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Via Electronic Mail

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1828-P
Mail Stop C4-26-05
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements, Provider Enrollment; and Other Medicare and Medicaid Policies

Dear Administrator Oz,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are pleased to offer comments on proposed changes to the CY 2026 Home Health and DMEPOS Prospective Payment System proposed rule, published in the *Federal Register* on July 2, 2025 (CMS-1828-P). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Medtech companies are a critical component of the modern health care system, focused on a singular mission to save and improve lives in every care setting: hospitals, doctors' offices, clinics, nursing homes, and family homes. Medtech interventions enable longer, healthier lives, allowing patients increased mobility to exercise, enjoy family outings, play sports, and go for walks, reducing the negative outcomes a debilitating health condition can impose, all at a much lower cost than other types of medical interventions.

In this proposed rule, CMS presents the DME Competitive Bidding Program (CBP) as a tool to reduce Medicare expenditures for durable medical equipment (DME) and to remove fraudulent DME suppliers from the Medicare program. Unfortunately, a poorly designed competitive bidding program will have the opposite effect. The medtech market is intensely competitive, with numerous innovative companies routinely bringing similar types of products to market. There are over 6,500 medtech companies operating in the US, and the market dynamics have demonstrated medtech prices tend to be deflationary over time.

Using competitive bidding to further reduce Medicare payments for DME will reduce incentives for companies to continue to innovate and will drive established, high-quality suppliers from the program. We believe the proposed changes to the CBP methodology have not been clearly articulated. Therefore, the proposed rule cannot be finalized in its current form because CMS has not provided adequate information for stakeholders to fully understand the implications of the proposed rule. AdvaMed strongly recommends that CMS address the serious flaws with the proposed rule before proceeding to restart what is described as the DME competitive bidding program.

Our comments cover the following categories:

- Revising the Definition of 'Item' Related to Medical Supplies
- Separate and Distinct Product Categories for New Urological Supplies
- Use of Inherent Reasonableness Authority
- Payment for Continuous Glucose Monitors and Durable Insulin Infusion Pumps
- Remote Item Delivery (RID) Competitive Bidding Program
- Methodology for Calculating Single Payment Amounts
- DMEPOS Supplier Accreditation Process and Capacity

Revising the Definition of 'Item' Related to Medical Supplies

We strongly oppose the proposed revision to the definition of "item" at 42 C.F.R. § 414.402. CMS's proposal to expand the term "item" to include "[o]ther medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy and urological supplies." 90 FR 29108 constitutes a significant reinterpretation of statutory language, which AdvaMed believes exceeds the authority granted to the agency by Congress. In addition, the inclusion of these products in competitive bidding would have significant patient access and safety risks.

We are concerned that the inclusion of ostomy, tracheostomy, and urological supplies would significantly jeopardize patient access and safety. These product categories must be understood in the context of their distinct clinical use and individualized patient needs. Unlike many DME items that serve a broader and more uniform population, ostomy, tracheostomy, and urological supplies must be carefully matched to each beneficiary's unique anatomy, medical condition, and functional status. These supplies are critical to the daily management of complex and often permanent conditions, and any disruption in access to the appropriate product, particularly one that a patient has been successfully using, can result in serious medical complications, infections, emergency care, or hospitalization.

Moreover, access to patient and caregiver training is essential for the safe and effective use of these supplies. Proper education on usage, hygiene, and troubleshooting can be the difference between stable at-home management and costly medical interventions. In fact, CMS's own Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (2004) identified "large, negative and statistically significant" impacts on beneficiary access to training for urological supplies during the demonstration projects. This report underscores the tangible risks to patient care when competitive bidding is applied to product categories where clinical oversight and education are central to safe use.

Although the Balanced Budget Act of 1997 (BBA) authorized competitive bidding demonstrations for "all items and services" under Medicare Part B (except for physician services), the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) narrowed the scope of the current competitive bidding program to only three categories of items and services, notably omitting prosthetic devices, such as ostomy, tracheostomy, and urological supplies, from the scope of competitive bidding. Had Congress intended to include ostomy, tracheostomy, and urological supplies in competitive bidding, it could have done so by, for example, including prosthetic devices in the same manner that it included "durable medical equipment" by reference to its specific definition in the SSA or simply carried over the phrase "all items and services" from the BBA to the MMA.

Given the individualized nature of these supplies, the documented historical access issues from prior CMS demonstrations, and the absence of reliable utilization data to inform the bidding process, we strongly urge CMS not to proceed with finalizing the proposed definition of "item" as it relates to these product categories. Preserving patient access to clinically appropriate, individually tailored products must remain the priority.

