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Submitted electronically via www.regulations.gov

May 12, 2025

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

Re: Request for Information: Deregulation (OMB-2025-0003)

Dear Mr. Vought,

The Association of American Medical Colleges (AAMC) appreciates the opportunity to respond to the Office of Management and Budget's (OMB) request for information on reducing regulatory burden. Academic medical institutions operate at the nexus of research, education, and clinical care, and must often navigate a complex and overlapping array of federal regulations. The AAMC agrees that the federal government should employ strategies to reduce unnecessary administrative burden such as revising outdated regulations, harmonizing duplicative requirements, and streamlining compliance processes while preserving the critical protections those regulations are intended to provide. We support OMB's commitment to fostering "American dynamism and creativity," through a thoughtful review of "onerous and unnecessary regulations," and encourage a balanced, evidence-informed approach that improves efficiency without compromising the original goals and public value of the regulatory framework.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, biomedical research, and community collaborations. Its members are 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited Canadian medical schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

Reports from the AAMC,[1] the National Academies of Sciences, Engineering, and Medicine (National Academies),[2] and the Government Accountability Office[3] have called for federal agencies to harmonize regulations, reduce administrative burden, and adopt a coordinated approach to regulation. The National Academies' 2016 consensus report found a lack of rigorous data quantifying regulatory burden and costs to researchers,[4] and highlighted the AAMC Conflicts of Interest Metrics Project as a model for systematically assessing the operational impact of federal regulatory requirements.

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[1] AAMC Analysis in Brief, Implementing the Regulations on Financial Conflicts of Interest, Results from the AAMC Conflict of Interest Metrics Project, Vol.15 (2015), https://www.aamc.org/media/8026/download.
[2] Nat'l Acads. of Scis., Eng'g, & Med., Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century (2016), https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.
[3] U.S. Gov't Accountability Off., GAO-16-573, Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements (2016), https://www.gao.gov/products/gao-16-573.
[4] Supra Note 2.

We suggest that any regulatory changes adhere to the Administrative Procedure Act's notice and comment requirements, which are critical to maintain transparency, accountability, and public engagement in federal rulemaking.

We also appreciate the Trump Administration's emphasis on regulatory reform in the health care system that reduces burden on health care providers, simplifies the health care system, and ensures patients receive optimal care. The increasing amount of administrative responsibility forced upon health care providers is unsustainable, diverts time and focus away from patient care and leads to burn out for providers. Reducing provider's administrative burden in the health care delivery system will improve quality of care, decrease costs, and enable better access to care.

A meaningful and lasting regulatory review must be deliberate, transparent, and grounded in dialogue between federal agencies and the regulated community. Over the years, the AAMC has identified numerous federal requirements that create disproportionate burden without yielding clear benefits. The recommendations that follow reflect specific federal regulations we believe should be revisited, revised, or harmonized to reduce unnecessary burden and promote more effective and sustainable health care delivery and biomedical research systems.

Reducing Biomedical Research Burden

Efforts to reduce administrative burden on the biomedical research enterprise are critical to preserving the productivity, efficiency, and global leadership of U.S. funded science. The following recommendations identify specific actions that OMB and federal agencies can take to support a more efficient and coordinated regulatory framework.

- **Harmonize Federal Conflict of Interest Disclosure Requirements Across Agencies**
  In accordance with Section 2304 of the 21st Century Cures Act—which directs the Secretary of Health and Human services to review applicable regulations and reduce administrative burden for federally funded researchers[5]— we recommend that OMB in coordination with HHS and relevant agencies, and in consultation with the regulated community, identify and adopt common elements for financial conflict of interest (FCOI) disclosure and evaluation. The AAMC supports a harmonized approach to COI oversight—one that maintains research integrity while reducing burden and improving regulatory efficiency.

