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July 13, 2026

The Honorable Russell Vought
Director
Office of Management and Budget
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 Academy of Managed Care Pharmacy (AMCP) thanks the Office of Management and Budget (OMB) for the opportunity to provide comments in response to the proposed rule titled Regulation for Federal Financial Assistance.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.[1]

Federal financial assistance programs function most effectively when recipients can understand, anticipate, and comply with clearly defined requirements grounded in law, supported by objective standards, and applied consistently across administrations.

Summary of AMCP's Recommendations

1. **Revise § 200.202 to preserve statutory purpose.** Administration priorities should inform, but not override, statutory authority, eligibility criteria, or award expectations.
2. **Limit § 200.206 risk review to objective, award-specific criteria.** Risk determinations should be based on documented compliance, operational, or cybersecurity concerns rather than vague or undefined factors.
3. **Limit § 200.208 specific conditions to documented and proportionate risk.** New award conditions should be tied to identified recipient or programmatic risks, supported by notice and explanation, and implemented in a manner that minimizes disruption.

[1] Academy of Managed Care Pharmacy. *About AMCP*. Available at https://www.amcp.org/about

4. **Clarify that § 200.300 does not expand agency authority.** Material award requirements should be tied to identified legal authority and should not displace statutory criteria, peer review, or evidence-based health care standards.
5. **Implement § 200.303 through practical, risk-based internal controls.** OMB should recognize existing compliance frameworks and protect privacy, confidentiality, cybersecurity, and trade-secret interests.
6. **Require proportionate enforcement under §§ 200.339–200.340.** Agencies should generally use corrective actions and other graduated remedies before severe sanctions or termination and should consider effects on patients, research, and continuity of care.
7. **Provide prospective implementation and transition safeguards.** Material changes should be accompanied by implementation guidance, reasonable transition periods, and protections against disruptive application to existing awards.

[§ 200.202] Program Design Should Remain Grounded in Statutory Purpose

AMCP supports requiring Federal programs to have clear goals and objectives that advance the public purpose authorized by law. However, the proposed requirement that program goals align with "administration policies and priorities" warrants revision. Federal programs are authorized and funded by Congress to serve enduring public purposes that often require long-term planning and investment. Administration priorities may inform program implementation, but they should not supersede authorizing statutes, appropriations, published eligibility criteria, peer-review processes, or reasonable recipient reliance interests. AMCP therefore recommends that OMB revise § 200.202(a)(1)(iii) to clarify that alignment with administration priorities must remain consistent with, and subordinate to, statutory authority and applicable appropriations, and may not be used to alter program purpose, eligibility, or award expectations in a manner inconsistent with governing law.

[§ 200.206] Federal Agency Review of Risk Posed by Applicants Should Be Objective and Award-Specific

AMCP supports appropriate review of applicant risk before Federal awards are made. In health care and public health programs, risk review should be calibrated to the award and should not create barriers for qualified recipients that support medication access and public health. Overly broad or unclear criteria may discourage qualified applicants or delay patient-serving programs.

OMB should direct agencies to use objective, consistently applied risk criteria and to distinguish between material compliance risks and routine operational complexity inherent in health care programs. Agencies should not treat participation in complex health care delivery or pharmacy benefit arrangements as a risk factor absent specific evidence of noncompliance. The final rule should also encourage agencies to provide applicants with notice of material risk concerns and an opportunity to respond or provide mitigating information before risk findings affect award decisions. Agencies should document the specific award requirement at issue, the objective evidence supporting the risk finding, any mitigating information provided by the applicant, and why any resulting condition is necessary and proportionate. OMB should clarify that risk review under § 200.206 must be tied to the applicant's ability to comply with the specific award and should not be used to disfavor lawful, evidence-based health care practices.

[§ 200.208] Specific Conditions Should Be Limited to Documented and Proportionate Risk

Specific conditions should be limited to documented risks directly related to a recipient's ability to comply with award requirements and should not be based on generalized program concerns or undefined risk factors. Without such limits, recipients may face significant uncertainty regarding the obligations associated with Federal awards and may be unable to reliably plan long-term health care, research, or public health activities.

