AcademyHealth

July 6, 2026

Russell Vought
White House Office of Management and Budget
725 17th St., NW
Washington, DC 20503

RE: Proposed Regulation for Federal Financial Assistance, Docket Number OMB-2026-0034

Dear Director Vought:

As the professional home for health services and system researchers, AcademyHealth is pleased to offer input to guide the reconsideration of the proposed rule on regulation for federal financial assistance, published May 29, 2026. This proposed rule would recast 2 CFR from a statement of "Uniform Guidance" to a binding "Uniform Grants Regulation", alongside numerous mandatory changes in how grantmaking procedures and grantee actions are governed.

AcademyHealth believes the proposed rule raises substantial concerns regarding research independence, grant administration, scientific dissemination, and the long-term effectiveness of federal research investments. We call on the Office of Management and Budget to rescind the proposal.

In short, this proposed rule would severely degrade the ability of the United States of America to support health and scientific innovation at any meaningful level and would destabilize research organizations and entities that taxpayers have supported and invested in for decades. Such research has driven billions of dollars in economic output, improved American health care, and established America as the world leader in innovation. This rule would corrupt every stage of the research enterprise: whom and what gets funded, what methods are permissible, whom researchers can work with, and how findings get disseminated. This proposed rule would subject researchers to coercion and censorship. Moreover, the rule does not adequately consider the significant consequences these radical changes could have not only on the research itself, but also on the downstream implications for policy, care delivery, and health outcomes broadly. It is arbitrary, capricious, and an abuse of administrative discretion that puts vague and shifting political review and censorship throughout the grantmaking and administrative processes. The Administrative Procedures Act (APA) would direct the courts to find such agency action unlawful under 5 U.S. Code § 706(2). The proposed rule should be rejected in its entirety and immediately withdrawn.

The explicit objectives for this rule include "improving transparency, accountability, and oversight for use of Federal funds" and "reducing recipient burden". These are goals that we could support, however the rule fundamentally fails on both accounts. The federal research enterprise was built on three core tenets: public money, publicly accountable methods, and publicly available findings. This rule breaks each leg of that bargain.

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It makes the criteria for public money opaque and subject to political interference that could compromise the integrity of the research and its outcomes. A new pre-issuance review process requires senior political appointees to confirm that every discretionary grant is consistent with the President's policy priorities before it is awarded. This is not some expansion of existing agency discretion. It codifies and authorizes political appointees to subject research proposals to unconstrained review and potentially arbitrary decisions that are not based on published standards and without appeal opportunities. Peer review – a cornerstone to robust and reliable research valued worldwide – is explicitly reduced to an advisory function. The rule states plainly that the results of rigorous peer review "does not replace agency discretion", stating that it can be ignored or rejected. Under current practice, scientific merit is presumptively sufficient absent a specific reason to override it. Under this rule, political alignment is an affirmative threshold every award must clear. This insertion of politics into the core of every funding decision means that researchers would be compelled to conform project proposals to the vague requirements set by political appointees that may or may not appease them. Because political appointees are subject to change at any moment, researchers will be forced to constantly conform their projects to ever-shifting political priorities—and face the loss of years of work if they cannot do so.

It constrains the methods through which accountability is established. The rule embeds compliance standards defined by executive order rather than statute, including "Gold Standard Science," "gender ideology," and unlawful DEI activity. Because executive order definitions can be revised without rulemaking or public comment, the grant conditions imposed by the rule effectively track political priorities in real time. Recipients cannot plan compliance against a standard that moves without notice. There is no adjudication process before adverse action is taken and no recourse afterwards. There is no meaningful right of appeal when an award is terminated for political rather than performance reasons. The government can define the rules, change the rules, and penalize you for purportedly violating them without opportunity to be heard. This arrangement is facially invalid because it violates procedural and constitutional due process rights. See *Mathews v Eldridge* 424 U.S. 319 (1976).

