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# August 27, 2025

# Dr. Mehmet Oz, Administrator

# Centers for Medicare & Medicaid Services

# Department of Health and Human Services

# 200 Independence Ave., S.W.

# Washington, D.C. 20201

# Re: Comments on CMS-1828-P, “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” (CMS-1828-P, 90 Fed. Reg. 29108, July 2, 2025) (the “Proposed Rule”)

# Dear Administrator Oz:

VGM & Associates, Inc. (VGM) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services’ (CMS’) Proposed Rule cited above. VGM is a nationwide member services organization representing DMEPOS suppliers, distributors, manufacturers and other industry stakeholders, all of whom play a crucial role in the health care continuum ensuring Medicare beneficiaries receive the products and services they need to remain in their homes. VGM’s comments address the DMEPOS provisions in the Proposed Rule.

## Competitive Bidding Program

## Remote Item Delivery (RID)

**CMS proposes to create a Remote Item Delivery Competitive Bidding Program (RID CBP) for high-volume items typically shipped to patients, including but not limited to**:

* Continuous glucose monitors (CGMs).
* Insulin pumps.
* Urological and ostomy supplies.
* Off-the-shelf upper extremity orthoses.

VGM strongly opposes the proposed RID CBP across all product categories under consideration. A nationwide or regional bidding program will unfairly disadvantage smaller or regional suppliers, and we oppose its implementation. In addition, the proposed rule did not define what “regional” means, which is a critical element.

Further, under a regional or national RID model, winning bidders would need to hold a DME license in every state that requires one in order to dispense DME items in those states. Many prospective bidders would not have those licenses in place today. This rule only serves to add confusion for the industry and does not promote patient choice and satisfaction.

Similar to the licensure issue, there are also states that require a brick and mortar or physical location to be owned by a supplier within their state before they are allowed to dispense DME items within that state. Again, suppliers are not going to be willing to go acquire brick and mortar locations in the states that require them until they know for sure that they are going to actually be dispensing DME in those states, meaning they would have to be awarded the contract before they would be willing to do that. The licensure and brick and mortar issue could take several months to resolve after contracts are awarded.

Furthermore, many DME products and supplies are vital time sensitive items such that any delay in shipping and delivery would be harmful to patients and potentially create access to care issues. Given the challenges outlined above, VGM recommends CMS consider a pilot program within a small defined geographic area, such as a single state or CBA, rather than implementing a national or regional RID CBP.

## Expansion of Product Categories

**CMS is proposing to add new categories to the CBP Categories include**:

* + Urological, ostomy, and tracheostomy supplies.
	+ Off-the-shelf upper extremity orthoses.
	+ Continuous Glucose Monitoring (CGM).

CMS proposes to include urological, ostomy, and tracheostomy supplies by changing the definition from medical supply to medical equipment. Per SSA §1847(a)(2), CMS is limited to the following categories to include in the competitive bid program:

* Durable medical equipment and medical supplies excluding Class III medical devices, certain complex rehabilitative wheelchairs, certain manual wheelchairs, and drugs and biologicals.
* Items and services described in § 1842(s)(2)(D):
	+ Medical supplies
	+ Home dialysis supplies and equipment (as defined in § 1881(b)(8))
	+ Therapeutic shoes
	+ Enteral nutrients, equipment, and supplies
	+ Electromyogram devices
	+ Salivation devices
	+ Blood products
	+ Transfusion medicine
* Off-the-shelf orthotics

As a result, we believe the addition of urological, ostomy, and tracheostomy supplies conflicts with statutory limitations and creates legal and compliance uncertainty. Further, VGM opposes inclusion of medical supplies as CMS does not have the legal authority to recategorize products or include medical supplies that are expressly excluded in the CFR.

VGM opposes inclusion of off-the-shelf upper extremity orthoses. Off-the-shelf orthoses still require a modicum of clinical fitting, training, and instruction. Without the clinical services associated with the delivery of these orthotics, beneficiaries may receive clinically inappropriate or unnecessary orthoses putting them at risk thereby potentially increasing Medicare spend and compromising the integrity of the Medicare orthotic benefit.

