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July 14, 2025

Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again (AHRQ-2025-0001)

Dear Secretary Kennedy:

The AAMC (Association of American Medical Colleges) welcomes this opportunity to comment on the Department's "Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make America Health Again," 90 *Fed. Reg.* 20478 (May 14, 2025), seeking feedback on deregulatory initiatives to better promote the health and well-being of the American people.

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. We encourage HHS to consider the output of a current initiative from the National Academies, *Improving the Regulatory Efficiency and Reducing Administrative Workload to Strengthen Competitiveness and Productivity of U.S. Research.* This effort is expected to deliver a data-driven roadmap for regulatory reform this fall.[5]

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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).
[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).
[3] U.S. Gov't Accountability Off., GAO-16-573, Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements (2016).
[4] *Supra* Note 2.
[5] Nat'l Acads. of Scis., Eng'g, & Med., Improving the regulatory efficiency and reducing administrative workload to strengthen competitiveness and productivity of U.S. research (*forthcoming*).

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 provider burnout. Reducing providers' 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 sustained dialogue between federal agencies and the regulated community. As outlined in the AAMC's May 2025 letter to the Office of Management and Budget on reducing unnecessary regulatory burden (OMB-2025-0003), we emphasized the need for government-wide coherence in identifying and eliminating duplicative or outdated requirements that undermine efficiency across agencies. We also underscored the value of an evidenced-based approach to regulatory evaluation, one that improves efficiency while preserving the original intent and value of the regulatory framework.[6] To that end, we strongly recommend that any regulatory changes adhere to the Administrative Procedure Act's notice and comment requirements, which are essential to ensuring transparency, accountability, and meaningful public participation in federal rulemaking. Further, we urge HHS to establish an inter-agency framework for ongoing retrospective regulatory review, guided by defined criteria for prioritizing regulations for evaluation.

Over the years, the AAMC has identified numerous federal requirements that create a disproportionate burden on the regulated community without yielding clear benefits. The recommendations that follow reflect specific federal regulations we believe, in general, should be revisited, revised, or harmonized to reduce unnecessary burden and promote more effective and sustainable health care delivery and biomedical research systems.

Reducing Health Care Delivery Burden

Regulations that require an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively

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 HHS to invest in the infrastructure needed 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)

[6] AAMC, Comments on OMB's Request for Information on Improving and Modernizing Regulatory Review (May 2025).

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 on 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.

Eliminate Duplicative "Look Back" Validation Surveys of Accrediting Organizations and Permanently Adopt Concurrent Validation Surveys

Currently, CMS regulations include duplicative "look back" validation surveys of accrediting organizations (AOs) at 42 CFR § 488.9. As part of its oversight process, CMS conducts a full re-survey of hospital compliance with Medicare Conditions of Participation on a representative sample of hospitals each year, comparing each hospital's results with the most recent accreditation surveys. Instead of fulfilling CMS' goal of assessing AO performance, the validation surveys result in rework and disruption for hospitals and health systems. CMS should instead permanently adopt concurrent validation surveys that would allow the agency to directly observe AO performance.

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 the 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.

Reform Hospital Quality Performance and Reporting Programs

The AAMC is concerned with the considerable burden in hospital quality measurement and recommends CMS remove chart abstracted measures and structural measures from hospital quality programs to better maximize health care system resources for measurement that can drive meaningful quality improvements. Instead of chart abstracted measures and structural measures, CMS should focus on outcomes measurement. Chart-abstracted and structural measures require significant clerical effort, requiring hospitals to divert resources away from clinical care. 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 reflect a hospital's resources and interpretation of attested-to structures and documented activities. Removing these measures and instead prioritizing outcomes measurement would more effectively use resources to drive quality improvement and performance.

Removed Duplicative Measurement in Hospital Quality Performance Programs

The AAMC is concerned with the considerable burden in hospital quality measurement and recommends simplification by removing duplicative measurement across performance programs to better maximize health care system resources for measurement that can drive meaningful quality improvements.