The proposed rule makes the dissemination of publicly funded findings administratively and financially untenable. Article processing charges and open access fees are broadly unallowable, a direct conflict with NIH's own public access mandate, which simultaneously requires public dissemination of federally funded findings while this rule prohibits paying for it. Conference attendance requires advance agency approval baked into original award terms, meaning researchers cannot present findings at venues that become relevant after a grant is issued. Professional memberships require prior written approval; journal subscriptions are categorically unallowable. Together, these provisions restrict all three legs of the infrastructure through which federally funded science becomes useful: access to literature, participation in professional communities, and dissemination of findings.

Additionally, this proposed rule would chill free speech by injecting arbitrary and capricious coercion onto organizations that host convenings, contrary to the constitutional rights of freedom of speech and association. A federal agency could punish organizations with whom it disagrees politically by threatening to withhold federal grant money from grantees who associate with the organization. The arbitrary nature of the vague political demands can lead to a chilling effect

among scientific and health entities, which is in itself a coercive act that causes duress and pressures individuals and organizations to act contrary to their will and priorities. There is a rich history of the Supreme Court rejecting just this form of coercion in blocking funding for organizations that do not align with political priorities under the First Amendment, such as Rosenberger v. Rector and Visitors of the University of Virginia, 515 U.S. 819 (1995) and Legal Services Corp. v. Velazquez, 531 U.S. 533 (2001). This rule would also run afoul of the First Amendment's protections against compelled speech and association.

The American scientific enterprise has in large part been successful because of the norms, regulations, and statutes governing the grantmaking process, which has allowed for scientists to ask the questions they need to ask, use the methods they need to use, freely exchange the ideas that they have, and have the stability to invest in research. This proposed rule could materially disrupt long-standing practices that support scientific inquiry and evidence generation.

The loss of innovation and harm to both the research community and citizens is not a theoretical concept. Examples of recent federal research investments that would likely have been unfunded or subject to inappropriate and political constraints reducing their benefit to the taxpayer and patients include:

- **All of Us Research Program.** This NIH program innovates beyond "one size fits all" health care by building a diverse database that can inform thousands of studies on a variety of health conditions, identify what treatments work or do not for patients of different backgrounds, improves use of technology to improve health, and developing the cutting edge of precision medicine. Key successes of this program include: developing AI tools for speeding up the search for medication to treat Alzheimer's disease; using AI to predict strokes, including in ways that help across diverse racial groups; identifying post-operative pain management tools that reduce the risk of chronic opioid use; and identifying variations in patient DNA that affects how chemotherapy works for patients. All of Us is built to study how treatments differ across patient backgrounds. That design depends on collecting and analyzing demographic data and applying the results to improve care across groups, which is precisely the activity § 200.218 restricts when it permits demographic analysis only if the results are not applied to any activity under the award. The program's central scientific purpose and the rule's central prohibition are the same activity. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

- **Black Youth Suicide Prevention.** Throughout the federal government, grants support efforts to address the growing rate of suicide deaths among Black youth and young adults. The Substance Abuse and Mental Health Services Administration (SAMHSA) supports the Black Youth Suicide Prevention Initiative (BYSPI), which has developed cross-cutting initiatives to improve efficiency in federal agencies, identify and promote best practices, and collect and publish data for researchers and policymakers. The National Institute of Mental Health (NIMH) has funded studies to understand the epidemiology and precipitating circumstances of suicide by sex and age group in Black youth. Federal research into rising suicide rates among Black youth requires the

disaggregation by race and age that § 200.218 would prohibit a grantee from applying to prevention efforts under an award. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

- **Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative.** This NIH initiative was launched in response to high rates of pregnancy-related complications and deaths in the U.S. This initiative includes an emphasis on populations that are disproportionately affected. This led to the creation of 12 research centers and an implementation science hub which are developing innovative approaches to improve maternal health outcomes and patient safety, standardize data collection, and supporting AI and machine learning in service of maternal health. Because IMPROVE was designed around the populations most affected by maternal mortality, its core framing is the kind of equity-driven priority-setting § 200.300(b) would prohibit a federal award from supporting. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

