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September 12, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via Regulations.gov

Re: CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1832-P)

Dear Administrator Oz,

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) proposed rule for CY 2026. We appreciate this opportunity for public review and submission of comments on proposed payment policies. Stakeholder feedback is vital to ensuring that proposed policies support the delivery of high-quality care without unintended consequences, while providing adequate payment for the services provided by our members.

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 care, transformative research and innovative education to improve the lives of patients with blood and bone marrow disorders. With these goals in mind, we provide comments on the following policies of importance to hematologists and their patients:

- Conversion Factor for 2026
- Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential
- Proposed Efficiency Adjustment
- Potentially Misvalued Services Under the Physician Fee Schedule
- Payment for Medicare Telehealth Services under Section 1834(m) of the Act
- Request for Information on Prevention and Management of Chronic Disease
- Autologous Cell-based Immunotherapy and Gene Therapy Payment
- Status Indicator for CPT® Code 38228 – *Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*

Conversion Factor for 2026
2026 marks the first year that there are two separate conversion factors: one for practitioners working in a qualifying advanced alternative payment model (APM) and the other for those not participating in a qualifying APM. The conversion factor for the former will increase to $33.59, an increase of 3.83%, and the conversion factor for the latter will increase to $33.42, an increase of 3.62%. These increases reflect the 2.5% adjustment to the 2026 conversion factor included in the *One Big Beautiful Bill Act* recently adopted by Congress.

Understanding that updates to the conversion factor require an act of Congress, the Society appreciates the positive increases as outlined in the proposed rule. The Society recognizes that the positive updates to the conversion factor are a step in the right direction, but has concerns that when the proposed payment policies in this rule are implemented altogether, namely the efficiency adjustment and changes to the practice expense payment for services performed in the facility setting, the policies will negate any much needed gains from the updated conversion factor. The Society would be remiss if we did not elevate these concerns after 30 years of stagnating reimbursement. The Society will provide detailed comments on the efficiency adjustment and changes to the practice expense payment further on in this letter.

Additionally, we encourage the agency to continue exploring permanent solutions for updating the yearly Medicare physician payment rate. Physicians have experienced more than 30 years of flat payments and in some years even negative adjustments to the conversion factor. Meanwhile, other payment systems under the Medicare program receive annual inflationary updates. As we have noted in prior comment letters, providing payment rate increases to hospitals, skilled nursing facilities, outpatient centers, and ambulatory surgical centers while withholding comparable updates for the physicians who furnish care in those settings is unjustifiable. The healthcare system needs physicians to deliver care to Medicare beneficiaries. The agency must work with Congress to create a permanent sustainable payment solution for physicians paid under the Medicare program.

Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential
CMS proposes to change the methodology for the allocation of indirect practice expenses (PE), which cover rent, utilities, staff salaries, within the physician payment formula. As described in the rule, "for each service valued in the facility setting under the PFS, we propose to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to nonfacility PE RVUs beginning in CY 2026." According to the agency, this proposed change will reflect the current state of clinical practice given that there are fewer physicians working in private practice settings, and therefore, "the allocation of indirect costs for PE RVUs in the facility setting at the same rate as the non-facility setting may no longer reflect contemporary clinical practice."

The Society recognizes that physician practice ownership patterns have changed since the inception of the Medicare PFS. However, reducing the PE portion of the physician payment formula is not a sustainable way to address concerns around consolidation. As proposed, this policy reduces reimbursement for hospital employed physicians as well as for private practice physicians who may perform procedures in a facility setting. This proposed reduction may therefore lead to greater consolidation due to lower payment rates for services provided.

In fact, physicians providing services in the facility setting may continue to incur indirect PE costs (rent, utilities, staff salaries) at the same rate as for services provided in the non-facility setting, and, based on feedback from ASH members, we believe that there is no set standard for how facility-based physicians might pay for these indirect costs. ASH members have directly shared that even though their practice is physically located within the hospital, they must still pay rent for their office space and the salaries of their support staff. Additionally, scheduling a service or surgery to be performed in the facility setting consumes more time and resources than scheduling the same procedure in the physician office setting, requiring the coordination of operating room availability, nursing and surgical assistant staff, and physician availability. This scheduling activity equates to indirect costs that the physician bears and therefore cutting payment for indirect costs would again impact physicians' ability to care for patients.