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. Additionally, there is a growing concern with the budget-neutral design of MIPS under which the amount of funds available to reward superior performance cannot exceed the payment penalties imposed on clinicians for poor performance. This model design should be replaced with payment adjustments that are based on the Medicare Economic Index to account for inflation. The current program is too costly, requires reporting that is unnecessary, and diverts time away from 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 number 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)

Regulations that impose requirements on the wrong individual or group

Reconsider Price Transparency Rules to Avoid Duplication, Reduce Burden, and Ensure Patients Have Meaningful Information
The AAMC supports the goal to increase health care price transparency and strongly believes patients should have the information that they need to make informed decisions about their health care. We support patient access to consumer-friendly and personalized out-of-pocket cost estimates for shoppable services. Hospitals and health systems have invested considerable time and resources to comply with the Hospital Price Transparency Rule and the No Surprises Act. Many hospitals and health systems have embraced new technologies that enable patients to obtain tailored out-of-pocket cost estimates through online tools that can be very effective.

However, we have concerns with the administration's current approach to price transparency, which is overly burdensome and costly for health systems and hospitals, does not enable patients to understand what they will actually pay for a healthcare service, and has resulted in widespread confusion for patients. Hospitals and health systems and insurers are subject to several different price transparency policies, including:

- **Hospital Price Transparency Rule**. This rule requires hospitals to publicly post via machine-readable files five different "standard charges": gross charges; payer-specific negotiated rates; de-identified minimum and maximum negotiated rates; and discounted cash prices. It also requires hospitals to provide patients with a consumer-friendly display for at least 300 shoppable services, which can be satisfied by offering an online price estimator tool that provides personalized out-of-pocket pricing information.
- **No Surprises Act - Good Faith Estimates**. The No Surprises Act requires hospitals and other providers to share Good Faith Estimates with uninsured/self-pay patients for most scheduled services. "Convening providers" are required to seek and combine information on their price estimates from other unaffiliated providers involved in the patient's care to provide uninsured/self-pay patients with a single, comprehensive Good Faith Estimate of the cost for an episode of care.
- **Advanced Explanation of Benefits**. The No Surprises Act requires insurers to share advanced explanations of benefits with their enrollees. This policy has not been implemented yet due to

operational challenges. In the future, hospitals will need to provide Good Faith Estimates to health insurers under this policy.

- **Transparency in Coverage Rules**. These rules, which apply to health insurers and group health plans, require health plans to post three separate machine readable files (MRFs) each month that contain: 1) in-network negotiated rates for all covered items and services, 2) out-of-network allowed amounts and billed charges for all covered items and services, and 3) negotiated rates and historical net prices for covered prescription drugs.

Given the potential patient confusion and regulatory burden resulting from these multiple different price transparency rules, the AAMC urges the administration to review and streamline the existing price transparency policies.

The large amount of data that hospitals are required to provide results in machine-readable files that are so large that it is extremely difficult for patients to navigate to find "payer-specific negotiated charges" corresponding to their health plan issuer and health plan type. To provide context, many AAMC member-hospitals have contracts with over 100 different plans, often with multiple negotiated rates depending on the type of health plan (e.g., Medicare Advantage, HMOs, individual preferred provider organizations (PPO), self-insured plans), and therefore are required to include thousands of negotiated rates in the MRF. If patients are able to locate this information, they would still be many steps away from deriving a personalized estimate of their out-of-pocket costs due to their health plan's benefit design. In fact, CMS itself has acknowledged that MRFs are not intended for direct patient care use as they are not consumer friendly. Specifically, in the CY2024 OPPS final rule, CMS stated: "The MRF format is designed to be used by machines for further processing of the data and is not tailored for direct use by individual patients. In short, MRF formats are not consumer friendly."[7]