- **Patient Safety Research**. The Agency for Healthcare Research and Quality (AHRQ) is the leading federal agency that invests in research and implementation grant projects to advance patient safety. AHRQ-funded research focuses on improving patient safety with a strong emphasis on addressing the needs of diverse, vulnerable populations. From 2000 to 2024, AHRQ funded 137 patient safety projects related to medication safety alone. AHRQ analysis on sepsis found that in 2021, more than 2 million Americans were hospitalized with sepsis, 300,000 lives were lost, and hospital costs exceeded $52 billion, accounting for 14 percent of all hospital costs. This research helped health systems identify causes and disproportionate cases among non-white patients, which in turn reduced overall risk of sepsis, the kind of finding § 200.218 would prevent researchers from applying to interventions under a federal award. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

- **EvidenceNOW Initiative**. AHRQ EvidenceNOW Model is an initiative providing external support for primary care practices to improve the delivery of care for patients. As part of the EvidenceNOW: Managing Unhealthy Alcohol Use initiative, AHRQ awarded 3-year grants to six institutions to support the dissemination and implementation of evidence-based practices for screening and treatment of unhealthy alcohol use in roughly 750 primary care practices that serve diverse communities of patients. Another significant initiative, EvidenceNOW: Building State Capacity, awarded funding to Alabama, Ohio, Michigan, and Tennessee to establish state-level cooperatives that will help address disparities and advance equity in heart health. Tennessee Heart Health Network (THHN) implemented a wide range of interventions targeting blood pressure control and tobacco cessation, with the goal of reducing disparities in cardiovascular disease outcomes. Additionally, AHRQ awarded grants to five institutions through EvidenceNOW: Managing Urinary Incontinence in Women initiative to improve nonsurgical treatments for urinary incontinence (UI) among women in primary care

practices. The University of California – San Diego implemented a practice-based UI intervention across 54 practices serving an ethnically diverse population of women to determine if the intervention can reduce disparities in care. These initiatives improved care in primary-care practices serving diverse communities, and several were structured explicitly to reduce documented disparities, the express purpose the rule would defund. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

- **Multicenter AIDS Cohort Study (MACS) / Women's Interagency HIV Study (WIHS) Combined Cohort Study (MACS/WIHS-CSS).** This initiative aims to understand and reduce the impact of chronic health conditions, including heart, lung, blood, and sleep (HLBS) disorders—that affect people living with HIV. Originally, MACS was a study of gay and bisexual men, while WIHS was a study of women who had other risk factors for HIV, before the studies merged and the patient populations they serve were expanded. This research includes: improving motor and executive performance for older adults with HIV; interventions for loneliness in older adults to reduce frailty; improving kidney function for adults receiving highly active antiretroviral therapy (HAART); and understanding gut bacteria associations with diabetes. This cohort has produced findings on kidney function, cognitive performance, and diabetes risk in people living with HIV, an aging patient population whose care depends on exactly the demographic specificity § 200.218 restricts. All of this research could have been prevented based on the prohibitions of disparate research in §200.218 or political interference in equitable and effective access in § 200.300(b).

Sectional Analysis

Pre-Issuance Review by Senior Appointees [200.205]

Section 200.205 makes two changes that operate together. It establishes a pre-issuance review under which a senior political appointee must confirm that a discretionary award is consistent with the President's policy priorities before the award is made, and it requires applicants to commit to compliance with "Gold Standard Science" as that term is defined by Executive Order 14303. The first supplies an authority. The second supplies the standard under which the authority is exercised. Their combined effect is the substance of our objection, and it is greater than the sum of the two provisions read separately.

First, the proposed rule would create a new level of political pre-issuance review over all discretionary awards. It claims that, "[a] merit review is an objective process of evaluating Federal award applications in accordance with the written standards of the Federal agency". But the proposed rule replaces the existing objective pre-issuance review process with a system that requires grant proposals to "advance the President's policy priorities", rather than what is in statute and would be funded by typical peer review processes. This explicitly means that political and partisan considerations would preempt scientific merit, peer-review by independent experts, innovation needs, feasibility of programming, and public health and health system needs. It will also preempt the statutes and intentions of bipartisan congressional majorities. And

this will all happen without clear parameters, forcing researchers to conform their grant proposals, their research, and their conclusion to what could appear to be political whim. This would reduce the predictability for grant recipients and in turn have unintended consequences for scientific rigor and public trust. Stakeholders – research institutions, industry, healthcare providers, patients, state and local governments – have relied on the stability of the current system, and this proposed rule ignores those reliance interests and destroys the underlying system.