Ostomy, tracheostomy, and urological supplies do not fall within any of the three categories of items and services that the Social Security Act explicitly authorizes for inclusion in the DMEPOS Competitive Bidding Program under SSA §1847(a)(2). These products are not classified as "durable medical equipment," nor are they "supplies used in conjunction with" such equipment. Instead, they are distinctly categorized under SSA §1861(s)(8) as prosthetic devices, which are covered under a separate statutory benefit from DME. CMS has consistently recognized these supplies as prosthetic devices in its Medicare Benefit Policy Manual and other policy documents. As such, these items are not "covered items" as defined by SSA §1834(a)(13), and therefore, do not fall within the scope of items that CMS may legally subject to competitive bidding under current law.

Given this statutory framework, CMS's proposal to broaden the definition of "item" in a manner that could encompass prosthetic devices—specifically, ostomy, tracheostomy, and urological supplies—raises significant legal concerns. The term "covered items" in SSA §1834(a)(13) refers explicitly to durable medical equipment, as defined in §1861(n) and §1861(m)(5), and does not extend to prosthetic devices covered under §1861(s)(8). Expanding the definition of "item" in this context risks conflating distinct benefit categories and exceeds the authority granted to CMS by Congress under the statute.

AdvaMed urges CMS to not finalize the proposed revision to the definition of 'item'. We believe that without explicit Congressional action, this change lacks a valid statutory foundation and could create substantial legal uncertainty for suppliers, reduce market transparency, and potentially impact beneficiary access to these necessary products.

In addition, there is currently a lack of robust and transparent utilization data specific to these supply categories. Notably, CMS created new HCPCS codes for certain urological supplies that will not be effective until January 1, 2026. Hence, there will be no utilization data for those HCPCS codes for at least another calendar year. Without this data, CMS will be unable to accurately identify the lead item, and bidders will be unable to appropriately estimate the volume, variety, and complexity of products needed to adequately serve the Medicare population. This uncertainty not only increases the risk of underbidding and access disruptions, but also makes it difficult for CMS to ensure beneficiaries will receive high-quality care and appropriate product choice through the program.

AdvaMed strongly opposes the proposed redefinition of 'item' to include ostomy, tracheostomy, and urological supplies due to the patient safety and access risks, lack of authority, and lack of appropriate information to base bids from.

Separate and Distinct Product Category for Hydrophilic Intermittent Catheters

CMS recently established new HCPCS codes for hydrophilic intermittent catheters based on clinical evidence that hydrophilic intermittent catheters provide a clinical benefit compared to non-hydrophilic catheters. Historically, CMS included all HCPCS codes in a single product category, generally defined within a local coverage determination ("LCD"). If CMS proceeds with including urological supplies, we urge CMS to create a product category for hydrophilic intermittent catheters that is separate from other urological supplies including non-hydrophilic catheters. Hydrophilic intermittent catheters are more expensive to manufacturers than non-hydrophilic intermittent catheters, and the current Medicare fee schedule amounts for these items do not account for these significant cost differences. The extra expense arises from the hydrophilic coating and distinct design and materials that reduce pain during catheterization, reduce infections, and increase treatment compliance. The higher acquisition cost of hydrophilic catheters results in lower margins for the suppliers. Even though hydrophilic catheters will be under separate HCPCS codes starting in 2026, these catheters will be under a significant risk of non-medical switching by the suppliers because most prescribers do not use HCPCS codes on prescriptions.

If hydrophilic catheters were grouped into the same product category as non-hydrophilic catheters, the single payment amount will be the same and suppliers will be incentivized to furnish non-hydrophilic catheters instead of hydrophilic catheters in order to address competitive pressures of competitive bidding. Most providers prescribe intermittent catheters based on features and not the HCPCS codes so non-medical switching will likely continue even with the new HCPCS codes. We note such risks were identified in the demonstration programs in Polk County, which led CMS to conclude in its Final Report that "If prices did not cover costs, suppliers had an incentive to offer inferior products or pursue other strategies that could limit product selection."[1] To address the risks to quality and patient access, CMS would need to have a distinct product category for hydrophilic intermittent catheters separate from other urological suppliers, including non-hydrophilic catheters.

If CMS proceeds with including urological supplies in competitive bidding, then AdvaMed recommends that CMS have a distinct product category for hydrophilic intermittent catheters separate other urological supplies including non-hydrophilic catheters

Use of Inherent Reasonableness Authority

CMS's authority to adjust Medicare Part B payment amounts based on "inherent reasonableness" (IR) originates in statute and has been further defined through regulation and guidance. AdvaMed does not believe that CMS has met the requirements to use inherent reasonableness due to the lack of evidence that these services are 'grossly excessive or grossly deficient', and lack of published data or beneficiary access

[1] Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

impact assessments. Under the Balanced Budget Act of 1997 HCFA was granted the authority to adjust payment amounts for items or services deemed "grossly excessive or grossly deficient." This authority is limited to adjustments of no more than 15 percent in a single year unless CMS undertakes full notice-and-comment rulemaking.