ASH urges CMS not to finalize this policy as proposed. Instead, ASH requests that CMS provide the empirical data and associated methodology that was used to support this policy. If no such data exists, the Society recommends that the agency delay this proposal until such time that CMS can collect and provide the data and methodology for public review and comment. If this policy is finalized, we urge CMS to minimize the financial disruption to physician practices by phasing implementation over a four-year period as the agency has done in the past with other impactful changes to the PE methodology.

Proposed Efficiency Adjustment

For the first time, CMS proposes an efficiency adjustment to reduce the work RVUs and intraservice physician times for non-time-based services reducing reimbursement based on the rationale that physicians who perform these services become more efficient over time. Specifically, CMS proposes to apply an efficiency adjustment of -2.5% to the work RVUs and intraservice time for nearly all services on the MPFS including procedures, radiology services, and diagnostic tests. The adjustment would not apply to time-based services, including evaluation and management (E/M) visits, behavioral health services, maternity global codes, and care management services.

The Society acknowledges that our members primarily report services that are time-based, including E/M services, and thank the agency for excluding these services from this proposal. However, the Society does not support the proposal because hematologists also provide critical services that would be subject to the proposed efficiency adjustment. Some treatments may not be structured in a way where efficiencies can be gained over time, while other diagnosis services may be impacted by scientific innovations and an abundance of new information.

For example, bone marrow transplants are vital, lifesaving interventions that are quite often the last chance for a Medicare patient suffering from leukemia, lymphoma and other life-threatening hematologic disorders. Bone marrow transplants are performed by hematologists, and we note that even with technological advances, bone marrow transplant procedures are not necessarily becoming more efficient. There are required steps involved for a patient preparing to receive healthy marrow, including conditioning the body using chemotherapy. This step takes time and oversight, and infusing chemotherapy must be performed correctly for the patient to move forward with a transplant. Cutting reimbursement for these procedures by -2.5% will have a profound effect on access to care.

Additionally, for diagnostic services, there are thousands of data points available to hematologists from electronic health record chart notes to genetic tests, blood tests, and other data requiring interpretation. All this data requires time, expertise, and the attention of hematologists to interpret and to make sound medical decisions regarding the treatment of their patients.

While the Society agrees that there may be efficiency gains to some procedures over time, based on the above examples, we refute that technology necessitates efficiencies. ASH requests that CMS define what it means to be efficient for non-time-based services. Additionally, ASH requests that the agency share the empirical data and associated methodology used to support this proposal for public review and comment.

The agency also seeks comment on using the Medicare Economic Index (MEI) to arrive at the -2.5% adjustment; ASH does not support the use of the MEI to arrive at a 2.5% payment reduction to non-time-based services. The agency indicated in the proposed rule that there is a similar productivity adjustment policy as is outlined in this proposal that is already applied to the inpatient and outpatient payments systems. However, these other Medicare payment systems notably also receive an inflationary update based on MEI. Our Society believes that using the MEI to arrive at the -2.5% proposed efficiency adjustment is not appropriate given that physicians do not also receive an inflationary update. Penalizing physicians with a productivity adjustment is therefore not comparable to what occurs under the Medicare Inpatient Prospective Payment System and the Hospital Outpatient Prospective Payment System. Additionally, the agency proposes to revisit the rate of the payment adjustment every three years, but this methodology does not include a floor, which means that at some point, with continued reductions to the work RVU and intraservice time, the RVUs would approach zero. Even with efficiency gains, procedures will always require some physician work.

CMS also proposes to apply the efficiency adjustment to all recent RUC reviewed services. The agency argues that when a code is reviewed by the RUC, two to three years usually pass between the collection of the survey data and its

use by CMS in setting rates. CMS' annual deadline for proposed rule consideration is February 10 and the MPFS proposed rule is released annually at the beginning of July with an effective date of January 1 the following year. Therefore, we note that the oldest data in a given cycle is less than two years old and in some instances is closer to one year old. It would be difficult for data to be any more current given the constraints of the agency's rulemaking cycle.

The agency has asked for comments on alternative methods to value physician services. The Society has previously advocated that CMS appropriately value E/M services. Understanding that the efficiency adjustment is not applied to E/M services, we do believe more can be done to more accurately value E/M services. We would support the use of time and motion studies that would accurately capture the time and work required for E/M services, procedures and other services on the MPFS. Additionally, chart note time stamps are another tool that may inform the value of office visits. However, this method would not capture work performed outside of the patient visit.