VGM also opposes inclusion of all respiratory products generally in the CBP. However, if included, VGM recommends CMS expressly exclude liquid oxygen. Very few suppliers continue to provide liquid oxygen because it is extremely costly, time-consuming, and very few beneficiaries continue to use it. Therefore, it is not well-suited for the CBP.

New Rate-Setting Methodologies

**CMS proposes to revise lead item and bid ceiling rules.**

Lead item

VGM opposes use of lead item bidding in the CBP. Lead item bidding assumes a rational relationship among all products in a category that often does not exist. The result is disproportionately low and unsustainable rates for non-lead items. Additionally, due to the lack of adequate reimbursement, particularly for high-end or advanced products, lead item bidding may disincentivize manufacturer innovation and supplier investment in higher-quality products for the Medicare population.

Although non-lead item/whole product category bidding results in additional work for suppliers, it is preferred to avoid disproportionate cuts in reimbursement to non-lead items under lead item bidding. VGM recommends that CMS seek bids for the entire code set within the product category for more accurate bidding, sustainability, and to incentivize innovation and investment in high-quality products.

Limit on Bid Ceiling

**CMS proposes the below changes related to the bid ceiling:**

* **For product categories previously included in the CBP, the bid amount cannot be more than the lesser of (1) 110% of the previous SPA, or (2) the unadjusted fee schedule amount for the item.**
* **If it has been more than one year since a SPA was paid in a prior round, the bid amount cannot exceed the lesser of (1) the most recent SPA for the item increased by the CPI updates since then plus 10%, or (2) the unadjusted fee schedule amount for the item.**
* **For product categories that have been included in previous rounds but are being bid in a new CBA, the bid amount cannot exceed the lesser of (1) the adjusted fee schedule amount for the lead item plus 10%, or (2) the unadjusted fee schedule amount.**

VGM strongly opposes the bid ceiling limitations outlined above. CMS acknowledged the unsustainably low rates from prior rounds by increasing the bid ceiling during the most recent competition, Round 2021. Additionally, in a true competitive bid competition, bid ceilings do not exist and the bids submitted more accurately reflect true market rates. As outlined above, CMS stated in the proposed rule that the tolerance for any increase in reimbursement on the lead item is capped at 10%. For Round 2021, the ratios that were assigned to non-lead items were such that a 10% increase on the lead item could still result in a decrease on some of the non-lead items of up to 50%. While we understand the proposed rule states that the ratios for non-lead items may be modified and different from Round 2021, for product categories that already have razor thin margins, suppliers cannot absorb these deep cuts to reimbursement. If the bid ceiling is set at 110% of previous rates, and the ratios still result in drastic cuts on non-lead items, many providers will not be willing or able to submit bids because they know that doing so will result in rates that they cannot sustain. This is especially the case when providers who are awarded contracts are expected to provide ALL products within a category, even if reimbursement went down by 50% on that product, to ALL Medicare beneficiaries who come to them needing that product. A low bid ceiling coupled with arbitrary and unfair ratios is a recipe for unsustainable reimbursement.

Therefore, VGM recommends that CMS eliminate the bid ceiling altogether and allow supplier bids to reflect true market pricing. However, if CMS proceeds with a bid ceiling, VGM recommends against using the methodology described above as it will drive prices down which can negatively impact access and quality of the products provided. These elements should be taken into consideration when determining bid ceilings. While we understand that the purpose of the program is to save money, it should not be done to the detriment of the beneficiary population. Instead, CMS should at a minimum base the bid ceiling on the current unadjusted fee schedule.

