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July 7, 2026

Russel Vought

Director

Office of Management and Budget

Eisenhower Executive Office Building, Room 252

725 17th Street, NW

Washington, DC 20503

Re: Proposed Rule on Regulation for Federal Financial Assistance (RIN 0991-AC35)

Docket ID: OMB-2026-0034

Dear Director Vought,

The American Psychiatric Association (APA), the national medical specialty society representing over 40,000 psychiatric physicians and their patients, appreciates the opportunity to comment on the Office of Management and Budget's (OMB) notice of proposed rulemaking on the Regulation for Federal Financial Assistance. APA is extremely concerned that the proposed revisions to 2 CFR 91 Fed. Reg 32198 politicizes science and public health by taking away the funding and award decisions from the scientific experts. **Because of the enormous impact on the mental health and substance use community, we strongly urge you to withdraw this proposed rule.** While our withdrawal request is for the entire proposed rule, we are providing additional comments on specific sections of the proposed revised guidance.

Section 200.205 Federal Agency Review of Merit of Proposals

APA supports rigorous, transparent, and accountable merit review for federal grants and contracts. Scientific merit must be evaluated through clinically relevant, methodologically sound, and viewpoint-neutral standards. The proposed rule's requirement that political appointees or designees conduct additional pre-issuance review would cause unnecessary administrative delays and create a risk that funding decisions will be influenced by factors other than scientific merit, patient need, scalable health impact, and the capacity of applicants to deliver evidence-based services or research. Federal support for all research, including mental health and substance use disorder programs, must be guided by statutory objectives, peer review, and potential impact on the field, not by subjective or shifting priorities.

APA is opposed to the Administration's proposal on "gold standard science" as it is currently drafted. The proposed rule has yet to define what is meant by "gold standard science" and leaving it without meaning or how it would be operationalized

could lead to different standards across agencies. In medicine, the strongest evidence usually includes randomized controlled trials, systematic reviews, validated clinical guidelines, reproducible methods, transparent data practices, and peer-reviewed research. But psychiatry, like other medical fields, requires study designs that reflect real-world clinical care, including longitudinal studies, health services research, community-based research, qualitative research, and mixed-methods approaches. Many urgent questions in mental health cannot be answered through randomized trials alone. Furthermore, as research advances, newer methods and technologies will become available, and previous “gold standards” will become outmoded. A rigid or undefined “gold standard” may unintentionally exclude newer methods and high-quality evidence that is clinically meaningful, ethically necessary, and essential to serving patients in real-world settings.

APA also opposes the proposal to give preference to institutions with low indirect costs. Indirect costs are calculated based on an institution’s expenses to support the infrastructure necessary to conduct responsible research and deliver safe, accountable programs. This includes regulatory compliance for human-subjects protections, academic library internet infrastructure, research administration, clinical trial compliance, HIPAA/privacy and data security, research integrity and conflict-of-interest systems, grants management and audit infrastructure, data and safety monitoring board/safety-monitoring support, secure computing and data storage, clinical research infrastructure, procurement and subaward oversight, and training in responsible conduct of research. Similarly, deprioritizing institutional prestige should not mean discounting years of demonstrated expertise, research capacity, clinical experience, or a strong record of responsible stewardship. Prestigious institutions or those with high indirect costs may have research facilities or technologies that are not available at other institutions. The goal should be to broaden opportunities while preserving standards that ensure scientific integrity, patient safety, and effective use of federal funds.

We urge the administration to withdraw this proposal and refer to the nine tenets of rigorous criteria to ensure that federally-funded research is: 1) transparent, 2) reproducible, 3) communicative of error and uncertainty, 4) collaborative and interdisciplinary, 5) skeptical of its findings and assumptions, 6) structured for falsifiability of hypotheses, 7) subject to peer review, 8) accepting of negative results as positive outcomes, and 9) without conflicts of interest. Additionally, any definition of gold standard science must be applied methodologically, not ideologically. This is particularly important in an area of knowledge in which the integration of biological, behavioral, and social determinants of health and disease are particularly important.

Merit-based award selection grounded in objective statutory, scientific, and technical criteria is necessary to protect research rather than imposing a presidential-alignment mandate and/or broad ideological and subject-matter restrictions. Merit review of research proposals must be based on written and objective criteria, relevant clinical and scientific expertise, transparent scoring, peer review or comparable expert review, methodological rigor appropriate to the question being studied, protection of research participants and patients, and the likelihood that the award will improve health, safety, access, quality, or outcomes.

