AMERICAN SOCIETY OF HEMATOLOGY
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Unleashing Prosperity Through Deregulation of the Medicare Program – Request for Information: American Society of Hematology Comments

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

General Comments

The American Society of Hematology (ASH) appreciates the opportunity to provide information and comments on the Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information. ASH represents more than 18,000 clinicians and scientists who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. Our mission is to foster high-quality, accessible care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

ASH offers comments with the perspective that the well-being of Medicare beneficiaries should be at the forefront when developing policy that eases the burden of administrative tasks throughout the healthcare system. The Society encourages policymakers to ensure that changes in regulatory requirements do not compromise the delivery of appropriate and timely patient care. Any changes made should be for the betterment of patient care, while simultaneously relieving administrative and regulatory burden for the physicians and other providers who care for patients.

Additionally, we note that when regulations are promulgated by government agencies, like the Centers for Medicare & Medicaid Services, the regulatory comment period provides an avenue for expert and stakeholder input. As the administration navigates deregulation, ASH appreciates this same opportunity to comment and provide insight and guidance about how proposed changes or revisions may impact the ability of our members to care for patients before regulations are changed or rescinded.

Streamline Regulatory Requirements

The Medicare Laboratory Date of Service Rule:

The Medicare Laboratory Date of Service, or 14-day, rule refers to a billing policy under which certain laboratory tests ordered in connection with hospital outpatient services must be billed by the hospital, and not the performing laboratory, when the test is performed within 14 days of the patient's hospital outpatient discharge. Of the many regulatory burdens placed on hematologists, the 14-day rule continues to have an outsized negative impact on the timely diagnosis and management of patients with complex hematologic conditions, including leukemias, lymphomas, myeloproliferative neoplasms (MPNs), and bone marrow failure diseases.

Many hematologic malignancies require molecular and cytogenetic testing for accurate diagnosis and subsequent treatment selection. These tests are often ordered after a patient has had an outpatient encounter, like a bone marrow biopsy. The sample is then sent to an independent laboratory for testing. However, according to the 14-day rule, if the test is performed within 14 days of a hospital outpatient visit, the clinical laboratory is prohibited from billing Medicare directly. The 14-day rule

disincentivizes laboratories from performing the test in a timely manner given they will not be able to bill Medicare directly and receive timely reimbursement. This creates barriers to accessing essential diagnostic tests, potentially delaying diagnosis and treatment. Hematologic diseases can progress rapidly, and any delay in diagnosis could have a profound impact on patient outcomes. The 14-day rule undermines coordinated care models by introducing billing obstacles and communication challenges between hospitals, laboratories, and physicians, further complicating continuity of care for patients.

The billing and administrative complexity introduced by the 14-day rule places undue burden on physicians and their staff who have to navigate the complex payment rules associated with the policy. The complexity of this rule also leads to unnecessary delays in payment, leads to time-consuming resubmission of claims, and adds increased cost to care delivery while potentially interfering with patient outcomes.

Finally, the patients ASH members treat are often elderly and immunocompromised, and conducting a timely diagnostic test is critical to reducing hospitalizations and ensuring appropriate therapy selection. The delays and confusion created by the 14-day rule may disproportionately impact the Medicare population, many of whom are already navigating a complex, fragmented, and burdensome healthcare system.

The Society understands that there are exceptions to the 14-day rule that include advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests, however there are still many essential laboratory tests that may be captured under the rule. ASH suggests that CMS consider revising the 14-day rule to allow the performing laboratory to directly bill Medicare for tests ordered in connection with outpatient services. Revising the 14-day rule will reduce administrative complexity, improve timely and appropriate reimbursement, and most importantly, enhance access to critical diagnostic services for patients with hematologic conditions.

Telehealth:
Telemedicine plays a critical role in the practice of hematology. ASH views the use of telehealth services as a workforce multiplier that creates additional points of access to care at a time when there is a shortage of hematologists. The use of telehealth services allows Medicare beneficiaries to receive care and follow-up in their homes or other sites of service while decreasing unnecessary and burdensome travel.