Altogether, these proposed reductions to physician payment are counterintuitive to the goals of an administration that wants to reduce the burden of chronic diseases. As mentioned in the above comments on the conversion factor, the creation of the efficiency adjustment coupled with cutting payment for indirect PE costs negates the statutory 2.5% update to the conversion factors. We are therefore concerned that the agency continues to search for ways to cut physician payment when there are proven physician workforce shortages throughout the US, particularly in the field of hematology.[1] Without an adequate physician workforce, patients living with chronic conditions cannot access medically necessary care to treat their conditions and prevent the development of others. Many physicians have chosen to leave the profession entirely or to eliminate Medicare patients from their panels due to continued Medicare payment reductions. ASH is concerned that this policy and further reductions in physician reimbursement for Medicare services will have a detrimental impact on the physician workforce as well as access to care; reduced reimbursement will lead to growth in attrition rates for the physician workforce and physicians who do continue to practice may not be able to continue serving Medicare patients.

The Society recommends that CMS not finalize the efficiency adjustment. Instead, we recommend the agency work with medical professionals to develop time and motion studies for high volume procedures to determine if there are or have been any efficiency gains over time. We believe the agency needs empirical data to support this policy. Additional data points may be captured by analyzing EHR data that includes time stamps for E/M visits and even some procedures. Finally, if the agency were to finalize the efficiency adjustment proposal, it should not be implemented until such time that an annual MEI inflationary adjustment is applied to the MPFS.

Potentially Misvalued Services Under the Physician Fee Schedule

Mechanical Separation of Plasma from Blood (CPT® code 36514)

An interested party has nominated CPT code 36514 (*Therapeutic apheresis; for plasma pheresis*) as potentially misvalued stating the code is undervalued due to incorrect equipment utilization assumptions and price of the cell separator system practice expense input, and the assigned clinical labor code of RN/OCN which undervalues the therapeutic apheresis nurse operating wage costs. The agency disagrees with the nominator that the service is misvalued.

The Society agrees with the agency and does not believe that code 36514 is misvalued. The therapeutic apheresis CPT code family was nominated as potentially misvalued as part of CMS rulemaking for CY 2025. In response, the RUC reviewed the clinical labor type associated with CPT code 36514. The RUC agreed that the clinical staff code L042A (RN/LPN) assigned to CPT code 36514 did not appropriately represent the work of an apheresis nurse specialist. Since there is not a clinical staff code for apheresis nurse specialist, the RUC agreed with the specialty societies' recommendation that the training and experience of an oncology nurse (clinical staff code L056A, RN/OCN) would accurately reflect the work of an apheresis nurse specialist. The RUC submitted new practice expense recommendations for this code family based on the use of the L056A clinical labor type. These practice expense recommendations were finalized by CMS without refinement as part of 2025 rulemaking.

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[1] American Society of Hematology. (2022). *The Future of Hematology: The Growing Demand for Subspecialists and Ideas to Increase Interest in the Field Among Medical Residents*. Retrieved from https://www.hematology.org/education/trainees/fellows/hematopoiesis/2022/the-future-of-hematology

ASH participated in the process to reexamine and revalue the clinical labor inputs for these services at the January 2024 RUC meeting and supported the RUC recommendations at that time. We continue to support the practice expense values of this service and CMS' decision that the service is not misvalued.

Payment for Medicare Telehealth Services under Section 1834(m) of the Act

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS proposes to permanently remove frequency limitations on furnishing services via telehealth for subsequent inpatient visits, subsequent nursing facility visits, and critical care consultation services. The Society supports this proposal. Allowing physicians the capability to care for patients via telemedicine when it is medically most appropriate allows greater flexibility for both the physician and the patient and increases access to care. Telehealth services eliminate the need for transportation, which can be a barrier for underserved populations, including those in rural areas or for patients with conditions with higher severity, acuity, or complexity. Telehealth is especially important for hematology, as many hematologic conditions are complex and require extensive or involved follow-ups and supportive care services.

