CANCER PRECISION MEDICINE COMMONS CMS COMMENT (14 DAY RULE)

WEB FORM:

https://www.cms.gov/medicare-regulatory-relief-rfi

REQUEST FOR INFORMATION BACKGROUNDER:

Request for Information: Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information

While the Cancer Precision Medicine Commons recommends the term “biomarker testing” for communication with patients and caregivers, the term “molecular testing” is used in our comments as that is more commonly referred to within CMS rulemaking.

1) Streamline Regulatory Requirements

- **1.1** 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?

GENERAL: YOUR ORGANIZATION NAME

YOUR ORGANIZATION NAME is a national/regional nonprofit organization committed to improving outcomes for individuals impacted by CANCER TYPE. Thank you for the opportunity to respond to this RFI on reducing regulatory burden.

SUMMARY OF THIS REQUEST

We urge CMS to substantially modify the "14 Day Rule" with regard to laboratory tests. This rule creates a unique crisis for cancer patients, by blocking payment for molecular testing on inpatient surgical specimens until the test is ordered at least 14 days after inpatient discharge. No other service – such as imaging or physical therapy or drug administration – is blocked from payment in the weeks following discharge of the patient from the hospital.

What should CMS do? CMS should modify the regulation at 42 CFR 410.508, so that the date of service for a molecular pathology test is the date of test performance, for inpatient cancer specimens. This establishes parity for molecular testing of inpatient specimens (currently badly delayed) and outpatient cancer specimens (currently paid based on the date of test performance).

ANSWER TO QUESTION 1.1

The molecular test date of service rule (at 42 CFR 410.508) should be modified, and this will greatly reduce burdens and delays for Medicare patients with cancer. Currently, molecular testing can be performed on outpatient cancer specimens and billed based on the date of test performance. The test is billed by the laboratory that performs the test.

However, for inpatient specimens, the same tests are bundled and nonpayable, not just during the hospital stay, but until over two weeks later, after discharge. This is because the test on an inpatient specimen does not become payable unless ordered by the doctor at least two weeks after patient discharge.

Modifying the rule so that all molecular tests are billed by the date of test performance will improve patient outcomes by allowing faster access to crucial genomic information that guides therapy selection.

- **1.2** Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

Regulation 42 CFR 410.508 governs the assignment of the "date of service" of the test. If this falls during a hospital inpatient or outpatient stay, the test is bundled (not payable). The regulation creates a fictional world where the "date of service" of the test may be weeks in the past. Common sense provides that the date of service should generally be the date of test performance.

- **1.3** 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 providers?

Yes, simplifying the laboratory test date of service rule will reduce difficult and confusing manual judgments and calculations by billing staff. This would streamline workflows, reduce the need for workaround solutions, and ensure consistent access to precision diagnostics.

2. Opportunities to Reduce Administrative Burden of Reporting and Documentation

- **2.1** What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

Simplifying the billing framework for molecular testing by eliminating the 14-day rule would reduce redundant documentation and provider confusion. Laboratories and providers currently expend resources managing test ordering windows and duplicative test requests due to unclear or delayed billing authority.

- **2.2** Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?

Enabling direct lab billing without timeline restrictions would reduce the need for repeated test orders after the 14-day window, a practice that increases documentation volume and introduces the risk of conflicting results. A clear, consistent policy would eliminate rework and ease burdens on care coordination staff.

- **2.3** 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.

While not linked to a specific OMB form number, the 14-day rule indirectly leads to duplicative billing entries, redundant test requisitions, and added compliance reviews by hospital finance teams. This occurs via the creation and handling and auditing of hospital inpatient and outpatient claims, and comparison to other records, such as the date of inpatient surgery at another institution (other than the performing laboratory). Eliminating the rule would reduce the volume and complexity of such burdensome processes.

3. Identification of Duplicative Requirements

- **3.1** 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)?

The 14-day rule creates duplicative workflows by requiring hospitals to act as intermediaries in lab test billing, despite those labs operating independently. It also duplicates oversight efforts across hospital billing, lab compliance, and Medicare MACs.

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

Cross-agency collaboration could be improved by creating a unified billing policy for molecular diagnostics that applies across care settings, eliminating the need for differential treatment of inpatient vs. outpatient specimens. Similar rules can be applied across Medicaid, traditional Medicare, and Medicare Advantage. Audits by multiple bodies (such as internal compliance staff, Medicare MAC staff, and program integrity staff) can be eliminated as there is no confusing rule to audit.

- **3.3** 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?

This is one of the most important questions with regard to our request. Aligning Medicare policies with current best practices in precision oncology would recognize the crucial importance of rapid, streamlined access to molecular testing. Hospitals and labs have already invested in coordinated biomarker testing workflows; Medicare policy should enable, not disrupt, those systems.

4) Additional Recommendations

- **4.1** 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.

We have answered each question in sections 1, 2, and 3. We use Section 4 to provide readers with a single discussion of the problem, its cause, and its solution, as well as the benefits of reaching a solution.

SUMMARY OF COMMENTS ABOVE

YOUR ORGANIZATION NAME respectfully urges CMS to revise the Medicare 14-day rule, which prohibits independent laboratories from billing Medicare for molecular diagnostic tests ordered within 14 days of a patient's hospital inpatient discharge. Originally intended to simplify billing, this rule now causes delays in diagnosis, burdens providers, and impedes the timely use of life-saving precision oncology tools. The level of impact and dysfunction has grown, as the need for rapid molecular testing has grown.

Under the current rule, hospitals must pay for such cancer molecular tests from DRG funds or absorb the cost entirely. This creates strong disincentives to order molecular testing during the hospital encounter, leading to delays in treatment and worse outcomes. Hospitals often wait until after the 14-day window to avoid billing complications—contrary to the urgent, coordinated timelines required for modern cancer care. CMS itself has created this disincentive and time-consuming workaround, since tests ordered on the 14th day after discharge are payable.

For patients with non-small cell lung cancer (NSCLC)—85% of lung cancer cases—comprehensive biomarker testing is essential to determine eligibility for targeted therapies. Delays in testing result in suboptimal treatment selection. A JAMA Network Open study found that only 60.5% of eligible NSCLC patients received comprehensive biomarker testing, and that delays were associated with reduced survival (Kehl KL et al., 2021).

In September 2023, the Cancer Precision Medicine Commons, a coalition of patient advocacy, professional societies, and hospitals, surveyed 75 healthcare professionals across 23 states and Washington DC on barriers to biomarker testing. 44.9% report delays in ordering biomarker tests due to the 14 day rule, affecting a significant number of patients. (Understanding Barriers in Access to Biomarker Testing and Genetic Testing for Inherited Risk/Genetic Testing for Inherited Mutations, Selig W. et al. June 2024, Patient Centered Laboratory Utilization Guidance Services Summit)

In short, the 14-day rule:

- Discourages timely test ordering during hospital encounters.

- Creates payment delays and financial disincentives.
- Leads to redundant test orders, delayed care, and administrative waste.
- Diverts staff from patient-facing care to complex billing management.

We recommend that CMS:

1. Create a carve-out for molecular tests, allowing the performing lab to bill Medicare directly regardless of when or where the test is ordered.
2. Issue updated billing guidance to reduce disputes and clarify roles.
3. Consider pilot waivers or demonstrations to modernize molecular test billing in oncology.

CANCER NAME is aggressive and time-sensitive. The 14-day rule has become a policy relic misaligned with precision medicine and clinical best practices. Revising it will reduce administrative burden, improve care coordination, and save lives.