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July 14, 2025

The Honorable Robert F. Kennedy Secretary U.S. Department of Health and Human Services 200 Independence Ave. 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,

On behalf of AMGA, we appreciate the opportunity to comment on the Request for Information on Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again.

Founded in 1950, AMGA is a trade association leading the transformation of health care in America. Representing multispecialty medical groups and integrated systems of care, we advocate, educate, innovate, and empower our members to deliver the next level of high-performance health. AMGA is the national voice promoting awareness of our members' recognized excellence in the delivery of coordinated, high-quality, high-value care. Over 177,000 physicians practice in our member organizations, delivering care to more than one in three Americans. Our members are also leaders in value-based care delivery, focusing on improving patient outcomes while driving down overall healthcare costs.

In alignment with the directives set forth in Executive Order 14212 "Establishing the President's Make America Healthy Again Commission," and Executive Orders 14219 and 14192, which call on agencies to eliminate outdated, unlawful, or unnecessarily burdensome regulations that stifle innovation and impede effective care delivery, AMGA has identified several policies that warrant immediate reconsideration or repeal. The following sections outline specific Medicare regulations that fail to reflect contemporary clinical standards, impose unjustified administrative costs, or obstruct value-based care models. Reforming or eliminating these regulations would promote high-quality, patient-centered care by enhancing provider efficiency, supporting chronic disease prevention and management, and accelerating system-wide progress toward improved health outcomes and cost containment.

Three-Day Stay Requirement for Skilled Nursing Facility (SNF) Care (42 CFR § 409.30)

The longstanding Medicare requirement that beneficiaries must have a minimum three-day inpatient hospital stay to qualify for skilled nursing facility (SNF) coverage is outdated and misaligned with modern clinical practice. Enacted in 1965, this requirement reflected care patterns of an earlier era, when inpatient stays were substantially longer and transitional care was less structured. Today, advances in medicine and care coordination render the rule both

outdated and counterproductive.

Allowing providers to base SNF referrals on clinical judgment and patient needs, rather than an arbitrary inpatient duration, would ease unnecessary hospital utilization, streamline transitions to post-acute care, lower the risk of hospital-acquired infections and other complications, and generate system-wide cost savings. Notably, between 2014 and 2019, CMS tested a waiver of this rule under select Centers for Medicare & Medicaid Services Innovation Center models for Accountable Care Organizations (ACOs). These models demonstrated lower expenditures and improved outcomes when care teams could directly transition patients to SNFs without delay.¹

Eliminating the three-day stay requirement would align with priorities articulated in Executive Orders 14219 and 14192 by removing significant costs for Medicare that impede optimal care delivery, as well as reducing the administrative burden for providers and patients. Repealing this policy would reflect a broader commitment to aligning Medicare regulations with high-quality, patient-centered care delivery.

Annual Wellness Visit Documentation Requirements (42 CFR § 410.15)

The Medicare Annual Wellness Visit (AWV) is intended to promote preventative care by supporting the development of a personalized prevention plan and a comprehensive health risk assessment. However, current regulatory requirements around documentation and data formatting undermine this goal by prioritizing form over function. Specifically, CMS requires providers to re-document or reformat information, most of which already exists in the electronic health record (EHR), simply to meet prescriptive administrative standards. This approach places significant burden on clinicians without improving care quality or patient outcomes.

This regulation stands in opposition to administration priorities identified in Executive Orders 14219 and 14192, which direct federal agencies to eliminate unnecessary costs, reduce administrative complexity, and support innovation in care delivery. The AWV documentation rules exemplify the type of outdated regulation that imposes measurable costs with little to no public benefit.

Reforming AWV documentation requirements and promoting interoperability would reduce provider burden and better support the delivery of preventative care. CMS should consider updated guidance that focuses on the clinical substance of the AWV rather than its format, promote interoperability to reduce duplicative documentation, and refocus compliance efforts on rewarding quality care.