  Researchers and institutions are subject to multiple, overlapping FCOI disclosure requirements across federal agencies, including the FDA (21 C.F.R Part 54), National Institutes of Health (42 CFR Part 50, Subpart F & 45 CFR Part 94), Centers for Medicare and Medicaid Services (42 CFR Part 403, Subpart I), and the National Science Foundation (NSF Proposal & Award Policies & Procedures Guide, Chapter IX.A). Notably, these requirements differ in definitions, disclosure thresholds, and reporting timelines. As the AAMC noted in its comments to the FDA on its Regulatory Reform Agenda: such variation in COI requirements, "imposes significant financial and administrative burden on institutions and researchers, diminishing the productivity and return of federal investment in research."[6]

[5] 21st Century Cures Act, H.R. 34, 114th Cong., Pub. L. No. 114-255, 130 Stat. 1033 (2016), https://www.congress.gov/bill/114th-congress/house-bill/34/text.
[6] Association of American Medical Colleges, Comment Letter on Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration (2024), https://www.aamc.org/media/13356/download.

- **Establish a Research Policy Board to Improve Regulatory Oversight and Efficiency**
  Consistent with Section 2034 of the 21st Century Cures Act and in alignment with recommendations from the National Academies' 2016 report, the AAMC urges OMB to take a leadership role in establishing a research policy board. The research policy board would bring together federal agencies and representatives from the regulated community to coordinate regulatory policy, reduce administrative burden, and promote transparency.

  The research community operates within a complex, fragmented, and often inconsistent regulatory landscape which creates significant challenges to compliance. As documented in the National Academies' consensus report, the absence of cross agency coordination has contributed to a proliferation of duplicative requirements, increasing administrative burdens on researchers and institutions, reducing research productivity, and ultimately diminishing the overall effectiveness of the U.S. research enterprise.[7] Although the 21st Century Cures Act called for the establishment of a permanent research policy board, it has not been implemented as of date. The AAMC has repeatedly supported this recommendation, most recently in its 2024 letter to Congress on the 21st Century Cures and Cures 2.0 Acts, where we emphasized that the research policy board would "serve as a powerful tool in transparency and in reducing regulatory burden," and offer a trusted forum for structured engagement between the government and regulated research community.[8]

- **Align FDA Advisory Committee Conflict Standards to Minimize Administrative Confusion**
  The AAMC recommends that the FDA clarify the distinction between statutory COI under 18 U.S.C. § 208(b) and the "appearance issues" under 5 C.F.R. § 2635.502 (known as "Section 502"), and take steps to align its procedures for evaluating both. Providing the regulated community with clear, consistent guidance would improve the transparency of advisory committee determinations and reduce confusion among nominees such as individuals from the academic medical community who may be unfamiliar with these distinct standards.

  The FDA currently applies two separate legal frameworks for assessing eligibility for participation on advisory committees: the statutory conflict of interest standard (18 U.S.C. § 208(b)) and the "appearance issue" under the government-wide regulation of ethical conduct for government employees (5 C.F.R. § 2635.502). While the agency issued final guidance in 2008 on the process for determining a COI under 18 U.S.C. § 208(b),[9] it was not until 2016 that the FDA released draft guidance on evaluating appearance issues[10] —marking the first time the agency has formally addressed its evaluation process under Section 502. As of date, that draft guidance has not been finalized. In comments to the FDA, the AAMC expressed concern that the distinction between actual and apparent conflicts of interest is not commonly made in other federal COI regulations, policies, or practices. This unfamiliarity may create confusion and inconsistencies in disclosure and eligibility determinations. Greater clarity from the FDA would greatly improve understanding of disclosure expectations, the rationale supporting eligibility determinations and trust in the advisory committee selection process.[11]

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[7] Supra Note 4.
[8] Association of American Medical Colleges, *Letter to Congress on Cures 2.0 and Research Policy Reform* (Aug. 2, 2024), https://www.aamc.org/media/78581/download.
[9] U.S. Food & Drug Admin., *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (2008), https://www.govinfo.gov/content/pkg/FR-2008-08-05/pdf/E8-17998.pdf.

[10] U.S. Food & Drug Admin., *Draft Guidance: Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees* (2016). https://www.fda.gov/media/98852/download.
[11] Association of American Medical Colleges, Comment Letter on Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration (2024), https://www.aamc.org/media/13356/download.