Ultimately, for patients the information that is most important and useful to them is knowing their financial obligation or out of pocket costs for the services they receive, which will be based on their insurance coverage. These out-of-pocket costs depend on their plan-specific cost-sharing requirements such as their deductible and co-pay amounts. Where patients are in reaching their deductible and total out-of-pocket spending amounts will impact their payment amount. Additionally, the patients' insurer may cover only a portion of the services and/or bundle some of the services in ways that do not "add up" to the negotiated rates from the provider. All of these specifics make up a health plan product's benefit design, and only the insurer is in a position to make this type of information available to the patient. Therefore, we believe that the information that the insurer is required to provide to the patient under the Transparency in Coverage rules may be much more relevant than any pricing information that providers would be able to deliver to the patient. For patients that are insured, actionable pricing information can be obtained via price comparison tools that insurers are required to make available under the Transparency in Coverage rules."

For patients that are uninsured/self-pay, the No Surprises Act requires hospitals and other providers to furnish the patient with a good faith estimate of their costs for the episode of care. Therefore, much of what is required under the hospital price transparency rule is unnecessarily redundant and burdensome.

Under the No Surprises Act Good Faith Estimates, Eliminate the Requirement that the Convening Provider Obtain Information About Charges from Unaffiliated Providers as it is Not Feasible to Operationalize

Provisions of the No Surprises Act and CMS regulations, effective Jan. 1, 2022, require, among other things, that all licensed healthcare providers must give "good-faith estimates" (GFEs) to uninsured/self-pay patients upon scheduling any service at least three days in advance, or upon request. (45 CFR §

[7] 88 FR 81540, at 82081 (Nov. 22, 2023).

149.610; Requirements Related to Surprise Billing; Part II, 86 FR 55980 [October 7, 2021]). The GFE requirements are in place now for uninsured/self-pay patients, with requirements for commercially insured patients on hold until further industry development of standards and additional CMS rulemaking. For uninsured and self-pay patients, the rule requires that the convening provider or facility contact all applicable co-providers and co-facilities no later than 1 business day after the request for the GFE is received or after the primary item or service is scheduled and the patient requests submission of expected charges for the items or services. Creating GFEs that include services providing by convening providers and other co-providers and co-facilities is challenging as providers and facilities need to establish systems and procedures for providing and receiving the required information from other providers and facilities. AAMC members report that it is difficult and costly to operationalize this process for the uninsured and self-pay patients. To create these GFEs, providers are having to implement new workflows (often manual) and communication channels to exchange information between providers in addition to having to purchase costly technology updates to support these processes.

To promote greater price transparency and give patients a reasonable expectation of the costs of planned treatment, the No Surprises Act requires health plans to deliver an Advanced EOB to patients prior to care delivery. (Public Health Service Act section 2799B-6, as added by section 112 of title 1 of Division BB of the Consolidated Appropriations Act [December 27, 2020]). The AEOB is created by insurers using good faith estimates (GFE) from providers in advance. We support this type of meaningful price transparency that aims to provide patients with reliable, personalized estimates of their out-of-pocket costs. We appreciate, however, that CMS has delayed enforcement of these provisions until a standard industry process for such information exchange can be adopted via regulation to ensure that these estimates can be created as efficiently and accurately as possible. When CMS moves forward with implementation in the future, we urge CMS to allow each billing provider to submit a GFE to the health plan for items and services that will be billed directly to the health plan for the patient and do not require the convening provider to obtain information about charges from other providers. The responsibility for combining the GFEs into one Advanced EOB should rest with the insurers. Since insurers already receive and process claims from distinct providers, it is unnecessary to require the convening provider to obtain the information about charges from other providers. Accurate Advanced EOBs could be best established by leveraging existing provider and health plan workflows and standards and technologies for claims submission and adjudication.

Regulations that carry excessive penalties

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 CMS to work with the HHS Office of the Inspector General (OIG) 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 CMS and OIG 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.