Provider Education in Dual Eligible Special Needs Plans (D-SNPs) (42 CFR § 422.107)

Dual Eligible Special Needs Plans (D-SNPs) are designed to coordinate care for individuals enrolled in both Medicare and Medicaid—one of the most vulnerable and complex patient populations. However, existing provider education requirements tied to D-SNP participation undermine this mission. These mandates are frequently duplicative, overly complex, and poorly aligned with clinical workflows.

Rather than enhancing integration, the current education requirements divert physician time away from direct patient care and impose compliance tasks that offer little practical benefit. This

¹ <u>https://www.cms.gov/priorities/innovation/dataand-reports/2023/snf-waiver-summary</u>

runs contrary to Executive Orders 14219 and 14192, which call for the elimination of such practices in favor of more efficient and patient-centered models of care. CMS should streamline D-SNP education requirements to focus on equipping clinicians with actionable information in simplified training formats as well as integrating relevant content into existing continuing education structures.

Support a National or Multi-State Licensing Framework for Clinicians

AMGA recommends that CMS and Congress work to create a national or multi-state licensing framework for healthcare professionals. The current state-by-state licensure model imposes significant administrative burdens on clinicians (particularly for multisite systems), telehealth providers, and clinicians participating in value-based care arrangements across state lines. This fragmented licensing infrastructure limits provider flexibility, delays onboarding, and creates unnecessary regulatory duplication.

A harmonized licensure framework would reduce credentialing delays, increase provider supply in shortage areas, and allow greater responsiveness during public health emergencies or disaster declarations. It would also enhance continuity of care for Medicare beneficiaries who relocate seasonally or reside in states different from their providers.

These commonsense reforms would allow providers to better combat the chronic disease and mental health crises across the nation in support of Executive Order 14212, while reducing private party costs with no clear public benefits, slashing regulatory burden, and promoting enterprise and entrepreneurship – principles outlined in Executive Orders 14219 and 14192. CMS should support interstate licensure compacts or other means of creating reciprocity for parallel licenses across states lines, and federal legislative action that facilitate provider mobility and expand access to care while preserving necessary quality and disciplinary standards.

Disincentives for Information Blocking (45 CFR § 171; RIN 0955–AA05)

Finalized under the Biden administration, the rule titled "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" seeks to promote health data sharing but does so through an overly punitive and flawed enforcement model. The regulation assigns enforcement responsibility across three distinct agencies—CMS, ONC, and OCR—without establishing a unified oversight framework. This fragmentation creates the risk of duplicative audits, inconsistent compliance expectations, and confusion among providers, all in direct opposition to the goals articulated in Executive Order 14192. Additionally, the rule imposes significant penalties without providing a reasonable pathway for corrective action, education, or technical assistance prior to enforcement. This type of approach raises concerns under Executive Order 14219, as it imposes substantial private-sector costs that are not clearly outweighed by public benefits and unjustifiably impedes innovation in interoperability and health information exchange. These penalties, in practice, discourage providers from proactively investing in new data-sharing tools out of fear of triggering unclear or unevenly applied enforcement mechanisms. HHS should revise the rule to streamline oversight through a single agency and emphasize provider support and remediation before penalties are levied. This shift would reduce unnecessary legal and administrative costs while improving adoption of interoperable systems—a central goal of the 21st Century Cures Act, this administration, and relevant Executive Orders.

Low-Volume Thresholds in MIPS and CMMI Models (42 CFR § 414.1305)

The low-volume thresholds established under the Merit-based Incentive Payment System (MIPS) and replicated in numerous Center for Medicare and Medicaid Innovation (CMMI) models were originally designed to reduce reporting burden for providers with minimal Medicare billing. However, these exemptions now undermine efforts to scale team-based, value-driven care by excluding large bands of the provider population from meaningful participation in quality programs. These low-volume threshold disproportionately impact providers in rural regions, as current regulations exempt providers billing less than \$90,000 annually, treating fewer than 200 beneficiaries, or furnishing fewer than 200 services per year.