CMS implemented this authority in an interim final rule issued in 2002,[2] and codified in the final rule[3] and statute in 2005.[4] These regulations established that any application of IR must be based on valid and reliable data, such as representative market prices, local acquisition or production costs, or payment amounts in comparable localities, and must not adversely affect access to care. CMS further explained that adjustments greater than 15 percent must be implemented through formal rulemaking in the Federal Register, while smaller adjustments may proceed through informal contractor mechanisms.

These criteria are further reinforced by findings from the Government Accountability Office (GAO), which reviewed CMS's IR rule and cautioned that the agency must develop and apply robust survey methodologies, ensure data validity, and monitor beneficiary access before invoking IR authority. Notably, the GAO emphasized that CMS had not used its IR authority at the time of the review in part because it had not met these foundational requirements. CMS has historically acknowledged these limitations and the procedural safeguards built into the IR framework.

In this CY 2026 proposed rule, CMS appears to be invoking inherent reasonableness authority or pursuing payment reductions that would typically require justification under the IR framework. However, the agency has not satisfied its own established criteria. The proposed rule does not include a new, formal notice-and-comment process specific to IR adjustments, despite proposing what may be significant payment reductions. CMS also fails to provide any valid and reliable data to demonstrate that current payment rates are grossly excessive or deficient, nor does it cite survey data, market pricing, or acquisition cost information as required under its own rules. Additionally, CMS offers no analysis to demonstrate that access to care for Medicare beneficiaries would not be adversely affected by the proposed changes.

Given these deficiencies, CMS has not met the regulatory or procedural thresholds that it has previously articulated as necessary to apply inherent reasonableness. In the absence of clear data, methodological transparency, and adherence to procedural safeguards, including a determination of whether the proposed adjustments exceed the 15 percent threshold, the use of IR is procedurally premature.

Therefore, AdvaMed requests CMS refrain from applying inherent reasonableness in this context until it has met the procedural requirements it has previously laid out including data, and patient impact assessments.

Payment for Continuous Glucose Monitors and Durable Insulin Infusion Pumps

[2] Centers for Medicare & Medicaid Services. (2002). Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services (Other Than Physician Services) [Interim final rule]. Federal Register, 67(220), 69312–69323.
[3] Centers for Medicare & Medicaid Services. (2005). Medicare Program; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services) [Final rule]. Federal Register, 70(224), 70116–70122.
[4] 42 C.F.R. §§ 405.502(g), §§ 405.502(h), and 405.515

AdvaMed supports the Agency in its goal of increasing choice and access to a variety of CGM devices and durable insulin pumps in the proposed rule. However, we have identified several important concerns with the proposal that we believe CMS must address before finalizing the proposal.

Lack of Program to Support Frequent and Substantial Servicing

We are concerned that this proposal is not consistent with the FDA regulatory status and labeling of these devices. Additionally, there is currently no clear program or infrastructure in place to support the return, update, and refurbishment of these devices. DME suppliers are generally not equipped to manage the complexities associated with refurbishing highly technical, software-driven devices like CGMs and durable insulin pumps.

We are concerned that continuous glucose monitors (CGMs) and durable insulin pumps are being considered for inclusion under the "frequent and substantial servicing" category. This classification appears inconsistent with the FDA regulatory status and labeling of these devices. CGMs—including sensors, transmitters, and readers—, as well as durable insulin pumps, are regulated by the FDA as Class II medical devices and are typically cleared through the 510(k) pathway for prescription use. Importantly, CGM systems and durable insulin pumps are not FDA-cleared or approved for refurbishment, reprocessing, or multi-patient use. In particular, CGM readers are labeled for single-patient use only, and no currently marketed CGM systems include FDA authorization for reuse across patients or for any form of refurbishment. FDA regulations require that reusable devices demonstrate validated cleaning, disinfection, and sterilization protocols to ensure patient safety; CGMs have not undergone such evaluations or received clearance under those standards. Additionally, many CGM components are prescription-only (Rx-only), setting them apart from most other DME items and further restricting how they may be distributed, handled, or reused. Including CGMs and durable insulin pumps in a servicing model that presumes the feasibility of refurbishment or ongoing reuse would be inconsistent with their FDA-cleared indications and labeling, and could raise significant regulatory and patient safety concerns.