## Change Winning Bid Methodology

**CMS proposes to change the winning bid from the maximum winning bid to the 75th percentile of winning bids and reduce the number of bids used to set the SPA by 25%.**

VGM opposes this proposed change. Using the 75th percentile as the winning bid is inherently unfair to suppliers and does not reflect a true competitive bid program. In rounds prior to the most recent CBP, CMS used the median bid to develop the SPA. In Round 2021, CMS recognized that this could lead to access to care issues and jeopardize the program and as a result, it proposed using the maximum winning bid, or clearing price, to determine the SPA. The industry supported this methodology, and it was finalized in the most recent round of the CBP. CMS is now reversing course proposing to calculate the SPA at the 75th percentile versus the clearing price. In doing so, the same concerns CMS raised before changing the methodology for calculating the SPA to the clearing price exist along with potential access to care issues for beneficiaries and making the entire CBP vulnerable and unsustainable. Using the 75th percentile will simply drive prices down and may negatively impact beneficiaries due to suppliers’ inability to provide services as a result of untenable rates.

In a fair and equitable CBP, VGM believes every bidder should be paid at their awarded contract rate just like the suppliers who negotiate with Managed Care Organizations (MCOs). While we recognize that it may be administratively challenging, CMS has already demonstrated its ability to do so currently by maintaining multiple rates for the same HCPCS codes in its fee schedule. This would allow for true and fair competition in the market. However, at a minimum, VGM recommends that CMS return to using the clearing price to determine the SPA. Using anything less would increase the number of damaging low-ball bids. Using the clearing price would foster more accurate bidding. It would also protect beneficiaries’ access to quality products. It is important to note that use of the clearing price to determine pricing is a standard practice in a majority of true competitively bid auctions throughout the country.

VGM also opposes reducing the number of bids used to calculate the SPA by 25%. This is very subjective and again, could create access to care issues, which CMS recognized in the proposed rule saying, “…there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition.” It is unclear why this risk would be taken unnecessarily with no plan to address likely access issues.

## Change Contract Award Threshold

**CMS proposes changing the threshold for awarding contracts to double the number of contract suppliers that previously furnished at least 5% of the items or services needed and lower the requirement to at least two suppliers per competition.**

VGM opposes this change and believes it will create access concerns for beneficiaries due to the decrease in contracted suppliers. It will also disadvantage smaller suppliers. Having only two contract winners is a significant reduction to the previous five contracted suppliers and raises significant issues. If either of the two suppliers has issues or outside influences that impact their ability to service beneficiaries, it would put an undue burden on the other remaining supplier. If an incident occurred that impacted both contract suppliers, beneficiaries would have no access. A prime example involves a recent incident with a large recall of CPAP devices that resulted in beneficiaries being unable to obtain devices from suppliers causing beneficiaries diagnosed with Obstructive Sleep Apnea to go untreated to their detriment. Beneficiaries who had a recalled device were unable to obtain a replacement so were forced to either continue to use the unsafe device or go without their therapy, again jeopardizing their health.

VGM also believes that by reducing the number of suppliers to two, it is unlikely that beneficiaries will have access to local suppliers with a physical location – which remains important to many beneficiaries with chronic conditions. If equipment needs to be repaired, beneficiaries may not have the access they need and so will be forced to come to some sort of resolution on their own, likely to their detriment.

Such a significant reduction would also cause reduced access to a variety of quality products and specific brands. Many beneficiaries with chronic conditions prefer certain brands of products and their treating practitioners may order brand-specific products based on the beneficiary’s unique needs. If neither of the two contracted suppliers carry the particular brand, the beneficiary will not have access to reimbursement for their desired product. Only having two suppliers creates a high risk for access issues.

VGM recommends, at the very minimum to keep the minimum number of contract suppliers to five as it has in previous rounds.

Elimination of the use of Supplier-Reported Capacity

**CMS proposes eliminating the use of supplier-reported capacity to determine the number of contracts to award in a competition and to instead determine capacity based on previous rounds of CBP or utilization data.**

VGM strongly opposes this proposed change.

VGM recommends CMS utilize supplier self-reported capacity and the same supplier’s Medicare historical utilization capacity when evaluating a bidder’s ability to service a contract and to identify the accurate number of contractors needed for a category. This in addition to VGM’s recommendations below regarding financial documentation requirements provide additional support of a supplier’s actual ability to meet self-reported capacity requirements.

Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

**CMS proposes not awarding contracts if the total payments under the CBP would end up being higher than what Medicare would otherwise pay. This includes payments resulting from improper billing and any other costs under the current DMEPOS fee schedules.**

VGM supports the proposal. However, VGM recommends “savings” be measured against the amount Medicare would have paid under the 2015 unadjusted fee schedule.

# Reducing Financial Document Requirements

**CMS proposes the following changes to the financial document requirements**:

* No longer require tax returns, income statements, balance sheets, and cash flows.

* Continue to submission of the business credit report (score or rating) but if the business does not have a numerical score or rating, the bidder would be required to submit:

(1) a business credit report showing no data or insufficient information to generate a credit score;

(2) personal credit report or the rating from the supplier’s Authorized Organization or Delegated Official listed in PECOS.

* The personal credit report must be of the Authorized Official or Delegated Official listed in PECOS; otherwise, the supplier would not be eligible for a CBP contract.

* Publish and use the applicable credit score list for each round in the round-specific Request for Bids (RFB) or in a Financial Scoring Methodology Fact Sheet.

VGM strongly opposes the proposed required documentation reduction. VGM recommends CMS continue to require tax returns, financial statements, an income statement, balance sheet, and a statement of cash flows as the combined documentation demonstrates the bidder’s financial ability and capacity to adequately service awarded bids.

**CMS proposes to no longer use credit scores to consider capacity.**

VGM supports this proposal. VGM urges CMS to continue to require bidders to submit the financial data listed previously to assess supplier capacity. VGM also encourages CMS to take DME supplier historical capacity when reviewing a bidder’s ability to increase capacity.

**CMS proposes continuing use of the five-tier scoring system in reviewing supplier credit scores, where 12 or higher is passing.**

VGM opposes limiting a bidder’s credit score alone to conduct the financial evaluation. VGM urges CMS to require the above-listed financial documentation to fully understand a bidder’s financial ability to increase their service capacity.

**CMS proposes adding a gross revenue field in the application.**

VGM supports requiring bidders to add their gross revenue, however it is not sufficient, even if taken with the credit score, to determine a bidder’s financial ability to expand and serve a CBA. As mentioned above, VGM recommends CMS require bidders submit a host of financial information for CMS to accurately assess a supplier’s financial capabilities to expand into larger contracts.

# Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

**CMS proposes to streamline evaluation and communication with the bidder on their covered document review date (CDRD). CMS will only provide two types of communication: missing documents or completed documents.**

VGM supports this proposal.

# Bid Surety Bond Review Process

**CMS proposes to give bidders one 10-business-day window to fix issues with their bid surety bond by submitting a corrected bond rider. CMS would notify bidders through the DMEPOS CBP’s secure portal if a bond is determined to be incorrect or incomplete. Bidders would be allowed to submit a corrected bond rider within the 10-business day window. CMS would only notify bidders of deficiencies able to be corrected with a bond rider.**

VGM supports this proposal.

# Other VGM Recommendations Related to the CBP

Bona Fide Bid Verification

VGM supports bona fide bid verification on outlier bids for both lead and non-lead items. This will address potential “low-ball” bids from inappropriately driving rates to unsustainable levels. Bidders should be able to prove that they are able to provide the product at an appropriate margin at the amounts bid. If the bidder is unable to do so, the bid should be eliminated from consideration.

Requirement for Medicaid Supplier Number in CBA

During previous rounds of CBP, CMS acknowledged that dual-eligible beneficiaries faced additional barriers and, in some instances, were inappropriately charged for products received because their supplier was not able to collect payment from Medicaid. This results in a program that is inequitable for this particularly vulnerable population. VGM recommends requiring a supplier submit a bid within a CBA to be enrolled in Medicaid to protect these beneficiaries and assure they have the same access to the products and services they need.

