented care. Studying the different access and utilization challenges between rural and urban emergency departments is needed to improve value-based care delivery and

¹ P. Magidson, J. Huang, A. Chanmugam, O. Sheehan, D. Roth, 168 Repeat Emergency Department Visits in Medicare Beneficiaries: Important Patient Characteristics, *Annals of Emergency Medicine*, Volume 72, Issue 4, Supplement, 2018,

² Greenwood-Ericksen MB, Kocher K. Trends in Emergency Department Use by Rural and Urban Populations in the United States. *JAMA Netw Open*. 2019 Apr 5;2(4):e191919. doi: 10.1001/jamanetworkopen.2019.1919. PMID: 30977849; PMCID: PMC6481434.

quality in rural areas. Beyond the research impacts, we are concerned that the proposed rule may have substantial negative impacts on rural access to care, specifically the implementation of the Rural Health Transformation Fund (RHTF). Changes to the Uniform Guidance will have widespread effects. We are concerned about the state's ability to spend funding in previously approved ways through the RHTF. With states facing strict new political compliance rules, new unallowable cost classifications, and heightened risks of sudden award termination, this could make it more challenging for states to improve the rural healthcare workforce or invest in long-term transformations, due to uncertainty around future funding.

We urge OMB to:

1. Explicitly clarify that lawful research examining patient outcomes, healthcare delivery, health services, implementation strategies, and algorithmic performance remains fully permissible and eligible for federal support.
2. Explicitly clarify that the Rural Health Transformation Fund is not subject to new compliance requirements and at risk of sudden termination.

[200.300—Statutory and National Policy Requirements]

Emergency medicine was founded as a specialty in the United States in 1979, and the world has looked to US training programs as a model ever since. That leadership is built upon rigorous, evidence-based training and a strong record of scientific productivity. SAEM supports compliance with federal nondiscrimination law. However, we are concerned that §200.300's broad and undefined terms could leave educators and investigators uncertain about what is permitted, deterring lawful, evidence-based work and eroding that standing without advancing any clear federal priority.

We are concerned that the proposed language in §200.300(b) is sufficiently broad that it may create uncertainty for educators, investigators, trainees, and institutions about what activities remain permissible. Terms such as “promote,” “encourage,” “subsidize,” and “facilitate” are not defined, and the absence of clear implementation guidance could deter lawful, evidence-based work that is central to improving emergency care.

Emergency medicine research and education routinely examine differences in access, treatment, diagnostic accuracy, communication, patient safety, and outcomes across diverse patient populations. Such work is necessary to identify preventable gaps in care, improve clinical decision-making, train physicians to provide appropriate care in high-acuity settings, and ensure that emergency departments remain prepared to serve every patient who seeks help. Ambiguous restrictions may discourage investigators from asking clinically important questions or deter educators from teaching evidence-based approaches to caring for patients with different clinical, social, and demographic characteristics, even when those activities fully comply with federal law and agency requirements.

We urge the OMB to:

1. Provide clear definitions and implementation guidance to ensure that the rule does not prohibit lawful, evidence-based medical education, clinical research, quality improvement, workforce training, or patient-care activities designed to improve outcomes, reduce preventable harm, and ensure appropriate emergency care for all patients.

[200.432—Conferences]

The proposed revision imposes an unnecessary administrative burden by requiring grantees to secure prior approval for conference attendance, potentially many years in advance. This requirement fails to account for the evolving nature of scientific discovery and shifting professional priorities. Furthermore, it may inadvertently penalize researchers for participating in relevant forums that were not explicitly identified at the time of the original award, even when such attendance directly advances the granted project's objectives and the priorities of the funding agency.

We urge OMB to:

1. Adopt a more flexible approach that permits reasonable conference-related expenses during the grant period, provided that there is appropriate documentation of relevance to project goals.

[200.461—Publication and Printing Costs]

We agree that the escalating costs of scientific publication and open access charges warrant strategic attention from federal agencies. However, the proposed revisions will shift this burden onto individual investigators, rather than addressing the underlying structural dynamics of the publishing industry. In response to previous NIH notice NOT-OD-25-138, our groups discussed how limiting the use of award funds for publication costs threatens to impede the timely communication of vital discoveries and restricts public access to the outcomes of federally supported science.

We urge OMB to:

1. Pursue cost-containment strategies that leverage the enormous scientific influence of the NIH to target sustainable agreements with publishers directly;
2. Consider investment in centralized open knowledge repositories outside of the traditional for-profit commercial publishing system.

Conclusion

Every single day in the US nearly a half a million Americans seek essential care in an Emergency Department. Emergency physicians are the front line of the nation's safety net, caring for every patient who comes through the door, at any hour, regardless of their ability to pay. The research efforts and medical education improving that care depend on the very features that this rule would disrupt: independent peer review, scientific independence, and stable funding. While SAEM shares OMB's commitment to prioritize merit, scientific rigor, and responsible stewardship of resources, we urge OMB to consider adopting the changes above to ensure that the final rule ultimately strengthens emergency medical care and disaster preparedness for the American people.