Unlike traditional DME, where statute (42 USC § 1395x(n)) provides examples of iron lungs, oxygen tents, hospital beds, and wheelchairs, these devices require precise handling of proprietary parts, software updates, calibration protocols, and safety checks which fall outside the traditional scope of DME supplier operations. Most suppliers have not historically needed technical expertise or facilities to inspect, repair, reconfigure, or validate the safety and performance of returned devices before placing them back into service. Expecting suppliers to take on refurbishment responsibilities without a clearly defined process or technical support framework raises concerns about patient safety, device reliability, and equitable access to high-quality equipment. Additionally, some states may also require additional licensing or written verification by a licensed therapist or RT technician to service products, and without updated standards suppliers may struggle to meet obligations and could further complicate implementation and end up being noncompliant.

In addition, we believe that this program should be up and running significantly before any potential bidding occurs, as the increased costs of this type of program to suppliers will impact bids, and sufficient time to understand the ongoing costs with this program are required to appropriately bid.

AdvaMed recommends CMS delay implementation of this policy until such a framework is established with appropriate stakeholder input, given the regulatory requirements.

Continuity of Care

While the reclassification of CGMs and durable insulin pumps as "Frequently and Substantially Serviced" products may provide beneficiaries the ability to switch to new products more frequently, it also raises significant concerns about potential disruptions in continuity of care when a beneficiary decides to change products. With the potential burdens associated with this program, suppliers would not be incentivized to offer the latest innovative technology, undermining one of the goals of this program change.

Under the proposed model, beneficiaries who wish to switch to a different product would likely be required to return their current device before receiving the replacement. This introduces the risk of a coverage gap, where patients could be left without essential diabetes management tools for days or longer. Any such interruption—even short-term—can negatively impact glycemic control and put patients at risk of significant or deadly health issues. These gaps may also happen due to suppliers not bidding for or offering all CGM models, forcing patients to switch brands and resulting in a loss of historical glucose data, and potential clinical adverse events associated with worsening of glycemic control.

Further, there is currently no clear framework outlining when or how patients will be expected to return devices, how returns will be coordinated, or how long transitions will take. This lack of clarity can create uncertainty for both patients and providers, making it more difficult to plan care and ensure continuous, uninterrupted use of life-sustaining devices. Additionally, return of these products is unfeasible under current processes and regulations. The devices contain protected health information and may be contaminated with blood which raises OSHA risks. The current FDA status of these products also does not allow for refurbishment. An alternative of not returning the products is also not feasible due to the risk of fraud, waste, and abuse.

In addition, when patients transition between device types, especially those with different user interfaces, app configurations, or insulin delivery algorithms, there is a real need for beneficiary training and clinical support. Manufacturers currently provide extensive patient support that suppliers do not offer. CMS should clarify under the new model who has the responsibility for the patient training and support. Without structured education and onboarding, patients may face steep learning curves that could result in user error, treatment delays, or disengagement from therapy altogether. There is also significant cost associated with providing the products and all of the supplies, and frequent switching by beneficiaries within a short period of time, while providing increased patient choice, would produce significantly increased costs.

We encourage CMS to build safeguards that prioritize continuity of care during device transitions. These may include allowing overlap periods for returns and replacements, setting standards for device transition timelines, and ensuring patients receive adequate training and support when switching to a new product.

In addition to continuity of care concerns, we urge CMS to recognize that unlimited switching of CGM devices or durable insulin pumps is unsustainable from a supplier perspective. Without reasonable guidelines, frequent switching undermines supplier financial and logistical sustainability, disrupting the ability to provide consistent service and maintain adequate inventory. This instability can directly impact beneficiaries, as suppliers may be forced to limit availability or reduce service quality.

Patient Data Concerns

AdvaMed also urges the agency to consider the implications for patient data continuity, privacy, and access. These devices do far more than deliver insulin or measure glucose—they collect, store, and transmit sensitive health information critical to diabetes management and clinical decision-making.

Transitions between suppliers or devices, whether due to returns, service requirements, or platform changes, raise the risk of data loss or fragmentation. This is especially concerning when patients move between device ecosystems that are not interoperable. Without a standardized approach for ensuring that patients and their care teams retain access to historical glucose trends, insulin dosing data, and device settings, important clinical insights could be lost during transitions. This may hinder effective care and reduce the quality of medical oversight.

In addition, questions remain about how patient data will be handled during returns, refurbishments, or reassignments of devices. In the proposed rule it is unclear who is responsible for securing or deleting personal health information from returned units. The absence of clear guidance could leave patients vulnerable to data privacy breaches or confusion about how their health information is being managed.