- **Harmonize FDA's Single IRB Requirement with the Common Rule and NIH Single IRB Policy** The AAMC recommends that FDA align its single institutional review board (sIRB) requirement for cooperative research (21 C.F.R. Part 56) with those established under HHS' revised Common Rule (45 C.F.R. §46.114), and NIH Single IRB policy. We also recommend a two year implementation period to evaluate whether additional guidance, exceptions, or flexibilities are warranted and to ensure a smooth transition. We appreciate the steps the FDA has already taken to promote harmonization and commend the agency for prioritizing alignment in key areas where coordination is needed.[12] However, as noted in the AAMC's December 2022 comment letter on the FDA's proposed rule on cooperative research (Docket No. FDA- 2021-N-0286), many institutions face significant operational challenges under existing sIRB mandates, often experiencing delays without corresponding improvements in protections for research participants. We encourage the FDA work closely with HHS and the regulated community to finalize the cooperative research proposed rule in a way that promotes coordinated oversight, consistent guidance, and supports shared best practices in the conduct of cooperative research.

- **Align USDA's Protocol Review Requirement with PHS Continuing Review Standards** To reduce administrative burden and improve regulatory consistency, we recommend that the U.S. Department of Agriculture (USDA) amend 9 CFR §2.31(d)(5) to align with the Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).[13] Specifically, the regulation should be revised to read as follows: "The [Institutional Animal Care and Use Committees (IACUCs)] shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in §2.31(d)(1-4) at least once every three years."[14]

  This change would preserve rigorous oversight while greatly reducing unnecessary protocol revisions for studies that remain scientifically valid and compliant with animal welfare standards. Under current USDA regulations, IACUCs are required to "conduct complete reviews of activities…at appropriate intervals… but not less than every 3 years" (9 CFR §2.31(d)(5)). This process creates redundance administrative work without demonstrable benefit to animal welfare protections. The AAMC has previously supported this change in comments to the National Institutes of Health[15] and as a contributing organization to the report, *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*.[16]

Reducing Health Care Delivery Burden

By reducing administrative burden, the administration can support the relationships between patients and their providers. Accordingly, the AAMC recommends the administration address the following concerns to reduce the regulatory burden for health care providers while also simplifying the health care system and ensuring patients receive optimal care.

[12] Association of American Medical Colleges, Comment Letter on FDA's Proposed Rule on Cooperative Research (Dec. 28, 2022), https://www.aamc.org/media/64386/download.
[13] U.S. Dep't of Health & Human Servs., Public Health Service Policy on Humane Care and Use of Laboratory Animals (rev. 2015), https://olaw.nih.gov/policies-laws/phs-policy.htm.
[14] 9 C.F.R. § 2.31(d)(5) (2024).
[15] Association of American Medical Colleges, Comment Letter on NIH OLAW Draft Report on Reducing Administrative Burden to Researchers for Animal Care and Use in Research (Feb. 20, 2019), https://www.aamc.org/media/12386/download.
[16] Association of American Medical Colleges et al., Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden (2019), https://www.aamc.org/media/12231/download.

- **Expand Medicare Coverage of Telehealth and Communication Technology-based Services by Removing Outdated Restrictions**
  The AAMC urges CMS to permanently change its regulations to permit practitioners to use their enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025. (89 Fed. Reg. 97710, at 97762). Requiring reporting of practitioner's home addresses for enrollment is likely to discourage practitioner's from providing telehealth services from their home, limiting access to care. Additionally, practitioners have expressed privacy and safety concerns associated with enrolling their home address.

  Unless Congress acts, starting October 1, 2025, CMS will begin to apply geographic limitations and limitations on the site of service Medicare patients may receive telehealth services. While the AAMC understands that CMS may not have the authority to waive these statutory limitations on telehealth services, we strongly support making permanent the waivers and regulatory changes established by CMS in response to the COVID-19 public health emergency that have facilitated the widespread use of telehealth and other communication technology-based services that have improved access to health care.

- **Permanently Allow Direct Supervision Through Virtual Supervision**
  The AAMC strongly supports CMS defining direct supervision to permit the presence and "immediate availability" of the supervising practitioner using audio-video technology on a permanent basis. *(*42 C.F.R. §§ 410.26, 410.32) This policy would enable expanded access to health care services while reducing risk of exposure to all infectious diseases (e.g., coronavirus, seasonal flu, and others). Our members have found virtual supervision of clinical staff to be safe and effective, and improved access to care.