Request for Information on Prevention and Management of Chronic Disease

In response to the Executive Order on "*Establishing the President's Make America Healthy Again Commission*," the agency is focused on the prevention and management of chronic diseases as a top priority. The agency requests feedback on how to enhance support for the prevention and management of chronic disease and is interested in comments that address the use of lifestyle interventions in prevention and treatment.

We thank the agency requesting information from stakeholders on how the agency can support innovative approaches to managing chronic disease. We note that lifestyle interventions alone such as medically tailored meals or exercise cannot be uniformly applied across patient populations or disease types. While medically tailored meals, an example noted by the agency as an intervention, are important to the health and wellbeing of patients, we do not want to see the agency focus on one aspect of care; to do so oversimplifies the complex care required for hematologic and other systemic conditions.

For example, sickle cell disease (SCD) is a chronic, multi-systemic condition that disproportionately affects populations with high rates of Medicaid coverage, and many SCD patients may eventually transition into Medicare. Even when patients adhere to optimal lifestyle practices, the disease is still present and requires lifelong specialized management. Interventions like proper hydration, adherence to hydroxyurea treatment, and regular follow-up care are extremely important for outcomes and help to minimize unnecessary emergency room visits. We want to emphasize that there is no dietary or lifestyle intervention that can "cure" SCD. Any programs or policy developed by the agency that focus on lifestyle interventions alone would risk neglecting the broader, evidence-based interventions these patients need. It is important to not assume that all chronic conditions can be managed in the same way as type 2 diabetes or obesity, where lifestyle interventions have a more direct and measurable impact.

Instead of focusing on lifestyle interventions, we encourage CMS to prioritize coverage and payment for the broader spectrum of care essential for patients with hematologic and other chronic conditions. This includes support and reimbursement for case management and care coordination, which is essential to ensure patients have access and adhere to treatment. Community health workers play a vital role in the care of patients with chronic hematologic conditions. Programs and payment policy created by the agency should support the use of community health workers, who support Medicare beneficiaries navigate upstream challenges like lack of housing and lack of transportation. For example, without adequate transportation, a patient suffering from a hematologic condition cannot attend vital health care appointments where they receive interventions that are essential to their health and wellbeing. Additionally, preventive services like vaccinations, screening, and patient education all play a critical role in patient care.

If CMS is interested in expanding coverage for lifestyle-related interventions such as medically tailored meals, there needs to be more funding and support for research to determine whether these interventions meaningfully improve

outcomes in diseases like SCD and other hematologic conditions. Without data to support the effectiveness of the use of an intervention, CMS cannot determine whether reimbursement is clinically or economically appropriate.

We recommend that CMS collaborate with medical specialty societies and other organizations to develop policy that meets the needs of those living with chronic diseases. We believe that lifestyle interventions are an important aspect of caring for patients with certain conditions, but these interventions should not be prioritized ahead of funding and reimbursement policy for clinical care, case management, mental health services, community health support, and preventive care, all of which are essential for improving outcomes in the Medicare population.

Autologous Cell-based Immunotherapy and Gene Therapy Payment
CMS proposes to integrate all preparatory procedures associated gene therapy into the payment for the therapy product, rather than reimbursing each step separately. This includes tissue collection and harvesting, preparation for transport, including cryopreservation, and storage, and preparation of cells or genes prior to administration to the patient. CMS views these steps as integral to the manufacturing process of the product, not as distinct reimbursable activities. CMS also proposes that preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and be included in the calculation of the manufacturer's average sales price (ASP).

The Society continues to fundamentally disagree with CMS. We have met with agency staff and submitted numerous comment letters objecting to this policy. We acknowledge CMS is citing statute to uphold their decision to not pay separately for the steps associated with creating CAR T-cells by noting that the agency does not pay separately for the steps involved in the manufacturing of a drug. While there are other cell and gene therapies captured under this ill-formed policy, CAR T-cell therapy serves as an illustrative example of the clinical care and services, and not manufacturing steps, involved with preparing and delivering these extraordinarily complex treatments.

To create CAR T-cells for infusion, each of the steps involved require the work, expertise, and clinical judgment of practitioners. These separate steps are not akin to harvesting a compound found in nature or creating a compound in a laboratory. These steps are procedures that must be performed in a healthcare setting, use equipment and supplies, and require interaction with the patient at certain points as well as participation of clinical staff.