It is the peer review process by which scientific inquiry functions. Peer review is the quality control filter on scientific questions, methods, and results, and it provides a highly rigorous and intentionally competitive system to ensure only the highest quality programs break through. It not only catches errors, unclear reasoning, and potential overreach of assumptions, it pushes authors to justify their choices, share data, and respond to criticism. It is a system designed to direct attention and resources towards more rigorous and reliable findings, which is critical for developing and sustaining trust of the public, scientific community, patients, and providers. Replacing peer review with political review inherently reduces the amount of trustworthy research that is responsive to the needs of this country. Additionally, by requiring that any research program only ask the questions that the government wants it to ask, and only use the methods the government wants it to use, and only report out the results the government wants to report out, this proposed rule would materially affect and corrupt the independence and earned credibility of federally supported research, which is a key economic and innovation engine for the United States.

Second, this proposed rule would require applicants to commit to complying with not just administrative priorities, but also "guidance respecting Gold Standard Science", a term that is vague, ill-defined, and subject to extensive subjective interpretation, all of which injects arbitrary and capricious uncertainty and inconsistency in grantmaking and grant management.

The rule does not attempt to define "Gold Standard Science", but does point to Executive Order 14303, "Restoring Gold Standard Science." First, reliance on an Executive Order for creating and maintaining a definition – which can be modified or rescinded at the Executive's discretion rather than through the rulemaking process, to define a term to which all federal grantees must adhere, means that grantees will be subject to significant uncertainty as to whether their activities are in compliance with federal regulation.

Second, EO 14303 fails to provide a clear and objective definition of the term, further opening the door to inconsistent, ambiguous, subjective, and political interpretations into compliance.

The Executive Order emphasizes scientific integrity, reproducibility, and the use of falsifiable hypotheses. While these are essential to scientific research, they exist in the status quo through peer review. Where the Executive Order begins to falter is in its prioritization of research that produces easily quantifiable data, like administrative metrics and clinical trial results, over the complex, adaptive realities of care delivery. This emphasis is also in opposition to patient-centered care research, which is defined by respect for and responsiveness to individual patient preferences, needs, and values. Applied to health services research, that emphasis is not neutral. This requires understanding the subjective reality of the patient—such as their trust in the

system, their communication difficulties, or their experience of bias. This context is captured via qualitative data (e.g., interviews, focus groups) and patient-reported experience measures (PREMs) like the CAHPS surveys. By warning against research based on "subjective claims," the Executive Order silences the patient's voice. If researchers are discouraged from funding work that captures this "unfalsifiable" context, they may produce interventions that are statistically sound but emotionally, culturally, and practically irrelevant to the people they are meant to serve. A standard that classifies that evidence as insufficiently rigorous does not raise the bar for science. It removes a category of findings from the record. The result is a system that is clinically efficient but humanly alienating.

The two provisions are dangerous in combination because the authority can be exercised through the standard. Pre-issuance review supplies the power to withhold or condition an award. Gold Standard Science supplies a facially methodological justification for doing so whenever a study's questions, methods, or anticipated findings are unwelcome. A grant can be declined, or a line of inquiry foreclosed, not on the stated ground that the findings are politically inconvenient, but on the ground that the methods producing them fall short of a standard the government defines and may redefine at will. The result is a system in which the questions that may be asked, the methods that may be used, and the findings that may be reported are subject to political determination, while each individual decision retains the form of a routine judgment about rigor.

This is the precise inversion of the rule's stated purpose. Executive Order 14303 describes Gold Standard Science in terms of falsifiability and reproducibility. Falsifiability requires that evidence be permitted to contradict a hypothesis. Reproducibility requires a stable standard against which results can be tested and retested. A pre-issuance political gate permits the government to decline funding for the studies most likely to produce contradictory evidence, and a standard revisable by executive order without notice is, by construction, not stable. The provision asserts the language of scientific rigor while installing the mechanism by which rigor is overridden. We do not dispute that public funds should be spent accountably. We object that § 200.205 substitutes political certification for the peer-reviewed assessment of merit.