Regulations that impede access to delivery of care or services

Ensure Prior Authorization Requirements do not Limit Patients' Access to Care by Streamlining Processes and Coverage Criteria

Hospitals and health systems have numerous contracts with different insurance plans. Each of these plans include different clinical criteria for coverage, rules and processes regarding how to communicate requests for prior authorization and associated documentation requirements. To improve patients' access to care and reduce provider burden, these rules and processes should be streamlined. CMS has taken significant steps by finalizing rules scheduled to go in effect in 2026 and 2027,[8] that set forth requirements for standardized electronic prior authorization processes that will improve the exchange of information. We also appreciate HHS's work with insurance industry leaders to adopt a voluntary pledge to streamline and improve prior authorization processes for patients covered by Medicare Advantage, Medicaid managed care, health insurance marketplace and commercial plans.[9] We urge the Administration to ensure timely implementation and enforcement of these rules, and to continue ongoing discussions with payers, providers, and patients to ensure prior authorization does not hinder access to care.

Prohibit Restrictive Uses of Prior Authorization by Medicare Advantage Plans That Depart from Traditional Medicare Fee-for-Service

The use of prior authorization by MA plans continues to impact patient access to timely care. In contract year (CY) 2024, the agency adopted regulations explicitly requiring plans to adhere to original Medicare coverage criteria and limiting plans from adopting their own coverage policies unless Medicare policies were not fully established. Providers strive to deliver quality health care in an efficient manner. However, the frequent phone calls, faxes, electronic health record (EHR) connectivity with payer systems, and different forms that physicians and their staff must complete to obtain prior authorizations hinder efficient care. Rules and criteria for prior authorization must be transparent and available to the physician at the point of care. In addition, if a service or medication is denied in any event, both the patient and the physician should be given a specific reason for the denial, information about rights to appeal the decision, and other alternatives that may be covered (e.g., different medications). Medically necessary care should not be denied because a physician and/or patient cannot jump through complicated, opaque hoops.

According to Kaiser Family Foundation, in 2021, more than 35 million prior authorization requests were submitted to MAOs on behalf of MA beneficiaries. Of these, more than 2 million prior authorization requests were fully or partially denied. Just 11 percent of prior authorization denials were appealed, but of those a whopping 82 percent resulted in the initial prior authorization denial being fully or partially overturned. The burden to respond to these denials rests squarely on providers and contributes significantly to burnout. If the beneficiary is required to follow-up on the denial, they often forego care due to the complexities of filing an appeal. We support changes to reduce the number and burden of prior authorizations in MA. To meaningfully reduce the number of prior authorization requests, we encourage CMS to put in place a system that requires MA Organizations to submit to CMS the number of prior authorization requests and results (e.g., approval / denial) to allow CMS to accurately track the number of prior authorization requests and denials and identify abuse of utilization management tools.

Further, timely decisions are needed for prior authorization requests to ensure patients receive access to care in a prompt manner to address healthcare needs. As it currently stands, CMS requires MAOs, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to provide notice of prior authorization decisions no later than 72 hours after receiving a request for

[8] 89 FR 8758 (Feb. 8, 2024).
[9] HHS Press Office, HHS Secretary Kennedy, CMS Administrator Oz Secure Industry Pledge to Fix Broken Prior Authorization System (Jun. 23, 2025).

"expedited" decisions, and no later than 7 calendar days after receiving a request for "standard" decisions. These standards still create burden for providers needing to offer expedited care and could jeopardize a patient's access to necessary medical care. Faster response times to prior authorization for impacted payers would erode these barriers to care. We urge CMS to consider more timely requirements of 24 hours of receipt of a request for urgent items or services and 48 hours for non-urgent care decisions.

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.