## Additional Rule Provisions

## Changes to Surveys and Reaccreditation Requirements

**CMS proposes to change survey and reaccreditation requirements to every 12 months for all providers.**

VGM strongly opposes this change. First and foremost, it increases the administrative burden and potential delays in certification. The amount of time and effort a supplier puts forth to obtain and maintain their accreditation is already a significant burden with a 3-year accreditation cycle. The costs of compliance with the quality standards are already a significant cost to suppliers. Many suppliers have to begin preparation up to six months prior to their reaccreditation. Having to do this annually would require a significant increase in resources and is unreasonably burdensome on suppliers. Additionally, there are serious concerns whether the accrediting bodies even have the capacity to meet the demands of annual surveys on its suppliers, which if not, would cause delays in reaccreditation and have negative consequences on suppliers and their ability to provide services to Medicare beneficiaries. Large suppliers with many locations would be even more burdened having to manage and maintain annual accreditation for hundreds of locations in some instances. We believe CMS highly underestimates the cost impact of this significant change and suppliers will bear the overwhelming bulk of the costs. An average cost for a survey is $1,500, which means even a small supplier with one location will see at minimum an increased cost of $3,000 to accommodate annual surveys, which does not include the significant additional overhead expenses on suppliers to manage the process. CMS indicates that this is a tool to protect the Medicare Trust Fund and reduce fraud, waste and abuse, although that is not what the accrediting bodies are designed to do. Their role is making sure suppliers remain compliant with the DMEPOS Quality Standards. If a surveyor has concerns of potential fraudulent or abuse activity, they should be required to report it to the appropriate authorities.

VGM recommends that CMS establish a method for the current Accrediting Organizations to communicate fraud, waste, and abuse suspicions to CMS who can then work with an appropriate entity, such as a Unified Program Integrity Contractor (UPIC), to investigate the issue. We also recommend CMS require a thorough AO review of a supplier’s compliance activities to assure the supplier has a comprehensive and sound compliance program that incorporates all the elements recommended by the Office of Inspector General (OIG).

If CMS continues with the proposed reaccreditation change, we recommend CMS maintain the current three-year process requiring on-site inspections triennially with a limited bench inspection to ensure compliance. limited documentation requirement the other two years.

## Prior Authorization Exemptions

**CMS proposes to create a process to exempt suppliers from prior authorization if they meet certain claim approval thresholds.**

VGM supports this proposal although specific guidelines for granting and withdrawing exemptions are not yet established. In developing that criteria, it is important to assure that a two-tiered system favoring larger, more established suppliers, is not created. Overall, VGM supports the current prior authorization program as it is managed efficiently, and we would further support expanding the program to other product categories as long as suppliers were given ample time to prepare and it is managed properly. VGM highly recommends that CMS clarify that suppliers eligible for an exemption are still permitted to submit prior authorization requests in the event they wish to do so.

Changes to CGM and Insulin Pump Payment Category

**CMS proposes changing Class II CGM and insulin pumps to Frequent and Substantial Servicing for both CBAs and non-CBAs, resulting in a one-time payment for the receiver.**

VGM opposes this change. Suppliers will have to pay manufacturers the entire purchase price up front for the receiver. Today they receive a one-time up-front reimbursement for that receiver of roughly $286. According to the proposed rule, if passed as written, suppliers would still receive roughly $286 for the receiver, but it would come in the form of monthly payments of approximately $4.77 per month over 60 months. It could take them a couple of years before that receiver is paid for. Adding CGMs to a frequent and substantial payment category means this is a continuous rental with burden on the suppliers where suppliers would assume ownership and responsibility long term. In addition, there would is financial burden that would lead to access issues for Medicare beneficiaries.

VGM recommends leaving CGM in its current payment category, the inexpensive and routinely purchased items category, to avoid both financial impact and access issues for Medicare beneficiaries in both traditional Medicare plan and Medicare Advantage plans. Beneficiaries are treating a severe diabetes condition that would limit access to proper treatment. The rationale in the proposed rule is flawed when calculating the monthly rental rate based on the 5-year reasonable useful life (RUL) of the devices and keeps suppliers on the hook for the cost of a replacement receiver if warranted, with no additional reimbursement available to offset the cost of the additional receiver. Suppliers cannot sustain the financial burden of the proposed payment methodology for diabetic patients.