Review of Risk Assessment by Applicants [200.206]

The proposed rule would expand the factors that agencies may consider in evaluating applicant risk, including affiliations with organizations that undermine national security or public safety, violate federal law, or advocate for the overthrow of the United States government. This is a significant broadening of risk and allows the government to subjectively determine the acceptability of an applicant's professional or extracurricular affiliations.

There are two concerns here. First, the rule does not provide any list, description, or source for what organizations the government would consider falling under any of these categories, and this vagueness makes compliance difficult or impossible. The lack of an objective, credible, set of criteria also means that covered organizations can be added in the middle of a grant, requiring research organizations to monitor any possible affiliation against this dynamic and opaque category. Second, these restrictions could pose a threat to the grantee's constitutional right to freedom of association, and there is no explanation about how these constitutional rights will be respected or preserved under this rule. In short, nothing in this section constrains the discretion it

creates, leaving its exercise to the agency's judgment with no standard against which a recipient or a court could test it. There is no language in this section that would indicate that the rules would not be applied in an inconsistent, arbitrary, and capricious manner to meet partisan goals over scientific innovation.

Prohibition on Disparate-Impact Theories [200.218]

Among the rule's many troubling provisions, Section 200.218 stands apart. Under this section, federal awards may not be used to promote or support disparate-impact liability, including by funding disparate-impact studies or award activity driven by assumed disparate-impact risk. Demographic analysis is permitted only if federal funds are not used for it and the results are not applied to any activity under the award. It is explicitly prohibited to investigate any differences or disparities in outcomes among races, sexes, or similar groups, even explicitly prohibiting any inquiries into discriminatory intent in a "facially neutral policy or practice."

To be direct about what this means, a researcher could not use a federal grant to study why Black women die in childbirth at three times the rate of white women, not if doing so implicates disparate-impact analysis. A health systems researcher could not use federal funds to document whether patients with physical or cognitive disabilities receive fewer evidence-based interventions, if the analysis supports disparate-impact liability. A Medicaid policy researcher could not apply demographic findings to federally funded work that might support disparate-impact accountability. Pathways through which research can support program integrity and good stewardship of taxpayer funds by more accurately describing federal policy implementations and inefficiencies are shut down.

Disparate impact is not a political framework. It is a legal and analytical tool for identifying harm that operates through facially neutral policies and practices, the kind of harm that, by definition, does not announce itself. Health services research depends on disparate impact research precisely because the most consequential inequities in US health care do not arise from explicit discrimination. They arise from coverage design, payment structure, care delivery patterns, and system architecture that produce unequal outcomes across populations. Prohibiting federally funded research from documenting and acting on these patterns insulates them from scrutiny and forecloses the interventions that laws governing equal protection, due process, and the Americans with Disabilities Act may require. It does not make these patterns disappear. It makes them invisible. And it does so using public money and using it coercively.

This is a rule that would hurt all Americans as the consequences of it are not confined to any one group, because every patient bears some risk of unequal access to high-value care. It makes it far more difficult for researchers, practitioners, and policymakers to treat patients and ensure they have access to medical interventions that work and are high value.

DEI and Gender Ideology Prohibitions [200.300(b)]

This section prohibits the use of federal awards and subawards to fund, promote, or facilitate two categories of activity. The first is "diversity, equity, inclusion, and accessibility" (DEIA) policies or practices "that violate any applicable Federal anti-discrimination laws." The second is "gender

ideology," defined by reference to executive order as theories that "deny the biological reality of sex or the sex binary in humans, or endorse or advocate for the notion that sex is a chosen or mutable characteristic." Both prohibitions carry the defects identified throughout these comments. Each rests on a definition supplied by executive order rather than statute, each can be revised in scope without rulemaking or public comment, and neither gives a recipient any way to determine in advance what conduct is covered.

To start, these restrictions are unacceptable on their face: they are discriminatory, anti-scientific, and non-evidence based.