With the maturation of standardized quality measures and widespread adoption of digital reporting tools, these exemptions are no longer justified and may in fact be counterproductive. They introduce inconsistencies in performance benchmarking, distort quality comparisons, and weaken the alignment of financial incentives across care teams. Eliminating or significantly lowering the low-volume threshold would promote equitable participation, reinforce value-based payment structures, and allow for more robust quality measurement across the Medicare program.

These changes directly align with Executive Orders 14219 and 14192, which call for deregulatory actions that eliminate unnecessary complexity and expand access to effective care models. A modernized approach would also be less burdensome overall, as current data systems make it increasingly feasible for even small-volume providers to comply with performance reporting requirements.

Prior Authorization Requirements in Medicare Advantage (42 CFR §§ 422.122, 422.568, 422.570, 422.572)

Prior authorization remains one of the most frequently cited administrative burdens in Medicare Advantage, with well documented downstream effects on both innovation and access to care. AMGA applauds recent commitments by commercial insurers alongside CMS to reform prior authorization, such as adopting electronic capabilities and limiting review timeframes—but urges CMS to codify these pledges in federal regulation to ensure consistent implementation.

For years, the prior authorization process has remained manual, opaque, and inconsistently applied across plans. This is particularly problematic for patients with chronic or complex conditions, who often face care delays due to repetitive documentation and unclear denial criteria. At the same time, providers are forced to devote substantial time and staff resources to navigating plan-specific requirements; resources that could otherwise be directed toward care delivery.

From a regulatory perspective, long-standing prior authorization practices impose significant costs on providers without commensurate public benefit, articulated by criteria five and six of Executive Order 14219. Further, the continued reliance on outdated processes is inconsistent with Executive Order 14192's call for modernization. HHS should take existing industry pledges further through setting explicit targets for the volume of services that should be excluded from prior authorization, and exempt high-performing providers—those with a strong track record of adhering to clinical guidelines—from certain prior authorization requirements altogether.

CMS should also mandate greater transparency in the criteria used by plans to evaluate

authorization requests. Codifying these insurance industry pledges which already apply to over 75% of the insured population is a commonsense way to create a powerful and timely accountability mechanism and scorecard for insurers. Expanding these obligations across the broader commercial insurance landscape would help ensure equitable protection for all beneficiaries. Together, these changes would improve care continuity, enhance system efficiency, and reduce administrative waste.

Fragmented Post-Acute Care Rules and Payment Models (IMPACT Act of 2014 and Related Regulations)

Post-acute care (PAC) delivery remains governed by a fragmented regulatory structure that varies significantly across care settings, including inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), long-term care hospitals (LTCHs), and home health agencies (HHAs). Each of these settings operates under distinct statutory authorities, assessment tools (e.g., IRF-PAI, MDS, OASIS), quality reporting requirements, and payment methodologies. This siloed approach creates an unnecessary administrative burden for providers who care for patients across multiple settings or support transitions between them. It also limits the ability to compare outcomes, reward efficiency, and allocate resources based on patient need rather than care setting.

These inefficiencies directly conflict with the aims of Executive Orders 14192 and 14219, particularly as they relate to reducing duplication, promoting infrastructure modernization, and supporting care innovation. CMS has a statutory foundation under the IMPACT Act of 2014 to harmonize these frameworks and has already made progress standardizing assessment data.

We urge CMS to accelerate the development of a unified, site-neutral PAC payment system that consolidates documentation, quality reporting, and payment rules. A harmonized model would not only simplify provider operations but also facilitate better patient outcomes, reduce costs, and encourage innovative care pathways. Additionally, a unified PAC delivery structure would be instrumental in advancing national goals around chronic disease management and care coordination under Executive Order 14212.

We thank you for your consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Darryl M. Drevna, senior director of regulatory affairs, at 703.838.0033 ext. 339 or at <u>ddrevna@amga.org</u>.

Sincerely,

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Jerry Penso, M.D., M.B.A. President and Chief Executive Officer, AMGA