Since the COVID-19 pandemic, the originating site and geographic site restrictions have been waived either under a public health emergency or through an act of Congress. We recognize that congressional intervention is needed to eliminate the originating site and geographic restrictions, but the administration should do everything possible to limit the burden of these requirements until Congress permanently removes them. The removal of these regulations will allow greater access to care to Medicare beneficiaries, while saving time and money for healthcare providers and patients.

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Opportunities to Reduce Administrative Burden of Reporting and Documentation

Prior Authorization:
ASH believes that prior authorization is one of the single most burdensome exercises within the healthcare system. Prior authorization requires an inordinate amount of physician and clinical staff time, is directly responsible for endless paperwork, and contributes to physician burnout, while leading to excessive costs, delays in treatment, and beneficiary dissatisfaction. Prior authorization, while intended as a tool to ensure that care is medically necessary, meets certain standards, and controls costs, frequently creates needless barriers to patients accessing timely and medically necessary care. Additionally, the extraordinary administrative burden often requires that physicians and physician group practices hire additional nursing and administrative staff dedicated solely to managing prior authorization paperwork. This additional staff leads to increased costs for providers, which then may be passed onto patients.

Hematologists report that prior authorization creates undue administrative burden. For example, there are several direct oral anticoagulants (DOACs) available to patients for the treatment of venous thromboembolism, which includes deep vein thrombosis, and pulmonary embolism, all of which are common conditions in the Medicare population. But, unfortunately, access to lifesaving drugs to treat venous thromboembolism, an acute and time sensitive hematologic event, is often delayed due to prior authorization policies. There may be many reasons why one DOAC is preferred over another, including the consideration of comorbidities such as renal insufficiency, liver disease, antiphospholipid syndrome, obesity, and bleeding risk. Decisions involving medication choice are based on clinicians' expertise, scientific evidence, as well as patient preferences and values, and those decisions are made through a shared decision-making process between the patient and the physician. The use of prior authorization, however, interferes with the physician-patient consultation and takes considerable time away from patient care.

The Society recommends that prior authorization be standardized across three of the healthcare programs administered by the government including Medicare Advantage, Medicaid, and the plans sold through the Health Insurance Marketplaces. Standardization of the prior authorization process for these programs would alleviate the administrative burden of navigating the varied submission requirements, criteria, and interfaces used by providers for prior authorization requests. When requesting coverage for a service, documentation guidelines should be the same regardless of the health plan. Standardized documentation guidelines could help alleviate the burden of understanding and navigating varied documentation criteria for each type of plan. Creating continuity could be achieved through an electronic interface, thereby eliminating burdensome and time-consuming prior authorization processes, which will begin to address the problems faced by providers.

Step Therapy:
Step therapy, also known as fail first, is a type of utilization management tool used by health insurance plans to control the use of high-cost medications. Step therapy requires patients to try one or more lower-cost or preferred medications, often generics, before an insurance plan will cover the more expensive or non-preferred drug prescribed by a health care provider. The use of step therapy,

however, is administratively burdensome not only creating endless paperwork for providers, but it also slowing access to clinically appropriate medication or therapy. Hematologists prescribe the most

appropriate medication based on several factors including age of the patient, comorbidities, allergies to medications, and tolerance to active ingredients. Step therapy often gets in the way of the collaborative physician-patient partnership by requiring a patient to first use what may be a clinically inappropriate medication, delaying access to the right drug at the right time for the right patient. This delay in access can lead to devasting effects including disease progression which may hasten death.

ASH recommends a standardized and streamlined process for exceptions and appeals to insurance plans that use step therapy. One of the priorities of the Trump administration is to alleviate overly burdensome and redundant processes. Streamlining step therapy protocols by mandating a standardized electronic prior authorization and step therapy override processes with clear clinical criteria and required response times would meet this goal.

For example, to override the step therapy process and allow patients to have access to the drug prescribed by their physician, exceptions criteria could be built into the electronic authorization process. Exceptions to requiring a patient to try a fail-first drug may include: the required fail-first drug is contraindicated or ineffective for the patient's condition, the patient has already tried and failed the preferred drug, or the preferred drug would likely cause harm to the patient. Other exceptions should include instances when a patient is stable on their current medication, making a fail-first requirement unnecessary, or when the preferred drug may interfere with daily functions due to undesired side effects.