The gender ideology provision carries a further defect that is fatal on the rule's own terms. It conditions eligibility for federal research funding on the recipient not reaching a particular conclusion about a contested empirical question. The objection is not that the rule selects the wrong answer. The objection is that it selects any answer at all and makes funding contingent on agreement with it. A rule that requires researchers to affirm a government-specified conclusion as a condition of award is incompatible with the production of independent science, irrespective of the subject. This same rule invokes "Gold Standard Science" under § 200.205 and describes it in terms of falsifiable hypotheses and reproducibility. A falsifiable hypothesis is one that evidence is permitted to refute. A conclusion mandated by regulation is not. The rule therefore compels under § 200.300(b) a conclusion that its own § 200.205 standard would have to classify as unfalsifiable, and so as unscientific.

The DEIA provision operates through a similar mechanism. The qualifier limiting the prohibition to practices "that violate any applicable Federal anti-discrimination laws" appears to narrow it, but the narrowing is illusory, because the operative question is who determines what violates those laws and under what interpretation. The Administration's interpretation of federal civil rights law, under which efforts to identify and reduce racial and ethnic barriers are themselves treated as unlawful, has not been adopted by the courts. The provision thus conditions federal funding on compliance with a legal interpretation the courts have rejected, and exposes grantees who follow existing statute and standing court orders to the loss of their awards for doing so.

Racial and ethnic disparities in health outcomes, and general health inequities, are widely found by researchers and scientists across the health care system. Research shows that Black individuals have an HIV diagnosis rate that is eight times higher than the rate for white individuals. Pregnancy related mortality rates among Black women are three times higher than for white women and infant mortality is twice as high. In fact, wealthy Black women have worse maternal health outcomes than poor white women, showing the importance of race in understanding health care access. The uninsurance rate among American Indian/Alaska Natives and Hispanic individuals is three times as high as their white counterparts. Hispanic adults are twice as likely to not have a primary care provider than white adults. Transgender patients face a disproportionately high burden of mental health conditions, including depression, anxiety, and suicidality, which can be tied to gender dysphoria, societal stigma and discrimination. None of these health care crises go away because researchers, providers, and policymakers are prohibited from solving them.

The rule does not dispute that the disparities health services research documents are real. It prohibits the use of federal funds to study them. Rhetoric and policies like those in this rule not only seek to hide the harms it causes, it further worsens it. It should be alarming to all Americans that the federal government is seeking to codify discrimination, bigotry, and attacks on the dignity of the people in our country.

AcademyHealth unambiguously supports access to high-quality, evidence-based health care for every patient, without regard to race, ethnicity, geography, disability, or gender or sexual identity. That commitment is not the basis of this objection to this provision. The basis of our objection is that § 200.300(b) directs the federal government to fund science on the condition that it not look where the evidence leads, under a definition of acceptable science that the rule's own standard of rigor cannot survive.

Termination and Suspension Authority [200.340]

The proposed rule would massively expand the authority of federal agencies to terminate or suspend active grants for functionally any reason. The language specifies that agencies would be able to terminate any discretionary grant "in part or its entirety" based on the federal agency determining that the termination is in the interest of the agency's priorities, goals, or national interest at any point in the grant's lifespan. The authority to terminate a grant for discretionary interest is new and incredibly broad, and allows for the Agency to terminate a grant even if the grantee is in full compliance with the award terms. Agencies are also able to terminate a grant if the Agency determines that the grantee did not sufficiently fill out the necessary paperwork for subawards on SAM.gov, adding a layer of bureaucracy that smaller grantees may not be able to meet. In the event of a termination, the agency is not required to fund necessary and reasonable closeout costs or provide the grantee any ability to appeal the termination or provide an objection to the decision. This rule would both significantly expand the ability of an agency to terminate a grant without cause while also eliminating critical procedural protections for grantees.

The priorities-and-goals ground is the operative change, and it is unbounded. By its terms it permits termination of an award that is in full compliance with every condition of the grant. A recipient that has met its scientific, financial, and reporting obligations without exception may nonetheless have its award ended, because the test is not the recipient's performance but the agency's present preference. Combined with the absence of any required statement of reasons, any closeout funding, and any avenue of appeal, the provision converts a federal award from a commitment on which a recipient may rely into a grant revocable at will and without recourse.