We do agree that there are frequent changes in technology within the CGM category, and there are certainly instances where a patient would need to change to a different/newer technology to better manage their diabetes. We applaud CMS’s recognition of this, and their willingness to allow patients to change devices within the 5-year RUL. However, the proposed rule, while allowing for a patient to change devices, does nothing to offset the cost of the provider having to provide a new device to the patient. In the proposed rule, payments would remain the same whether the patient stays on one device for 5 years or changes to a new device at some point during that 5-year period.

If CMS has a goal of making sure that patients are compliant with their CGM therapy, thereby achieving the best health outcomes for patients and lowering their total cost of care, they need to ensure that there is both adequate competition in the marketplace as well as rates that hold up the ability for providers to maintain that level of service with their CGM patients. Many (but not all) CGM providers currently provide additional support and routine engagement with their CGM patients to make sure they understand their devices and their treatment plans to ensure they are getting the best health results possible. If reimbursement is lowered, there is a good chance that some of that additional patient engagement will have to be removed from suppliers’ programs, and patient therapy adherence as well as health outcomes will diminish. A recent study published in JMIR Diabetes showed that patients who receive a CGM through a DME provider vs. other provider types such as pharmacies have a 23% higher compliance rate through the DME channel. This is due in large part to the ongoing patient engagement that is offered by several DME providers today.

Changing Payment Rate for Class III Insulin Pumps

**CMS proposes to change the payment rate for insulin pumps used with Class III CGMs to match the SPA for those used with Class II CGMs.**

VGM opposes this proposed change. First, Class III devices are specifically excluded from the CBP because they are considered high-risk, life sustaining medical devices. As a result, they should not be impacted by the CBP, and we believe doing so is outside of the legal authority of CMS.

**Provider Enrollment Proposed Changes**

Expanded Revocation Authority

**CMS is proposing to revoke a supplier’s PTAN if the beneficiary attests to never receiving the item or service listed on the supplier’s claim.**

VGM has deep concerns regarding the proposed expansion of CMS’ revocation authority, particularly the provision of allowing revocation of a supplier’s PTAN based solely on a beneficiary’s attestation that an item or service was not received. Often times, these attestations come years after equipment was reported to have been delivered. This approach lacks a formal process for suppliers to respond or clarify, increasing the risk of improper and erroneous revocations while creating significant barriers to reinstatement. This would affect not only Medicare FFS as a payer for the supplier and the beneficiary, it would affect payers like Medicare Advantage plans and state Medicaid payers causing a total disruption for beneficiaries and patients to have access to the care, the therapies, and products needed to stay at home maintaining quality of life. We strongly recommend continued oversight by the DME MACs given the unreliability of any shipping service and patient reporting and urge CMS to implement a stay of enrollment versus a revocation to allow suppliers the opportunity to respond to the issues before revocation.

Retroactive Revocation Date

**CMS is proposing to expand the number of scenarios where CMS may apply a retroactive revocation effective date. Retroactive effective dates would vary based on the reason for the revocation.**

VGM finds the proposal to expand retroactive revocation scenarios highly problematic. It fails to account for unintentional errors, administrative delays during ownership transitions, and disproportionately penalizes larger suppliers with multiple locations. Retroactive revocations would have devasting consequences for suppliers, their operations, and the patients they serve-especially when triggered by a minor error. In addition, this unnecessarily burdens the provider enrollment contractors and PEARC that processes the appeals. The DME MACs often initiate recoupment proceedings on claims paid, only to have to reverse the recoupment and reprocess claims following an overturned revocation. We recommend that retroactive revocations be reserved only for cases where the harm to the Medicare program clearly outweighs the harm to the supplier, and that CMS establish clear, objective criteria.

Other Provider Enrollment Proposed Changes

**CMS proposes suppliers are legally responsible for the accuracy and faithfulness of the applications, even if another party completed the applications.**

VGM supports this proposal.

**CMS proposes to have the right to request additional validation documents to ensure the accuracy of supplier application information.**

VGM supports this proposal provided detailed guidance on the kinds of documentation CMS may request what constitutes a sufficient response.