Delivery of CAR T-cell therapy typically includes cell collection, lymphodepletion, infusion of CAR T-cells, and patient monitoring either in the inpatient or outpatient setting. The site of service of the performance of each step may differ across institutions, meaning that each institution develops a plan that meets the needs of the patient, while remaining consistent with the institution's internal clinical processes as well as standards included as part of accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT). Given the move to deliver more CAR T-cell therapy in the outpatient setting, it is vital that the physician work included each step of the process be paid separately. Without separate payment for cell collection, preparation for cryopreservation, and other services, there is no other mechanism to account for the work performed when each of these services are provided.

If this policy were implemented, there are no mechanisms to ensure that each site of care involved in the CAR T-cell therapy process is properly reimbursed for the services provided. We have no examples of a single instance in which a drug manufacturer has reimbursed a facility for the costs associated with the necessary preparatory procedures for the therapy. This is likely because the manufacturer plays no part in the process until such time that the cells or tissue are received into the manufacturing facility. Therefore, including preparatory costs in the calculation of the ASP is not appropriate. Below is an example of the process of collection and preparation of cells for CAR T-cell therapy.[2]

1. **T-cells are collected from a patient.** T-cells are collected via apheresis, a procedure during which blood is withdrawn from the body and one or more blood components (such as plasma, platelets or white blood cells) are removed. The remaining blood is then returned to the body.

[2] Source: Leukemia and Lymphoma Society: Chimeric Antigen Receptor (CAR) T-cell Therapy Accessed August 22, 2025.

2. **T-cells are reengineered.** The T cells are sent to a drug manufacturing facility where they are genetically engineered, by introducing DNA into them, to produce chimeric antigen receptors (CARs) on the surface of the cells.
    a. **After reengineering, the T-cells are known as "chimeric antigen receptor (CAR) T cells."** CARs are proteins that allow the T cells to recognize an antigen on targeted tumor cells.
    b. **The reengineered CAR T-cells are then multiplied.** The number of the patient's genetically modified T cells is "expanded" by growing cells in the manufacturer's laboratory. This takes about 3 to 4 weeks. When there are enough of them, these CAR T-cells are frozen and sent to the hospital or center where the patient is being treated.
3. **At the hospital or treatment center, the CAR T-cells are thawed and then infused into the patient.** Many patients are given a brief course of one or more chemotherapy drugs to reduce the number of normal t cells in the body before they receive the infusion of CAR T cells. This is called "lymphodepletion," and it makes space for the new CAR T-cells. The new CAR T-cells are infused into the patient's bloodstream by IV or through an existing central line.

As described above, the only portion of this therapy where the manufacturer is involved is in the CAR T-cell engineering process. The other steps all require the participation of a physician and incur expense to the site of care. Without payment for all other steps, this life-saving therapy will not be an option for Medicare beneficiaries. We continue to urge the agency to reimburse providers for each of the steps in this process and not bundle payment into the ASP.

Status Indicator for CPT® Code 38228 – C*himeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*
CMS has assigned CPT code 38228 with a PC/TC indicator of "5" (incident to) in the MPFS RVU file. ASH requests that CMS change the PC/TC indicator for CPT Code 38228 from "5" to "0" (physician service codes) to appropriately capture the nature of the service and to align with other similar services in the MPFS (e.g., 38240, 38242). We note, at the time that this code was created as a Category III code for CAR T-cell therapy administration, CPT code 0503T (now 38228) was not assigned a PC/TC indicator of "5." We are unclear as to why the agency would make this change, and request CMS address this issue in the final rule to correct the associated RVU files with the appropriate PC/TC indicator.

CPT Code 38228 is not an incident-to service. This code is used to describe the steps during CAR T-cell therapy that are currently performed or supervised by physicians. The physician personally supervises the initiation of the product infusion and is present for the first 15 to 30 minutes. The physician then remains immediately available to manage toxicities and complications that occur during the infusion. Finally, the physician evaluates the patient at the end of the infusion.

ASH thanks CMS for the opportunity to share these comments on the Medicare Physician Fee Schedule (MPFS) proposed rule for CY 2026. Should you have any questions or require further information, please contact ASH Manager for Health Care Access Policy, Carina Smith at casmith@hematology.org.

Sincerely,

Belinda R. Avalos, MD

Belinda Avalos, MD
President