AMCP
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July 14, 2025

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

Submitted electronically via regulations.gov

Re: AHRQ–2025–0001

Dear Secretary Kennedy:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) for the opportunity to provide comments in response to the "Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again" Request for Information (RFI) (AHRQ–2025–0001).

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

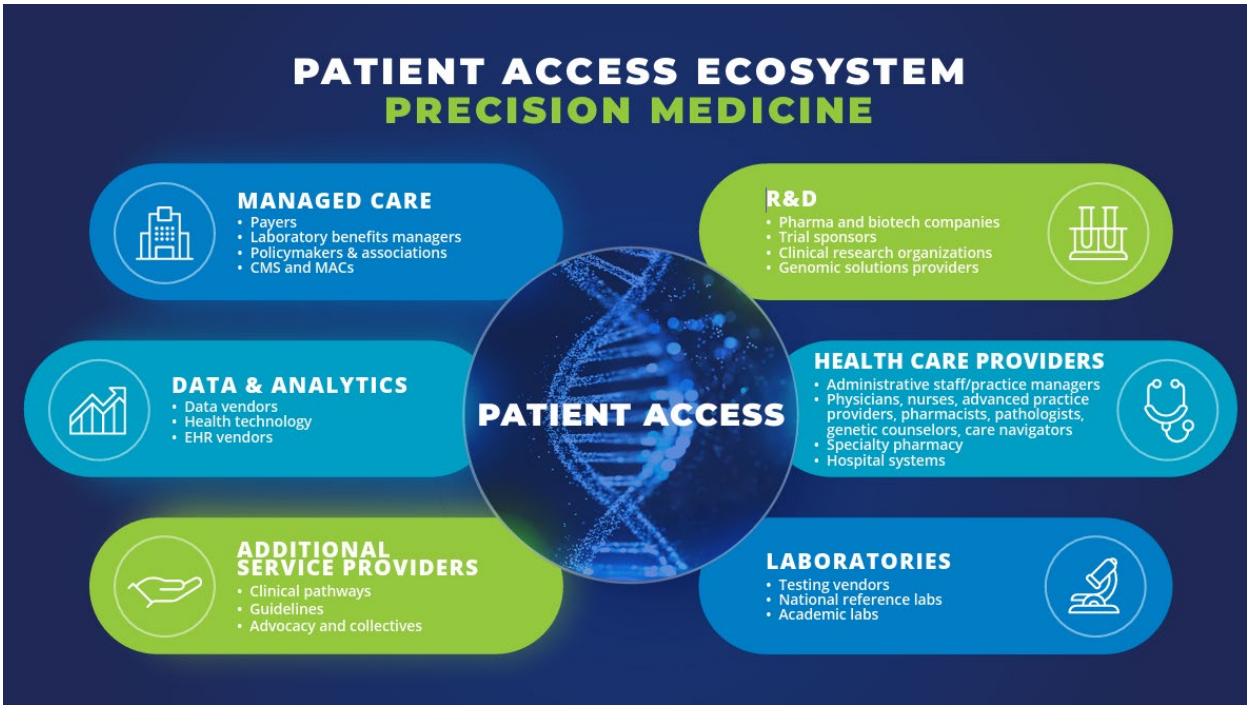
Precision Medicine

AMCP is working to ensure greater access to precision medicine—an innovative approach to healthcare that creates personalized treatment plans which incorporate "differences in people's genes, environments, and lifestyles."[1] Precision medicine has been used in common procedures like blood transfusions, but its application is rapidly expanding to other branches of medicine, such as oncology. Precision medicine is being increasingly adopted to guide the development of treatment options, improve treatment decision making, provide more patient-centered care, and better inform coverage and reimbursement decisions.

AMCP launched its Precision Medicine Initiative to support the broader implementation of precision medicine, to promote improved patient outcomes, and to better understand potential clinical practice gaps that may prevent patients from getting the right medication.[2] Through this initiative, AMCP is convening stakeholders across the precision medicine ecosystem and

[1] https://www.fda.gov/medical-devices/in-vitro-diagnostics/precision-medicine
[2] https://amcp.org/precision-medicine

developing solutions to help patients get the life-changing therapies they need. At the heart of AMCP's Precision Medicine Initiative is patient access to care.



The "14-Day Rule"

Through its Precision Medicine Initiative, AMCP has become aware of an issue impacting precision medicine which is caused by an unnecessary regulation on billing. AMCP urges HHS to reconsider and revise the regulation at 42 CFR § 414.510, referred to as the "14-day rule."