AdvaMed encourages CMS to work with device manufacturers, privacy experts, and health IT stakeholders to establish clear expectations for data retention, transfer, and protection under this new servicing model. Ensuring continuity of access to critical health data, and protecting that data from misuse, will be essential to maintaining patient trust and achieving the full potential of this policy.

Implementation Dates

AdvaMed also has concerns regarding the potential short timeline for implementing the "Frequent and Substantial Servicing" classification, if intended to take effect on January 1, 2026, although the proposed rule is unclear as to the implementation timeline. We believe that there is insufficient time to 1. Have all flagged products FDA-approved for multi-use 2. To build the infrastructure and supplier readiness needed to support this servicing model by January 1st, particularly in the absence of established refurbishment programs, updated supplier standards, and data protocols.

Any shift toward a model that assumes refurbishment or multi-patient use of CGMs or durable insulin pumps would require manufacturers to seek and obtain new FDA clearances or approvals which requires a significant amount of time. FDA review would be necessary to ensure safety, efficacy, and compliance with regulatory requirements. In parallel, suppliers would face significant operational changes that would also need time prior to implementation, including updating their systems to account for the payment changes, which can take considerable time to implement. These changes cannot be implemented quickly or without careful planning. We believe that the quick implementation could create confusion, delays, and inconsistent patient experiences. Furthermore, implementing this change before the return of the CBP raises serious concerns about future cost stability.

To mitigate these risks, we recommend CMS adopt a phased pilot program in one competitive bidding area or region prior to any nationwide rollout. A pilot would allow CMS, manufacturers, and suppliers to test the model, evaluate safety and operational feasibility, and address unforeseen challenges before scaling to the entire Medicare population.

Suppliers should also be afforded the opportunity to gain meaningful experience with the new frequent and substantial servicing category, if implemented, before the competitive bidding process requires bid

submission. Without such experience, bid amounts are likely to be speculative rather than reflective of actual costs and operational realities, which could destabilize the program. Allowing a transition period will ensure that bids are based on accurate data, thereby supporting program sustainability and fair supplier participation.

Complexity of Bidding Structure for CGMs and Durable Insulin Pumps

As CMS considers including CGMs and durable insulin pumps in a future round of the Competitive Bidding Program, AdvaMed urges the agency to carefully evaluate the complexity of bundling and bidding for these devices. Unlike traditional DME items such as wheelchairs or braces, CGM and durable insulin pump systems are made up of multiple interdependent components—often including a sensor, transmitter, and pump—not all of which are interchangeable across platforms.

This complexity raises important operational and policy questions that are not addressed in the proposed rule. One such question is: will suppliers be required to offer a single, predefined "bundle," or will they be expected to offer a variety of combinations to meet the needs of patients on different platforms? For example, a patient may use their phone as a display device, bypassing the need for a separate receiver. If competitive bidding is based on rigid bundles, it could limit the flexibility needed to accommodate individual patient needs and existing device ecosystems. Additionally, if there are rigid bundles there would be supplier concerns as suppliers who supply CGMs are typically not the same as those who supply insulin pumps. These devices are often manufactured by different companies, and manufacturers contract independently with suppliers. Many suppliers currently do not have relationships with all relevant manufacturers and may not be able to ensure consistent access or predict pricing for both types of devices. In some cases, products are designed to work together; in others, they are intended to be used independently. As currently proposed, the policy could inadvertently restrict patient choice and access to the most appropriate technologies for their care. This complexity is not unique to the CGM and insulin pump category and CMS should not apply this bundling policy to other product categories without public input. In addition, we believe that including CGMs and durable insulin pumps in the same product category could distort the bidding process as both items are distinct items and subject to different competitive market conditions. Over 5 years, the purchase of a new, class II CGM accounts for only a couple percent of the total CGM costs whereas supplies account for almost all the cost. In contrast, over five years, the durable insulin pump equipment cost accounts for almost half of total insulin pump costs with supplies accounting for just over half. The small percentage of the equipment costs associated with CGMs creates a strong incentive for competitors to bid aggressively within the CBP which would result in a larger discount than is likely if durable insulin pumps were bid separately. Because CGMs would be the lead item within the product category with durable insulin pumps, this would result in payment amounts for durable insulin pumps that are artificially lower than what would have occurred had durable insulin pumps had its own separate product category. As noted above, this could create even greater challenges for beneficiary access to durable insulin pumps, as well as stymie innovation.