Section 200.208 Specific Conditions

APA recognizes that federal agencies need appropriate tools to ensure that recipients comply with award requirements, maintain financial accountability, and achieve program objectives. In the psychiatric research and behavioral health care context, however, the proposed expansion of agency authority to add or adjust specific award conditions raises significant concerns if those conditions are imposed without clear and objective standards, timely notice, and an opportunity for recipients to respond. Psychiatric researchers, academic hospitals, and community health centers operate in highly regulated environments and often use federal awards to support clinical research, workforce training, integrated care, crisis services, substance use disorder treatment, and services for individuals with serious mental illness. Additional conditions that are vague, inconsistent across agencies, or imposed late in the award process could add additional compliance burdens, increase costs, disrupt patient-facing programs, delay research activities, and reduce access to care in communities already facing behavioral health workforce shortages.

For academic hospitals and research institutions, a recipient's "ability to meet goals" or "financial capacity" should be assessed in a manner that reflects the realities of clinical research and health services delivery. Mental health research often depends on multi-site recruitment, longitudinal follow-up, community partnerships, institutional review board oversight, data safety monitoring, and protections for patients and research participants. Delays or deviations may arise due to appropriate ethical safeguards, recruitment challenges among underserved populations, or changes in clinical practice—not from poor performance or mismanagement. If agencies use these situations to impose additional conditions without considering the clinical and scientific context, recipients may be discouraged from undertaking complex but necessary research.

Community health centers and other safety-net behavioral health providers may be especially affected by overly broad or discretionary use of specific conditions. These providers frequently serve patients with high acuity needs, limited insurance coverage, housing instability, co-occurring substance use disorders, and barriers to specialty psychiatric care. They may also have smaller administrative teams and fewer unrestricted resources than large institutions. Additional reporting, prior approval, documentation, or financial conditions could divert scarce clinical and administrative capacity away from patient care unless such conditions are narrowly tailored to a documented risk and scaled to the recipient's size, resources, and patient population.

APA recommends that OMB withdraw this proposed change or, at minimum, revise Section 200.208 to require that any specific conditions be based on documented, objective, and award-related findings; be proportionate to the identified risk; be communicated in writing with sufficient explanation; and include a reasonable opportunity for the recipient to respond, cure deficiencies, or seek reconsideration.

Section 200.218 Prohibition of Using Federal Awards to Promote or Support Theories of Disparate-Impact Liability

APA is concerned that section 200.218 is overly broad and could discourage lawful, evidence-based work to identify and address inequities in mental health access, quality, and outcomes. Psychiatry routinely

relies on population-level data to understand whether policies, coverage rules, workforce shortages, utilization management practices, or program design have differential effects on patients and communities. Such analyses are essential to improving care, reducing suicide and overdose risk, addressing maternal mental health needs, strengthening services for older adults, and ensuring that federal programs reach people with serious mental illness and substance use disorders.

As written, the language could be read to restrict grant-supported research, training programs, technical assistance, quality improvement, and program evaluation that examine disparities by race, sex, or age, even when the purpose is to improve access to clinically appropriate care. This uncertainty may deter recipients from collecting or analyzing demographic data, evaluating whether interventions are equitably effective, or tailoring services to populations with documented unmet behavioral health needs.

Section 200.340 Termination and Suspension

The proposed language will give federal agencies sweeping authority to terminate lawful, competitively awarded grants based on shifting agency priorities or an undefined assessment of the “national interest” at the time of termination. For psychiatric research, academic medical centers, teaching hospitals, community mental health providers, and substance use disorder programs, this standard is far too broad and uncertain. Federal awards are not merely administrative instruments; they support ongoing patient care, clinical trials, workforce training, data collection, quality improvement, and community-based services for individuals with serious mental illness, substance use disorders, suicidal ideation, and other urgent behavioral health needs.

Allowing agencies to terminate awards because priorities have changed after an award has been made would create instability across the behavioral health system. Recipients make long-term commitments when they receive federal awards: they hire clinicians and research staff, enroll patients and participants, enter subrecipient agreements, establish community partnerships, invest in data systems, and build service delivery models. Abrupt termination could interrupt patient treatment, compromise continuity of care, undermine participant protections, strand trainees, and leave community partners without the resources needed to serve patients. These risks are especially acute in psychiatry, where trust, continuity, and sustained engagement are often essential to effective care and research participation.