AMCP recommends that agencies document the basis for any specific condition, explain why it is necessary, consider less burdensome alternatives, and provide recipients an opportunity to respond before imposing material conditions whenever practicable.

[§ 200.300] Statutory and National Policy Requirements Should Be Tied to Clear Legal Authority

AMCP supports compliance with duly authorized statutory and national policy requirements. However, § 200.300 should be implemented in a manner that preserves transparency regarding the legal basis for recipient obligations and does not permit agencies to impose substantial compliance requirements through broadly worded award conditions that are untethered from identifiable statutory or regulatory authority.

OMB should clarify that recipients must be able to identify the legal authority supporting material award requirements and that § 200.300 may not be used to circumvent program-specific statutes, eligibility standards, peer-review requirements, or congressionally established program objectives.

[§ 200.303] Internal Controls Should Be Risk-Based and Practical

Internal controls should be risk-based, practical, and consistent with existing compliance frameworks. Many health care recipients already maintain sophisticated compliance, audit, privacy, cybersecurity, and program-integrity controls that serve the same objectives as § 200.303. OMB should clarify that internal-control requirements must be implemented consistent with applicable privacy, confidentiality, cybersecurity, and trade-secret protections. Oversight objectives can generally be achieved without requiring disclosure of protected health information, confidential commercial information, proprietary methodologies, or other unnecessary sensitive data.

[§§ 200.339—200.340] Enforcement and Termination Should Protect Research Continuity

AMCP supports effective enforcement when recipients fail to comply with Federal award requirements. Enforcement actions should be proportionate to the nature, severity, duration, and consequences of the noncompliance and should be supported by objective, documented decision-making. A predictable and transparent enforcement framework promotes accountability while preserving participation by qualified organizations and ensuring that Federal programs can continue to achieve their intended public purposes.

OMB should encourage agencies to use graduated remedies whenever appropriate before imposing severe sanctions. In many cases, corrective action plans, technical assistance, enhanced monitoring, targeted reporting requirements, prospective conditions, and reasonable

opportunities to cure deficiencies can effectively address compliance concerns while protecting Federal interests and preserving program continuity.

To promote transparency and consistency, OMB should require agencies to document the basis for selecting an enforcement action, including the nature of the noncompliance, the risks posed to program performance or Federal funds, any corrective actions undertaken by the recipient, and the reasons less restrictive measures would be insufficient. Agencies should also consider the practical consequences of enforcement actions on program beneficiaries, ongoing operations, research activities, and continuity of care when selecting among available remedies.

Because termination is among the most consequential actions available to an agency, OMB should clarify that termination generally should be reserved for circumstances in which lesser remedies would be ineffective or inappropriate. Before terminating an award, agencies should evaluate whether alternative measures could address the underlying compliance concern while maintaining critical services, research activities, or public health functions.

For awards supporting health care services, medication access, pharmacy infrastructure, public health activities, or health services research, agencies should consider potential effects on patients, continuity of care, research participants, and program beneficiaries. If termination is necessary, agencies should provide reasonable notice, document the basis for the decision, and undertake appropriate transition planning to minimize avoidable disruption.

Implementation Guardrails Are Necessary to Prevent Disruption of Existing Awards

AMCP recommends prospective application of material changes, a reasonable implementation period, and publication of plain-language implementation guidance, FAQs, and model award terms. Recipients may need time to update grant-management systems, compliance programs, reporting processes, and subrecipient agreements. New requirements should not be applied to existing awards in a manner that disrupts ongoing patient-facing programs, research, or public health activities.

Conclusion

AMCP appreciates OMB's efforts to improve accountability and stewardship of Federal financial assistance. OMB should revise the proposed rule to preserve statutory purpose, objective award administration, proportionate enforcement, confidentiality protections, and prospective implementation. These safeguards will help ensure continued support for medication access, evidence-based health care, and public health programs.

AMCP appreciates your consideration of AMCP’s concerns and looks forward to continuing work on these issues with OMB. If you have any questions regarding AMCP's comments or would like further information, please contact me at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Geni Tunstall, JD
Associate Vice President, Regulatory Affairs