Prior to moving forward with this proposal, we encourage CMS to engage stakeholders to ensure that competitive bidding for CGMs and durable insulin pumps is structured in a way that maintains flexibility across component parts, supports device compatibility, and reflects real-world usage patterns. Without such careful consideration, the program may unintentionally restrict access to appropriate, individualized diabetes management tools. CMS should provide a mechanism for ongoing stakeholder engagement and

provide an ongoing, transparent process. This should include submitting the 'Request for Bid' document for public comment to get stakeholder feedback and ensure the proposed bids are appropriately designed for the desired result.

Risks of Substandard Products and Unvetted Foreign Suppliers

We are also concerned that the inclusion of CGMs and durable insulin pumps in a Competitive Bidding Program, combined with the reclassification to "Frequent and Substantial Servicing," could create opportunities for unvetted or bad actor foreign entities to enter the Medicare market with substandard or non-compliant products. In an environment focused heavily on cost reduction, there is a real risk that suppliers may seek the lowest-cost options from manufacturers that have not demonstrated long-term reliability in the Medicare or Diabetes patient population. The result could be an influx of devices or suppliers that lack proper quality controls, cybersecurity protections, or interoperability standards, putting vulnerable Medicare beneficiaries at risk. Additionally, incompatible products may enter the market which could result in restricting beneficiary choice. AdvaMed strongly urges CMS to implement strong supplier vetting criteria, manufacturer quality standards, and device approval safeguards to ensure that all products made available under this policy meet the highest standards of safety, efficacy, and patient support.

Remote Item Delivery (RID) Competitive Bidding Program

In the Proposed Rule, CMS solicits comments on its proposal to establish a nationwide infrastructure for remote item delivery (RID) by selecting a limited number of companies to provide DME items in geographic areas not subject to competitive bidding. By limiting RID to a small number of suppliers selected through a national process, the proposal risks displacing local suppliers who currently serve beneficiaries with knowledge of their unique conditions and needs to be dependent on large, national suppliers. This shift would diminish beneficiary choice and reduce access to individualized services that are often essential for appropriate care. Such an initiative also risks putting many of these local, specialized suppliers out of business and creating confusion and restricting access for beneficiaries, particularly those that choose to pick up items from suppliers with whom they have long and trusting relationships. Under a RID program, beneficiaries will be required to use a mail-order supplier since, as CMS noted in its commentary, remote item delivery items will typically be furnished to beneficiaries from remote supplier locations that are several hundred miles away. To the extent a beneficiary needs to obtain items in person from a noncontracted supplier, CMS indicated that beneficiaries will be expected to pay out-of-pocket, after signing an Advance Beneficiary Notice of Noncoverage, to obtain such items, even for delays that are outside of either the beneficiary's or contract supplier's control. The RID proposal also poses disproportionate risks for vulnerable subpopulations. Rural beneficiaries depend on geographically accessible suppliers who understand and can respond to the logistical challenges of their communities.

The creation of a RID competitive bidding program risks severely limiting beneficiary access while displacing a substantial number of DMEPOS suppliers, along with the jobs and economic activity they support. CMS itself has estimated that a nationwide RID competition could result in only seven contract awards for urological supplies, eight for ostomy supplies, and nine to ten for off-the-shelf (OTS) braces—

meaning the vast majority of current suppliers would be excluded from serving Medicare beneficiaries. Small and rural suppliers would be disproportionately affected, as they are less able to bid at the same price levels as large suppliers. Even among large suppliers, it is unrealistic to expect all of them to rapidly scale to meet demand, or to carry comprehensive inventories covering all relevant HCPCS codes. As a result, contract winners would face additional administrative and operational burdens, such as subcontracting to fill product gaps. CMS should require explicit safeguards for CGM-durable insulin pump interoperability, and suppliers should be required to stock or obtain all available product pairings to prevent forced device switching, putting patients at clinical risk.

By allowing for only a few national suppliers per category, the proposal raises serious concerns about competition, sustainability, and supplier diversity. Once established, these suppliers could maintain leading positions that could be difficult to displace, potentially resulting in suppressing innovation and reducing patient choice. Restricting the number of contractors in this way will inevitably increase risks of access problems for beneficiaries if one or more winning suppliers are unable to procure or deliver products.

AdvaMed urges CMS to carefully reconsider the structure of the RID proposal to ensure that it supports beneficiary access and safeguards quality and cost of care.