This massive expansion in agency authority makes long-term federal funding and scientific planning unpredictable and requires grantees to assume a significant risk of losing funding due to vague and unappealable political and partisan decisions. There is very little that is more corrosive to scientific and health innovation than making continued funding contingent upon factors outside the control of the research institute. Given that many research grants, including at AHRQ and NIH, are five-year grants, this rule would make it impossible for any grantee to assume continued funding across (or even within) Administrations regardless of compliance with the award's terms and progress towards its goals. Research is not a light switch that can be turned off and then turned on again – the disruption of clinical trials, staffing, patient engagement, internal

review board approvals, and more all make it disruptive to the point of ineffective to restore funding after a lapse.

This raises two distinct concerns. The first is procedural. The Supreme Court held, in Mathews v. Eldridge, 424 U.S. 319 (1976), that the process due before the government deprives a person of a protected interest is determined by weighing the private interest affected, the risk of erroneous deprivation under the procedures used, and the government's interest including administrative burden. A provision that permits termination of a compliant, multi-year award with no statement of reasons and no opportunity to respond gives the recipient no means of identifying or correcting an erroneous decision, and raises serious concerns under that standard.

The second concern is institutional. These are funds that Congress has appropriated and that an agency has obligated through award. A standing authority to deobligate them mid-performance, on no ground more specific than the agency's evolving priorities, places the disposition of appropriated funds within the discretion of the executive after Congress has directed their use. This raises significant legal and constitutional concerns based on the Impoundment Control Act of 1974, which largely prohibits Executive agencies from withholding or slow walking the execution and spending of programs appropriated by Congress. This proposed rule is designed in a manner that makes it highly unlikely that federal research agencies will be able to fully spend the dollars that Congress has required of them. In fact, due to decisions by the Office of Management and Budget and Department leadership, many federal research agencies, such as the Agency for Healthcare Research and Quality (AHRQ) are unable to spend any of the money that Congress has required it to. Adding in the burden, risk, and preemptively canceled research programs that would happen under this proposed rule, the ability of grantmaking agencies to fulfill their statutory responsibilities under appropriations laws would almost certainly be unlawfully limited. The Government Accountability Office (GAO) has regularly found that policy withholdings and policy choices violate the ICA, and do not constitute as allowable programmatic delays based on external, bona fide implementation factors.

AcademyHealth firmly believes that a termination authority this broad, exercised without stated cause, sits in evident tension with the principle that appropriated funds are to be spent as Congress has directed, and that the experience of AHRQ over the past year, where appropriated research funds have gone unobligated and expired unspent, illustrates the consequence this provision would generalize and entrench.

Simply put, it is unreasonable to expect the scientific and health enterprises to be maximally innovative in an environment where their grants may be terminated at any time, for any reason, including political reasons, and where they would lack any opportunity to contest those terminations. This regime makes the sustained, multi-year commitment that serious research requires unsupportable, regardless of the recipient's compliance.

Hidden behind every funding cut are the stories of individuals whose lives are profoundly affected—both personally and professionally. For SeYeon Chung, PhD, research funding cuts and uncertainty lead to “a delay in discovering new knowledge and developing new treatments” in her research uncovering the causes of birth defects and reducing infant mortality. For aspiring PhD students, funding cuts result in many being turned away by research labs, forcing them to

abandon their research interests. For scientists like Rachel Sirianni, PhD that design pediatric cancer treatments, fundings cuts mean colleagues are leaving labs while she faced the tough decision of maintaining "personnel who took years to train, keep equipment running, or bet it all on one final, risky study." For population health researchers like Michael Green, funding cuts mean "having to fight the overwhelming feeling of dread and pointlessness that are the intention of the current chaos." For Debra Houry, M.D., M.P.H., former Chief Medical Officer at CDC, funding cuts translate to witnessing "colleagues lose jobs they had devoted their careers to, and expertise built over decades at the agency disappear overnight." When grant funding can be terminated at any time for any reason, they become stories of delayed discoveries, disrupted careers, and uncertain futures in a less healthy and innovative America.