Ensure Alignment in Care Management Services and Remote Mental Health Services by Allowing Hospital Staff to Provide Care Management Services Remotely

Under the Outpatient Prospective Payment System (OPPS) regulations at 42 CFR § 410.27(a)(1)(iii), mental health services provided to beneficiaries in their home are excepted from the requirement that incident to services be provided in the hospital or critical access hospital (CAH) or in a department of the hospital or CAH. However, CMS requires hospital staff providing care management services to be present in the hospital even when the patient is no longer there. In the last 10 years, CMS has developed codes and payment for care management services that are helpful to primary care physicians that treat patients with one or more chronic care conditions. While CMS can pay for these services under the OPPS under general supervision (meaning the physician does not need to be immediately available while the services are taking place), CMS' regulations continue to require the hospital staff (who may be furnishing the services through a contractor "under arrangements") to be present in the hospital even though the patient is no longer there. To ensure parity between remote mental health services and care management services provided remotely, CMS can revise 42 CFR § 410.27(a)(1)(iii) to add the following language after the words "communication technology:" "and care management services when the patient is not physically present in the hospital."

Expand Medicare Coverage of Telehealth and Communication Technology-based Services by Removing Outdated Restrictions

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 due to statutory language (Section 1834(m)(4)(C) of the Social Security Act; regulations at 42 CFR 10.78(b)(3) and (4)). 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. Specifically, we recommend the following: remove geographic site restrictions on telehealth; remove originating site restrictions to enable patients to receive telehealth in their homes; remove the in-person visit requirements for behavioral health telehealth (Sec. 1834 (m)(7) of Social Security Act and 42 CFR section 4180.78(b)(3(xiv).

Additionally, 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.

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.

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 these codes 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. Another barrier is guidance for CPT® code 99452 that 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 recommend the guidance 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.

Work with Model Participants to Improve the Mandatory Transforming Episode Accountability Model (TEAM)
TEAM, as a mandatory model, will require over 700 acute care hospitals to assume financial responsibility for post-procedural care through bundled payments for five types of surgical episodes, irrespective of whether it is feasible for the hospitals to implement the bundles. The model particularly targets hospitals with low levels of existing experience with voluntary episodic payment models, increasing the risk that participating in such a model could financially destabilize them, threatening access to care for everyone in the community. We encourage CMS to work with participating hospitals to improve model design to mitigate this risk, including by revising the pricing methodology, implementing a consistent, well-tested set of quality metrics for the duration of the model, and amending the primary care referral requirement to reduce burden on participating hospitals. Specific to the pricing methodology, we encourage CMS to ensure adequate risk adjustment for differences in costs between elective and non-elective procedures, to increase the lookback period for hierarchical condition categories, establish a low-volume threshold with no downside risk for hospitals that do not have sufficient volume to meet the threshold, and to use the Community Deprivation Index in addition to dual-eligibility status to apply a beneficiary economic risk adjustment factor.

Regulations that interfere with the ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans

Modify Stark Law and Anti-kickback Statute Regulations that Restrict Hospital and Health System Activity that is Beneficial to Patients and Communities
The Stark Law and associated regulations as well as the anti-kickback statute can impede arrangements that improve care delivery for patients. Historically, these laws impeded value-based arrangements involving care coordination, and we appreciated the steps taken by the Trump Administration as part of the "Regulatory Sprint to Coordinated Care" to encourage these value-based care arrangements through modifications to Stark. Even with these reforms, challenges still remain for hospitals and health systems that wish to undertake certain arrangements, preventing beneficial arrangements. We urge CMS to consider additional feedback from stakeholders on regulatory revisions that would help remove or mitigate obstacles.

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 the HHS can take to support a more efficient and harmonized 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[10] — 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.

[10] 21st Century Cures Act, H.R. 34, 114th Cong., Pub. L. No. 114-255, 130 Stat. 1033 (2016).