The RID program also has particular impacts for OTS braces. Although classified as "off-the-shelf," many of the back braces included in the proposed rule require in-person fitting and hands-on patient education. Proper measurement, education, and fitting at each appointment are critical to ensuring optimal fit and function; skipping these steps may negatively impact patient outcomes, increase patient dissatisfaction, and lead to additional follow-up calls to adjust or exchange the product. Many of the HCPCS codes proposed involve braces that are dispensed immediately following surgery or injury, where timely application is essential to the success of the patient's treatment plan. Consignment closets are a well-established component of orthopedic practices, and shifting to mail order delivery would disrupt physician workflows, introduce inefficiencies and additional costs, and delay patient care. At a minimum, any remote item delivery (RID) policy should be limited to items actually delivered from remote locations with an average delivery distance of 100 miles or more. Furthermore, the proposed OTS upper extremity braces were not previously included in competitive bidding, and new products should not be incorporated into an untested RID program.

CMS should reconsider rolling out a nationwide RID program across a broad range of product codes without first piloting the approach with a limited set of products in a defined geographic area.

Single Payment Amount Calculation

As CMS continues to develop and implement improvements to the single payment amount (SPA) methodology for future bidding rounds, we offer the following comments and recommendations to support transparency, sustainability, and equitable market access.

Clarification on Pricing for Non-Lead Items Without 2015 Baseline Rates

We request clarification on how CMS intends to establish SPAs for non-lead item products that lack a 2015 fee schedule baseline, particularly newly introduced items or those added since the last competitive

bidding rounds. In the absence of historical pricing data, it is unclear what methodology CMS will employ to derive baseline rates or ensure that pricing is rational, sustainable, and fair. An option available is that CMS update the non-lead item ratio using current market data rather than relying on outdated 2015 information, to ensure pricing reflects market realities. We recommend CMS clearly articulate its approach in future notice and comment rulemaking to avoid pricing anomalies that could affect both supplier participation and beneficiary access.

AdvaMed requests that CMS clarify the methodology it will use to establish Single Payment Amounts for non-lead items without a 2015 fee schedule baseline and update the non-lead ratio using current market data to ensure fair, sustainable, and consistent pricing for newly introduced products.

Safeguards Against Unsustainably Low SPAs for Non-Lead Items

We are concerned that the proposed methodology, which applies a CBA-specific ratio to lead item SPAs to calculate non-lead item SPAs, could result in price distortions. This poses a significant risk to supplier viability and may disrupt beneficiary access to essential equipment. To mitigate this risk, we recommend that CMS implement a safeguard mechanism to ensure non-lead item pricing remains within a sustainable range. One approach would be to establish a minimum pricing threshold based on historical fee schedule data. Alternatively, CMS could adopt a percentile-based floor—such as the 25th percentile of historical or bid data—to prevent excessively low pricing that could compromise supplier participation and, consequently, beneficiary access.

AdvaMed recommends that CMS implement a safeguard to prevent non-lead item SPAs from falling below sustainable levels that might jeopardize supplier participation and beneficiary access.

At the same time, CMS must account for the broader market effects of its pricing and contracting decisions. Aggressive SPA compression threatens to undermine innovation by limiting the ability of manufacturers to recover R&D investments and bring next-generation sensors and devices to market. Such underpayment risks slowing technology adoption in Medicare and could weaken U.S. leadership in diabetes technology relative to the EU and Asia, contrary to CMS's stated goals of advancing innovation.

Additionally, CMS should recognize the limitations of the 60-month rental model in supporting timely upgrades. Rental payments do not cover mid-cycle technology improvements, which creates an "upgrade trap" where suppliers may be unwilling to provide new devices and beneficiaries are forced to wait years for access, or else manufacturers and patients must absorb the costs. Without addressing this gap, CMS risks creating disincentives for both suppliers and manufacturers to deliver the most clinically effective, up-to-date devices to patients.

Assessing Supplier Capacity for New Entrants and Product Categories

We ask CMS to clarify how it will assess supplier capacity for two important scenarios: first, for new suppliers that did not participate in prior competitive bidding programs; and second, for existing suppliers who are bidding on new product categories for which they have not previously submitted Medicare claims or a significant number of Medicare or other third party payor claims but do hold the appropriate accreditation to furnish those items. Supplier capacity should play a critical role in both SPA calculations and contract awards. However, for these categories of suppliers, traditional methods based on historical claims data are not applicable. Therefore, we request that CMS clearly define alternative methods of

verifying capacity, such as reliance on accreditation status, projected service volumes, inventory levels, staffing plans, distribution strategy, the supplier's financial strength and wherewithal, and verifying that bidders have in place contracts with key product manufacturers or wholesale distributors for each category. If CMS does not account for supplier capacity when selecting contract winners, then we request that CMS clearly set forth its plan to protect beneficiary access should contract winners prove incapable of meeting beneficiary demand.