The proposed standard also undermines fairness, transparency, and scientific integrity. A recipient that complies with the terms and conditions of an award should not face termination simply because a later policy preference differs from the priorities in place when the award was competed, reviewed, and issued. Psychiatric research and mental health services must be guided by statutory objectives, clinical need, patient safety, scientific merit, and measurable outcomes, and not by retroactive and subjective determinations.

APA strongly recommends that OMB withdraw the proposed revision to Section 200.340 in its entirety. However, at minimum, any termination authority should be limited to material noncompliance with award terms, lack of statutory authority, mutual agreement, or other clearly defined and legally grounded circumstances and not based on shifting agency priorities or national interest.

Section 200.432 Conferences

Conference travel is essential to disseminating scientific findings, yet this proposed rule would add the requirement that costs for attending conferences are only allowable if approved by the agency and included in the terms and conditions of the award. Dates and locations of conferences are not published years in advance, and new conferences arise regularly that are impossible to predict but critical to attend to maximize the potential of the research investment. Invitations to specific conferences are also unpredictable, and as research projects develop, different conferences may be most appropriate.

Universities often already have stringent travel approval requirements that determine whether the proposed travel is consistent with the grant funding and enforce rules about travel expenses. Having this process controlled by political appointees would prevent networking among researchers that often leads to highly productive collaborations, harm graduate students, especially underrepresented and low-income students, by preventing them from sharing their research, and hurt medical societies like APA, which hold the conferences and use these venues to train students, educate the public, and build a stronger scientific community.

Existing OMB rules already require travel to be reasonable, necessary, documented, and award related. The proposed changes will only curtail the sharing of new discoveries and conflicts with the policy framework that acknowledges dissemination as a fundamental requirement of federally funded research.

Section 200.454 Memberships, Subscriptions, and Professional Activity Costs

The current OMB proposal will make the costs of subscriptions to APA's journals unallowable. These subscriptions allow funded organizations to stay on top of current research that continues to support the requirements of their grants to acquire and maintain the federally required levels of certification in support of high standards in the delivery of care.

Subscriptions also support publishing activities and provide the infrastructure for APA's ability to deliver rigorously reviewed research. These proposed limitations may weaken the scholarly publishing infrastructure that enables the evaluation, dissemination, preservation, and long-term accessibility of federally funded research.

Section 200.461 Publication and Printing Costs

Scientific publishing at APA continues to be critical to advancing the objectives of federally funded research, and publication and printing costs are essential components of the research system. A fundamental requirement of federal funding is that grant recipients disseminate the results of that research, aiming for the broadest possible reach. The proposal to disallow publication costs is inconsistent with this goal and impedes scientific progress and knowledge sharing. As a not-for-profit medical society publisher, APA differs from most commercial publishing organizations. Revenue generated through subscriptions, licensing, advertising, and publishing activities is reinvested directly into our mission of advancing mental health and delivering high-quality care to improve patients' lives. These funds support physician education, evidence-based clinical practice guidelines, public health initiatives, and resources that improve patient care. Policies that diminish the financial sustainability of scholarly publishing may

therefore have downstream consequences extending beyond journals themselves, affecting the educational and professional resources relied upon by psychiatrists, primary care, other mental health professionals, and health care systems nationwide.

Publishing is a complex ecosystem in which subscription and open-access models coexist and are supported through much-needed government funding. Policies that reduce funding flexibility may create unintended financial pressures on publishers, scholarly societies, academic institutions, and researchers, potentially reducing the capacity to maintain rigorous editorial standards, invest in technological innovation, support accessibility initiatives, and ensure the long-term preservation of the scientific record. Restrictions on the use of grant funds for article processing charges could limit publication opportunities for researchers and reduce the sustainability of high-quality open-access journals.

In conclusion, APA appreciates the opportunity to provide comments on the proposed regulation for federal financial assistance. While we support OMB's goals of improving transparency and accountability, we do not believe that the proposed changes will ensure that those goals are met. **APA respectfully urges OMB to withdraw this proposed rule and we encourage the Administration to engage medical societies and other relevant stakeholders to ensure that future changes support evidence-based research, innovation, and effective service delivery for individuals with mental health and substance use disorders.** Please contact Kristin Kroeger, Vice President, Advocacy, Policy, and Practice Advancement kkroeger@psych.org with any questions.

Sincerely,



MD, MBA, FAPA

Marketa Wills, MD, MBA, FAPA
CEO and Medical Director
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