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.[11] To promote harmonization, we recommend that HHS convene a cross-agency working group to explore the development of a unified FCOI framework, including shared definitions, reporting thresholds, and interoperable disclosure timelines. A streamlined disclosure framework would minimize institutional burden while maximizing consistency and transparency in federally supported research.

Establish a Research Policy Board to Improve Regulatory 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 HHS to establish a permanent research policy board. This board would serve as a formal mechanism to bring together federal agencies and representatives from the regulated community to coordinate regulatory policy, reduce administrative burden, and promote transparency and consistency in oversight.

The current regulatory landscape for biomedical research is fragmented, complex, and often inconsistent across agencies, 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 overlapping or duplicative requirements that increase administrative workload on researchers and institutions, reduce research productivity, and dilute the overall effectiveness of the U.S. research enterprise.[12] Although the 21st Century Cures Act authorized the establishment of a research policy board, it has yet to be implemented. Notably, the AAMC has repeatedly supported this recommendation, including in our 2024 letter to Congress on the 21st Century Cures and Cures 2.0 Acts, in which we emphasized that a research policy board would "serve as a powerful tool in transparency and in reducing regulatory burden," and provide a trusted, structured forum for ongoing engagement between agencies and research institutions.[13] We urge HHS to prioritize the establishment of a research policy board in partnership with other federal agencies to advance regulatory coherence and reduce redundant requirements, thereby enabling a more nimble and efficient environment for scientific advancement.

Clarify and Align FDA Advisory Committee Conflict Standards to Improve Transparency and Efficiency

The AAMC recommends that the Food and Drug Administration (FDA) issue clear and final guidance to clarify the distinctions between statutory COI under 18 U.S.C. § 208(b) and the "appearance issues" under 5 C.F.R. § 2635.502 (commonly known as "Section 502"). We further recommend that FDA align its internal procedures for evaluating both and streamline the review process accordingly. 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.

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[11] AAMC, Comment Letter on Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration (2024).
[12] *Supra* Note 2.
[13] AAMC, Letter to Congress on Cures 2.0 and Research Policy Reform (Aug. 2, 2024).

Currently, the FDA uses two separate legal frameworks to assess 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).[14] While final guidance was issued in 2008 on the process for determining a COI under 18 U.S.C. § 208(b), the FDA has only released draft guidance for Section 502 —and that draft guidance has yet to be finalized. As the AAMC noted in its comments to the FDA, these distinctions are not commonly reflected in other federal COI regulations or practices. This lack of clarity leads to confusion and inconsistencies in disclosure and eligibility determinations. We encourage the FDA to finalize and consolidate its guidance on COI determinations, clarifying the application of both statutory and appearance-based standards. Greater clarity would greatly improve understanding of disclosure expectations, the rationale supporting eligibility determinations increase participation from qualified experts, particularly within the academic medical community.

Harmonize FDA's Single IRB Requirement with the HHS 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 the federal sIRB requirements established under the revised Common Rule (45 C.F.R. §46.114), and the NIH Single IRB policy. We also recommend a minimum two-year implementation period to evaluate the operational impact—whether additional guidance, exceptions, or flexibilities are warranted.

We appreciate the steps the FDA has already taken to promote harmonization and commend the agency for prioritizing alignment in areas where coordination is critical. However, the AAMC noted in its December 2022 comment letter on the FDA's proposed rule on cooperative research (Docket No. FDA-2021-N-0286), many institutions significant operational and logistical challenges in implementing existing sIRB mandates, often experiencing administrative burden without measurable 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 shared best practices, promotes coordinated oversight, and consistent guidance in the conduct of cooperative research.

The AAMC appreciates the opportunity to submit these recommendations and we look forward to continued engagement with HHS to advance efforts that reduce regulatory burden on the academic medical community to improve the health and wellbeing of all Americans. If you have any questions, please contact Heather Pierce, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org) and Gayle Lee, Senior Director, Policy and Regulatory (galee@aamc.org).

Sincerely,

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Cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

[14] U.S. Food and 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).