- **Allow Virtual Supervision of Residents for Both Telehealth and In-person Services**
  The AAMC strongly supports revising the regulations to allow virtual supervision of residents for both in-person and telehealth services in all residency training locations permanently for services that may be furnished safely and effectively. (42 C.F.R. § 415.172) At a minimum, CMS should allow virtual supervision of residents for both in-person and telehealth services in underserved areas, as well as in non-metropolitan statistical areas. Allowing residents to provide these services while being supervised virtually is safe and effective, further expands access and promotes training opportunities.

- **Address Barriers to Uptake & of Interprofessional Consults**
  In 2019, CMS finalized payment for six CPT® codes to recognize interprofessional consultations (99446, 99447, 99448, 99449, 99451, 99452). (83 FR 59452, at 59491, November 23, 2018) The AAMC and its member health systems have found interprofessional consultations utilizing provider-to-provider modalities and peer-mentored care as an effective way to improve access to care. Patients benefit from more timely access to the specialist's guidance and payers benefit from a less costly service by avoiding the new patient visit with a specialist, not to mention likely downstream costs, when interprofessional consults take the place of a referral.

  CMS requires that providers collect coinsurance from their patients when billing for CPT® codes 99451 and 99452. While the AAMC understands that CMS may not have the authority to waive coinsurance for CPT® codes 99451 and 99452 or GIPC5 and GIPC6 under the Medicare fee-for-service program, we remain concerned that the coinsurance requirement is a barrier to providing these important services for several reasons. First, given the structure of two distinct codes, patients are responsible for two coinsurance payments for a single completed interprofessional consultation, which predictably induces confusion. Interprofessional consultations are often used for patients with new problems who are not established within the consulting specialty's practice and therefore do not

have an existing relationship with the consultant. A coinsurance bill for a service delivered from a provider that is unknown to the beneficiary could cause the patient to believe a billing error has occurred. Guidance for CPT® code 99452 clarifies that it should be reported by the treating physician/QHP for 16-30 minutes in a service day preparing the referral and/or communicating with the consultant. We believe that guidance should be changed so that the time for these codes should include all the activities associated with the interprofessional exchange between the treating provider and consulting physician, including follow-through on the consultant's recommendations. This clarification would help to expand the use of these valuable services in the future and ensure from a program integrity standpoint that patients and payers are realizing the intended value of this service.

- **Reform Hospital Quality Performance and Reporting Programs**
  The AAMC is concerned with the considerable burden in hospital quality measurement and recommends the following actions to better maximize health care system resources for measurement that can drive meaningful quality improvements.

  - CMS should remove chart-abstracted measures and structural measures from hospital quality programs and instead focus on outcome measurement. Chart-abstracted and structural measures require significant clerical effort, requiring hospitals to divert resources away from clinical care.[17] Currently, the SEP-1 measure is the only non-electronically chart-abstracted measure included in the Hospital Inpatient Quality Reporting (IQR) Program and was added to the Hospital Value-Based Purchasing (VBP) Program beginning with FY 2026 payment determinations. (88 FR 58640, at 59081, August 28, 2023) The IQR Program currently has three structural measures in place or set to take effect in the coming years: Maternal Morbidity, Patient Safety, and Age-Friendly Hospital. (See Table X.C.2, 90 FR 18002, at 18338, April 30, 2025). While these measures reflect important quality measurement topics, they do not directly measure outcomes or safety events. Instead, they require hospitals to manually abstract data from patient charts or attest to statements across multiple domains and better reflect a hospital's resources and interpretation of attested-to structures and documented activities. Removing these measures and instead prioritizing outcomes measures would more effectively use resources to drive quality improvement and performance.

  - CMS should remove duplication across performance programs, notably by removing the Safety Domain from the Hospital VBP as it is duplicative with the measures in the Hospital-Acquired Condition Reduction Program (HACRP). Previously, CMS proposed, but did not finalize, the removal of duplicative safety and condition-specific cost measures from the VBP program to better align measurement priorities across inpatient quality reporting and performance programs and reduce provider burden (83 FR 20163, at 20411, May 7, 2018). The AAMC has long recommended that CMS eliminate the measure overlap between the VBP and the HACRP to reduce the likelihood of mixed signals on performance due to the different versions of the measures in use and different scoring approaches across the two programs. In removing the Safety Domain from the VBP, CMS could double the weight of the Clinical Outcomes Domain, ensuring hospitals are incentivized to improve and maintain high performance on the overall effectiveness of the care they deliver.