Memberships, Subscriptions, and Professional Activity Costs [200.454] and Conferences [200.432]

The proposed rule would prohibit grantees from using funds to cover the costs of the recipient's or subrecipient's membership in professional, civic, business, and technical organizations unless the grantee received prior approval from the federal agency. Further, the costs of the recipient's or subrecipient's subscriptions to business, professional, academic, and technical periodicals are unallowable. Grantees would only be allowed to attend or participate in a conference if it is expressly approved by the federal agency and included in the terms and conditions of the award.

Taken collectively, these new restrictions represent a fundamental misunderstanding of the evidence infrastructure that supports scientific inquiry. Professional societies are not peripheral to the research enterprise. They are how researchers stay current, develop methodological skills, build peer networks, and enter the field. Restricting federal funds for memberships and conference participation does not just create administrative burden, it severs the connection between federally funded researchers and the communities of practice that make their work rigorous and relevant. The proposed controls over conference attendance, journal subscriptions, and memberships are administratively disproportionate to their cost and undermine the very mechanisms by which federally funded science becomes useful. What gets damaged by this rule is not individual research projects, it is the infrastructure of evidence-the datasets, the research networks, the investigator pipelines, the dissemination channels that policymakers, practitioners, and patients depend on to make decisions that affect lives. That infrastructure took decades to build. It cannot be rebuilt quickly or easily once it is gone.

Additionally, these provisions also fail the rule's own stated objective of reducing recipient burden. Memberships, subscriptions, and conference registrations are among the smallest line items in any research budget, frequently a few hundred to a few thousand dollars against awards many orders of magnitude larger. Subjecting each to advance agency approval does not reduce administrative burden. It creates burden, on the lowest-dollar items in the budget, and on both parties, requiring the recipient to seek and the agency to adjudicate approval for expenditures whose cost is exceeded by the administrative effort of reviewing them. A rule that imposes its heaviest process on its smallest costs is not an effective burden-reduction measure.

The restrictions on subawards also create significant administrative burden and barriers for institutions to work collaboratively with each other – these subawards are critical for research

networks to engage with multiple institutions, which will reduce their ability to undertake discoveries. Smaller institutions, patients, and community-based organizations often participate in the enterprise through these subawards.

Additionally, by making memberships and conference attendance subject to agency approval, this framework gives the federal agency discretionary leverage over the professional societies and research conveners whose events and memberships it must approve. A society that depends on federally funded members and attendees has reason to anticipate which lines of inquiry the agency favors, and to adjust accordingly, in advance of any instruction. An approval requirement that may be granted or withheld without a stated, objective standard is itself the mechanism by which that adjustment is induced, whether or not it is ever exercised. In that situation, these societies may be coerced to abandon lines of inquiry or evidence in order to stay in the good graces of the grantmaking agency. Even the threat or risk of being blacklisted would be corrosive, arbitrary, capricious, and undermine the robust and credible scientific and research enterprise in America.

Domestic-First Framework [200.202(e)] and Restrictions on Foreign Scientific Collaborations [200.220]

This section proposes a government-wide rule prohibiting grant recipients from using federal funds to support bilateral or multilateral collaborations, agreements, programs, or activities with covered foreign countries or covered foreign entities, unless expressly authorized by Federal statute. The rule provides very narrow exceptions as determined by a federal agency head that the activity does not pose a risk to national security.

Disease does not respect national borders, and much of the research required to address it cannot be conducted within them. For many scientific advances, especially for rare conditions where the patient population within any single country is too small to study alone, or to improve human health outcomes globally, or to prevent health crises from entering America, it is critical for researchers to have access to international collaboration, data sharing, and global clinical trials. Limiting the ability of researchers and providers to work in multilateral coalitions to identify, study, and implement cutting edge evidence and analysis makes it less likely that innovation and leadership will come from America. The rule's only exception, available where an agency head determines that an activity poses no risk to national security, supplies no criteria for that determination, and so leaves the scope of permissible collaboration to unbounded agency discretion.

Thank you for the opportunity to discuss the perspectives and concerns of the health services research community. For further comment, clarification, or inquiry, please email Josh Caplan at Josh.Caplan@AcademyHealth.org.