Moreover, CMS must explicitly guard against the risk of "suicide bidding," in which suppliers submit unrealistically low bids primarily to secure a contract, without the true capacity to deliver. Such bids not only compromise access for beneficiaries but also threaten the integrity of the program, and we have seen examples of this behavior in previous bidding rounds.[5] We urge CMS to establish a transparent and equitable process for evaluating bids to ensure suppliers submitting a bid are appropriately vetted and reviewed and are given a fair opportunity without compromising the integrity or operational readiness of the program.

AdvaMed requests that CMS clarify how it will assess supplier capacity for new suppliers and those entering new product categories by defining alternative verification methods and establishing a transparent, equitable evaluation process.

DMEPOS Supplier Accreditation Process

We share CMS's commitment to combating fraud and abuse in the Medicare program and recognize the critical role supplier enrollment oversight plays in safeguarding beneficiaries and trust fund integrity. However, the proposed shift to annual certification reviews for all DMEPOS suppliers, regardless of size, tenure, or compliance history, imposes a significant administrative burden, including on reputable suppliers with a long-standing track record of adherence to program requirements. In addition, this administrative burden on an annual basis could be a barrier to novel innovative technologies designed for home use and the small businesses that develop them. For example, certification could be limited to newly enrolled suppliers during their first year, or suppliers that change ownership. CMS should develop a specific list of issues that pose a serious risk of fraud, waste and abuse, such as prior instances of noncompliance, to identify requirements for annual certification.

CMS has outlined multiple changes to the supplier accreditation process in the Proposed Rule. We believe it is important to preserve the current site-specific enrollment and revocation framework, which provides targeted enforcement while protecting legitimate suppliers and beneficiary access. The existing Medicare enrollment framework appropriately treats enrollment and Provider Transaction Access Numbers (PTAN) as site-specific, ensuring that each DMEPOS location is separately accredited and held accountable for compliance[6]. At the same time, CMS retains the discretionary authority under 42 C.F.R. §424.535(i) to extend revocations across multiple enrollments where the facts demonstrate a broader pattern of noncompliance or fraud. This balanced approach is essential to protecting both program integrity and the viability of legitimate suppliers. We respectfully urge CMS to maintain the current site-specific PTAN revocation policy, which ensures that enforcement actions remain targeted to the location where

[5] Health Reform Built to Fail: How Medicare rigs competitive bidding and hurts patients.
[6] 42 C.F.R. §424.57(b)(1), (c)(24)

deficiencies occur.[7] While CMS retains authority under 42 C.F.R. §424.535(i) to extend revocations across an organization when warranted, the default site-specific approach prevents overly punitive outcomes. Maintaining the current approach protects beneficiaries' access to DMEPOS, preserves the viability of compliant locations, and recognizes that some revocations may result from administrative or technical errors rather than systemic fraud. This balanced framework protects the Medicare Trust Funds while ensuring fair treatment of legitimate suppliers consistent with CMS's statutory authority.[8]

We recommend CMS reconsider a blanket-based approach for supplier accreditation and consider supplier characteristics and a risk-based approach to accreditation timeline and requirements, while maintaining the site-specific revocation framework.

In addition, the sophisticated and complex nature of CGM and durable insulin pump systems rely on advanced software, interoperability across systems, and continuous data support, all of which directly affect patient safety and clinical outcomes. To ensure appropriate safeguards, we encourage CMS to re-evaluate existing supplier quality standards to ensure CGM and durable infusion pump suppliers have the capability to provide these innovative and complex technologies to patients in a timely and safe manner.

DMEPOS Supplier Capacity

We are concerned that the proposed rule lacks adequate mechanisms to verify supplier capacity. Both operational and financial capacity are essential to ensure that suppliers can realistically furnish services and equipment under the new program design and at sustainable rates. Without meaningful evaluation of supplier capacity, the program risks awarding contracts to entities that cannot sustain performance, thereby undermining beneficiary access and program stability. For this reason, CMS should require sufficient capacity verification not only as part of bid award determinations, but also as a prerequisite for submitting amounts into the bid pool. As currently proposed, the program is not operable, particularly without these safeguards.

AdvaMed recommends that CMS put in place requirements to verify supplier capacity prior to bid submission to ensure suppliers can furnish services under the frequent and substantial servicing model at sustainable rates.

We appreciate the opportunity to comment on the proposed rule. If you have any questions, please contact Carol Blackford (cblackford@advamed.org) and Zoe Guengerich (zguengerich@advamed.org).

Sincerely,

/s/ Carol Blackford

Carol Blackford

EVP, Head of Payment & Healthcare Delivery Policy, AdvaMed

[7] 42 C.F.R. §424.57(b)(1), (c)(24)
[8] 42 U.S.C. §1395cc(j)(1)