- **Reform the Quality Payment Program (QPP)**
  The AAMC continues to hear from its members that the Merit-based Incentive Payment System (MIPS) under the QPP should be less administratively burdensome and more clinically relevant. The current program is too costly, requires reporting that is unnecessary, and diverts time away from

[17] A. Saraswathula, et al., The Volume and Cost of Quality Metric Reporting, JAMA, 329(2):1840-1847 (Jun. 6, 2023).

patient care. In the 2025 PFS final rule, CMS estimated the total burden on the U.S. health care system due to the MIPS reporting requirements finalized for CY 2025 would be 586,877 hours and $70,166,672 (89 FR 97710, at 98470). Below are a few specific recommendations.

- CMS should retain MVP reporting as a voluntary MIPS reporting option and retain traditional MIPS as the agency works to develop the comprehensive, meaningful measures needed to advance MVP adoption and ensure that rules for subgroup reporting allow practices who opt to report MVPs can best represent the clinical context of care delivered within their practice
- All cost measures used in the MIPS program should be appropriately adjusted to account for clinical complexity and economic risk factors.
- CMS should utilize the authority granted to the Secretary through HITECH Act to permit reporting Promoting Interoperability (PI, previously referred to as "meaningful use") through yes/no attestations. Each "yes" would be worth a certain amount of points. In addition to relieving the reporting burden, an attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report PI objectives, and could help prioritize both existing and future gaps in health IT functionality.

- **Reform and Reduce Reporting Burdens for Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (SSP)**
  The AAMC recommends CMS make the following changes to the regulations for ACOs participating in the SSP to relieve burden and ensure continued participation in the largest value-based care model for Medicare providers.

  - CMS should modify quality measurement policies to support ACO participation and reduce burden by providing time to ramp up reporting new electronic clinical quality measures under the QPP's Alternative Payment Model (APM) Performance Pathway (APP) Plus measure set (42 C.F.R. § 425.510(b)(2)) and reverse the policy to require ACOs report QPP PI data, regardless of their Qualified APM Participant (QP) status (42 C.F.R. § 425.507).
  - CMS should delay the sunsetting of the Web Interface and MIPS CQM reporting options until at least 2028 and assure ACOs that the Medicare CQM option will remain available for the foreseeable future until digital quality measure reporting is feasible and successful.
  - CMS should expand the significant, anomalous, and highly suspect billing activity policy to allow ACOs to report suspected fraudulent Medicare billing to CMS to expedite investigations and allow ACOs to partner with the agency on combatting fraud, waste, and abuse in the Medicare program. (42 C.F.R. § 425.672)

- **Remove Respiratory Illness Reporting Requirement from Conditions of Participation**
  Beginning November 1, 2024, CMS added mandatory respiratory illness reporting under the infection prevention and control and antibiotic stewardship programs condition of participation, requiring all Medicare and Medicaid participating hospitals and critical access hospitals to electronically submit certain COVID-19, influenza and respiratory syncytial virus data to the Centers for Disease Control and Prevention on a weekly basis. (QSO-25-05-Hospitals/CAHs; 42 C.F.R. §§ 482.42(e), 485.640(d)) Failure to report this information may lead to termination of a hospital's participation in the Medicare and Medicaid programs. The AAMC understands the potential value of selected data on acute respiratory illnesses to inform public health initiatives. However, the use of CoPs to compel hospitals to share data with the federal government is inconsistent with the intent of the CoPs. The AAMC urges CMS, HHS and CDC to invest in the infrastructure needs to make voluntary sharing of this data on infectious diseases less burdensome and more meaningful.

