ASSOCIATION FOR MOLECULAR PATHOLOGY

*Providing global expertise in molecular testing that drives patient care*
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June 9th, 2025

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostic industry. Our members are subject matter experts in laboratory science and are cognizant of the burdensome requirements from CMS.

Please note: While AMP typically submits formal comments, the venue of submission did not allow for a complete document to be submitted. The information below shows the questions posed in the RFI and AMP's responses.

**Topic 1: Streamline Regulatory Requirements**

1A. Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?

The use of prior authorization in Medicare Advantage (MA) plans is often incompatible with the practice of laboratory medicine and with how clinical laboratory tests are used to inform patient care. MA plans refer to the Medicare Part B date of service rule (42 CFR § 414.510(a)) and set the date of service to be the date of specimen collection rather than the date the test is performed by the clinical laboratory. If the treating healthcare provider who ordered the test did not seek prior authorization prior to ordering the test and/or collecting the specimen, then the clinical laboratory will attempt to get prior authorization once it receives the test order and sample. Unfortunately, MA plans will deny the claim because the date of service has passed by the time the prior authorization request is made. This regulatory catch-22 creates an unnecessary burden for clinical laboratories seeking prior authorization. AMP urges CMS to address this by amending 42 CFR § 414.510(a) to clarify that when clinical laboratories submit a prior authorization request, the date of service is the date the test is performed.

The date of service rule also says that tests performed within 14 days of sample collection must be paid via a bundled (DRG) fund. CMS already issued regulations to enable independent laboratories to bill for the test directly and separately from a DRG fund when the sample was collected during an outpatient encounter. However, the 14-day rule continues to prohibit independent laboratories from directly billing for their tests if the sample was collected in an

inpatient encounter within 14 days of the test being performed. This is the case even if the laboratory performing the test has no affiliation with the hospital providing the patient's care. This results in either the hospital paying for the tests through DRG funds or absorbing the cost entirely, which not only creates disincentives to order molecular tests during the hospital encounter, but could also lead to hospitals waiting until after the 14-day period to order tests to avoid this billing complication. Delays in patient access to these critical tests can lead to significant health concerns, especially in conditions where timely access to biomarker-driven treatment is critical such as in advanced cancer. It doesn't matter which type of encounter the sample was collected from; the molecular pathology test is the same. Thus, CMS should streamline the regulations to remove this unnecessary distinction and artificially created bureaucracy for these critical tests, align the 14-day rule policy to be consistent in both inpatient and outpatient encounters, and allow independent laboratories to bill for their tests directly no matter when or where the sample is collected.

1B. Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

1C. Are there specific Medicare administrative processes, quality, or data reporting requirements, that could be automated or simplified to reduce the administrative burden on facilities and other providers?

**Topic 2: Opportunities to Reduce Burden of Reporting and Documentation**

2A. What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

Enacted in 2016, Sec. 216 of the Protecting Access to Medicare Act (PAMA) modified the methodology used to set Medicare Clinical Laboratory Fee Schedule (CLFS) rates so that they would be based on commercial payor rates for laboratory services. Unfortunately, the implementation of this law has been greatly flawed. Issues with the process for reporting private payer payment data resulted in highly skewed data that only reflected the payments made to independent laboratories, which should only account for approximately half of all claims paid under the CLFS. CMS lacked payment data from clinical laboratories at hospitals, physician offices, etc., throughout the nation, and this resulted in greater cuts to payment rates than intended. The data reporting process established by CMS was also highly burdensome and complex, leading to numerous errors in the data provided to CMS.

The first year implementation of Sec. 216 of PAMA was so problematic that since 2019, Congress has passed legislation annually that further delays PAMA's reporting requirements and subsequent automatic payment cuts. Currently, commercial payor rates and volumes from 2019 are to be reported to CMS beginning on January 1, 2026. Basing payment rates on data nearly six years old is a highly flawed approach and CMS can take action now to reduce this reporting burden and associated consequences. Now is the time for CMS to correct this process

and AMP strongly requests that CMS work with Congress to identify and implement a permanent fix to this regulatory burden that includes:

- CMS should maintain current CLFS rates in 2026 and pause further reductions of up to 15% on 800 tests scheduled to begin January 1, 2026.
- CMS should change the next PAMA data collection period from January 1 – June 30, 2019, to January 1 – June 30, 2025.
- CMS should conduct an aggressive education campaign to ensure that all applicable laboratories are aware of their obligations under PAMA to report information to CMS for purposes of rate setting.

2B. Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?

2C. Are there documentation or reporting requirements within the Medicare program that are overly complex or redundant? If so, which ones? Please provide the specific Office of Management and Budget (OMB) Control Number or CMS form number. (Note: The OMB Control Number consists of two groups of four digits joined by a hyphen and it generally appears on the top right of the first page of a Medicare form and the CMS form number generally appears on the bottom left of the page of a Medicare form.)

**Topic 3: Identification of Duplicative Requirements**

3A. Which specific Medicare requirements or processes do you consider duplicative, either within the program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?

3B. How can cross-agency collaboration be enhanced to reduce duplicative efforts in auditing, reporting, or compliance monitoring?

3C. How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

**Topic 4: Additional Recommendations**

4A. We welcome any other suggestions or recommendations for deregulating or reducing the administrative burden on healthcare providers and suppliers that participate in the Medicare program.

The National Correct Coding Initiative (NCCI) Medicare Policy Manual contains conflicting guidance, which creates confusion with compliance with the requirement and payment denials. Specifically:

- Chapter X, Section A, CMS includes language stating a general rule that "if a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service." This instruction is overbroad and unclear, increases the use of miscellaneous or unlisted procedure codes, needlessly adds to the complexity of CPT coding, and decreases transparency in information on the tests performed and corresponding pricing. Further, it is inconsistent with the American Medical Association's guidance to use CPT® codes to the greatest level of specificity.

  To address this inconsistent and confusing guidance, AMP requests that CMS delete the following sentence from the manual: "If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service." Further, any other instruction in Chapter X that conflicts with AMA guidance on coding should be deleted.

- Section F.5 and current procedure-to-procedure (PTP) edits prohibit reporting code 81445 for a Genomic Sequencing Procedure (GSP) of 5 to 50 genes for a solid organ neoplasm together with code 81450 for a GSP of 5 to 50 genes for a hematolymphoid neoplasm. The edit does not permit these to be reported together under any circumstance, even with a modifier indicating that these are distinct procedural services. This suggests that a patient could not simultaneously have a hematologic malignancy and a solid tumor for which both tests may be medically necessary.

  To remove this barrier to performing two clinical relevant and necessary procedures, CMS should modify Section F.5 to allow these two codes to be reported simultaneously with a modifier.

- Section F.8 prohibits the use of multiple component codes when billing for a next generation sequencing (NGS) procedure and would force laboratories to use the unlisted molecular pathology procedure code if there is no code for the specific combination of markers comprising the procedure. The language contained within the last sentence of this section indicates that a single procedure must be reported using one HCPCS/CPT® code with one unit of service remaining. This guidance is inconsistent with instruction provided earlier in Section F.8. Moreover, this policy contradicts existing CPT coding guidance that states when all of the components of a descriptor are not performed, Tier 1 and Tier 2 codes may be used to describe genes using next generation sequencing. It also does not consider that laboratories may run larger panels for operational

efficiencies, but actually report only those specific tests actually ordered for a particular patient. Laboratories should be permitted to bill for testing as ordered and consistent with coverage policies, even if it is operationally more efficient for the laboratory to perform such testing as a broader panel.

To address this regulatory burden, CMS should delete Section F.8 in its entirety.