The 14-day rule prohibits independent laboratories from billing Medicare for molecular diagnostic tests if they are ordered within 14 days of the patient's discharge from a hospital. Hospitals often wait until after the 14-day window to order these tests to avoid billing complications, potentially leading to delays in treatment and worsened patient outcomes. Although the rule was intended to simplify billing, the unanticipated consequences have included diagnostic delays, increased administrative burdens on providers, and other barriers to the use of life-saving precision oncology tools. Enabling direct laboratory billing without this timeline restriction would ensure consistent access to precision diagnostics. This rule meets several of the criteria for regulatory reconsideration articulated in Executive Order 14219:

Regulatory Burdens and Statutory Concerns

The 14-day rule raises substantial concerns under EO 14219 subsections 2(iii) and 2(iv):

- (iii) Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition;[3] and

[3] EO 14219 § 2(iii) https://public-inspection.federalregister.gov/2025-03138.pdf

- (iv) Regulations that implicate matters of social, political, or economic significance that are not authorized by clear statutory authority.[4]

The 14-day rule prohibits the laboratory from billing for most molecular diagnostic tests, when they are ordered within 14 days of a hospital outpatient service unless narrow exceptions apply.[5] This policy deviates from the broader statutory billing framework established under the Medicare program and creates confusion and fragmentation in laboratory reimbursement.

The statutory framework governing Medicare payment for clinical diagnostic laboratory tests is set forth primarily in the Social Security Act[6] and authorizes payment for such services under the clinical laboratory fee schedule (CLFS). The statutes address a variety of reimbursement issues including the conditions and methodologies for laboratory reimbursement,[7] defining laboratory tests as covered Part B services,[8] and establishing a market-based rate-setting process for laboratory tests, including a category of Advanced Diagnostic Laboratory Tests (ADLTs).[9]

Notably, though, none of these provisions explicitly authorize or require the "14-day rule" framework codified at 42 CFR § 414.508, which was promulgated through regulation by CMS to coordinate payment with the hospital outpatient prospective payment system. The absence of direct statutory support for this rule raises concerns about whether it reflects the best reading of Medicare's payment authority and whether it exceeds the bounds of HHS's delegated discretion under the Social Security Act. For these reasons, AMCP urges HHS to reconsider this regulation.

Disproportionate Impact on Small Laboratories

The 14-day rule also directly implicates section 2(vii) of EO 14219, which calls for reexamining regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship.[10]

Smaller and independent laboratories face significant financial and operational hurdles under the current rule. Unlike hospital-affiliated labs or large national reference laboratories, many community-based and innovative diagnostic firms lack billing relationships with hospitals and are unable to absorb the delays or denials associated with the current framework. The rule imposes a disproportionate administrative and financial burden on these entities and may result in reduced competition, market consolidation, and fewer choices for patients and health plans.

Impediment to Innovation and Value-Based Care

Finally, the 14-day rule should be reconsidered because it meets the criteria of section 2(vi) of EO 14219 ("Regulations that harm the national interest by significantly and unjustifiably

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[4] EO 14219 § 2(iv) https://public-inspection.federalregister.gov/2025-03138.pdf
[5] https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/date-service-policy
[6] 42 U.S.C. § 1395l
[7] 42 U.S.C. §§ 1833(a)(1)(D), 1833(h), and 1833(i).
[8] 42 U.S.C. § 1395x(s)(3)
[9] 42 U.S.C. § 1395m-1
[10] EO 14219 § 2(vii) https://public-inspection.federalregister.gov/2025-03138.pdf

impeding technological innovation, infrastructure development, disaster response, inflation reduction, research and development, economic development, energy production, land use, and foreign policy objectives.").[11]

By shifting billing rights away from the party performing complex molecular testing, the 14-day rule introduces unnecessary friction that may discourage investment in novel diagnostic technologies. As the health system continues to move toward value-based models of care, laboratory innovation—especially in pharmacogenomics, oncology, and infectious disease diagnostics—is central to realizing improved outcomes and better targeting of therapeutic interventions. AMCP believes the current regulation impedes innovation and interferes with the broader goals of data-driven, precision health.

Recommended Action

AMCP strongly encourages HHS to consider the following actions:

1. **Reexamine the statutory basis for the 14-day rule**, with particular attention to whether the regulation exceeds or misapplies agency authority under the Social Security Act.

2. **Engage stakeholders** through a dedicated rulemaking process to evaluate the creation of a carve-out for molecular tests, allowing the performing laboratory to bill Medicare directly, with the date of service as the date the testing is performed, regardless of when or where the test is ordered.

3. **Issue updated billing guidance** to reduce disputes and clarify roles.

4. **Consider pilot demonstrations** to modernize molecular test billing in oncology.

AMCP applauds HHS' commitment to regulatory reform and urges HHS to prioritize modernization of laboratory billing rules that better reflect contemporary clinical practices and technological advances. Revising the 14-day rule would represent a meaningful step toward aligning Medicare payment policy with innovation and patient-centered care.

AMCP appreciates your consideration of AMCP's concerns and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer

[11] EO 14219 § 2(vi) https://public-inspection.federalregister.gov/2025-03138.pdf