- **Re-Evaluate New Obstetrical Service Standards Conditions of Participation and Other Maternal Health CoP Changes**
  We ask the agency to consider re-evaluating the new Obstetric Service Standards conditions of participation (CoP) as well changes to the Emergency Services and Discharge Planning CoPs to address maternal health for efficacies in these requirements to ensure hospitals can meet these standards without undue burden**.** (42 C.F.R. §§ 482.59, 482.55, 482.43 - established by 89 FR 93912, November 27, 2024) The new CoP requires Medicare and Medicaid participating hospitals and critical access hospitals that offer Obstetrical services to implement several changes related to service organization, staffing, delivery of services, and training. This CoP also requires hospitals to use findings from their QAPI programs, to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis including updating training requirements for staff. While the AAMC supports efforts to improve maternal healthcare outcomes and agrees this is a critical issue facing the United States that must be addressed, the AAMC does not support the use of CoPs to drive these improvements. Further, since the new CoP is considered to be optional, this means that only hospitals that elect to offer this service must comply with requirements. Additionally, the changes to existing CoPs apply to all hospitals participating in Medicare and Medicaid and place varying levels of burden onto hospitals and CAHs depending on their capacity to meet these new standards. Failure to meet CoP requirements may result in sanctions on hospitals including corrective action plans, monetary sanctions, increased reporting requirements, and even termination from the Medicare program. If hospitals feel they are not adequately equipped to meet these standards or that additional investments must be made to meet these requirements, providers struggling to operate these services may ultimately make the decision to eliminate these services to avoid significant penalties for failure to meet CoP requirements. Due to this, the AAMC believes these requirements may be overly burdensome for providers.

- **Withdraw Prior Authorization Requirement for Hospital Outpatient Prospective Payment System (OPPS) Services**
  We urge CMS to withdraw the regulations establishing the use of prior authorization for OPPS services, due to its tenuous statutory authority and the clinical and access repercussions. (42 CFR § 419.80 - 419.83, established by 84 FR 61142, November 12, 2019) In 2020, CMS began requiring prior authorization for five categories of OPPS services, subsequently adding three categories of services in additional rulemaking for a total of eight services. This marked the first time CMS required prior authorization for hospital outpatient department services in Medicare fee-for-service. The use of prior authorization as a utilization management tool by payers often causes delays in patients' ability to receive timely, medically necessary care, imposes additional administrative burden on providers, and can result in increased costs for providers and patients. Furthermore, prior authorization in the Medicare FFS outpatient hospital context is not explicitly authorized by the Medicare statute. While the Medicare statute does clearly allow CMS to implement prior authorization for durable medical equipment, which CMS has done, the statute has no such reference to prior authorization in the OPPS.

- **Withdraw Proposed HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information**
  The HHS Office for Civil Rights should withdraw the proposed HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information. (RIN 0945-AA22, 90 FR 898, January 6, 2025) While we agree with the need for data security safeguards, we believe that the approach taken by Biden administration in proposing sweeping changes to the Security Rule was misguided, lacked a consensus-driven approach to consider feedback from all stakeholders, and grossly underestimated the costs associated with implementing the new safeguards. To that end, we call on the Trump administration to withdraw the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule and work collaboratively with stakeholders to

put forth requirements that will advance the shared goals of the administration and the private sector to protect patients' health information and prevent costly disruptions to the health care ecosystem.

- **Withdraw Information Blocking Disincentives Rule**
  We respectfully ask the agencies to withdraw the policy finalized in 2024 to impose Medicare payment disincentives on certain health care providers found to have committed information blocking. (89 FR 54662, July 1, 2024) CMS should withdraw the rule to support the critical real-world educational effort necessary to ensure that health care providers have a fair opportunity to self-correct and ensure their information sharing practices comply. Additionally, we call on the agencies to ensure that the investigative process and the right of appeal is fair and consistent across all actors regulated under the information blocking rules. Regarding the disincentives through CMS programs, we urge the agencies to adopt alternative approaches to reduce the significant financial impact and the outsized variance across different types of health care providers, where some providers will be penalized for the actions of another while others will see no reduction in Medicare reimbursement regardless of their conduct. An overly punitive approach could critically impact care delivery and reinvestment in value-based health care delivery for health systems. This would ultimately negatively affect patients and their families.

The AAMC appreciates the opportunity to submit these recommendations and we look forward to continued engagement with OMB and other federal agencies to advance efforts that reduce regulatory burden on the academic medical community. If you have any questions, please contact Heather Pierce, Senior Director Science Policy and Regulatory Counsel (hpierce@aamc.org) and Gayle Lee, Senior Director Health Care Policy and Regulatory Counsel (galee@aamc.org).

Sincerely,

Danielle P. Turnipseed

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