**CMS is proposing that the authorized official on the CMS-855S form must be the party to sign the liability insurance policy.**

VGM recommends CMS consider allowing the party signing the liability insurance policy to be a high-level executive with signing authority granted by the company. The current proposal does not account for the organizational structure of larger companies, leadership roles, and organizational signing authority. Larger companies have multiple corporate levels/structures and signing authority varies from the parent company to subsidiary. Further, VGM notes that the document required to demonstrate proof of liability insurance does not have a signature page.

**CMS proposes to expand Stay of Enrollment for rejected revalidations and change of information.**

VGM supports the expansion of stay of enrollment. However, CMS must address the significant delays in processing times from the PEARC and the national provider enrollment contractors. CMS should ensure the current provider enrollment contractors are following the original requirement of MM13349.

**CMS proposes changing the start of stay of enrollment to the beginning of the non-compliance or when the application is rejected.**

VGM opposes this proposal.

Decreasing the time frame for suppliers to rectify an enrollment issue would likely last beyond the current 60-day policy resulting in an invalid stay of enrollment. VGM recommends using the letter date as the start of the stay to give a supplier adequate time to address the issue and the NPE time to update the supplier file. VGM reminds CMS that a stay of enrollment should be used judiciously when clear evidence of an intentional violation exists due to the impact on all other payers a DME supplier is engaged.

VGM also requests CMS define the term “rejected”. Does “rejection” refer PECOS or to an enrollment contractor rejecting a revalidation?

**CMS proposes including a technical change in the wording of the regulation to clarify that the Stay of Enrollment is up to 60 days and therefore, it can be addressed in less than 60 days.**

VGM requests clarification that CMS is adding this technical change to make the regulation consistent with MLN Matters: MM13449.

**CMS is proposing a technical change to remove references to “60-day period” to “CMS assigned stay period”.**

VGM supports this proposal clarifying that the stay of enrollment can be active for less than 60 days.

**CMS proposes to revise § 424.57(c)(22) to clarify and strengthen accreditation requirements for DMEPOS suppliers**:

* Every DMEPOS supplier location, including those owned or subcontracted, must individually meet Medicare’s quality standards and be separately accredited in order to enroll and bill Medicare.
* A supplier can only be paid for products and services that are explicitly listed in its accreditation. The accreditation must clearly state which items the supplier is approved to provide.
* CMS may deny or revoke a supplier’s Medicare enrollment if it determines the supplier is not meeting the required quality standards.

VGM supports this proposal considering these requirements are currently in place.

**CMS proposes to notify affected suppliers of a suspension of the AO’s accreditation program and to inform them of whether their current accreditation will remain valid for the duration of the suspension or if they will need to seek reaccreditation through another process. Suppliers requiring reaccreditation would need to be reaccredited by their original AO once the suspension is lifted or obtain accreditation from a different AO.**

VGM recommends that suppliers affected by a suspension of their AO’s accreditation program should have their accreditation remain in effect until their next scheduled reaccreditation survey. Due to the current shortage of surveyors, it would be very difficult for another AO to have the capacity to immediately re-accredit affected suppliers.

**CMS proposes to mirror the change in majority ownership (CIMO) requirements for home health agencies and hospices. DMEPOS suppliers going through a CIMO *must* enroll as a new supplier and be newly accredited and surveyed if the CIMO occurs within the first 36 months of initial enrollment or last CIMO.**

* The definition of CIMO will be broadly applied to generally mean a transfer of more than 50% of ownership interest—either in one transaction or over two years.
* Allow CMS to deactivate Medicare billing privileges for suppliers that are undergoing a CIMO and fail to meet re-enrollment requirements.

Suppliers would not need to re-enroll as new suppliers if:

* Internal corporate restructuring (e.g., merger, consolidation) by the parent company.
* Change in business structure (e.g., corporation → partnership) where owners remain the same.
* Death of an owner

VGM supports this proposal only if the policy is limited to CIMOs occurring within the first 36 months of initial enrollment or the most recent CIMO.

VGM appreciates the opportunity to comment on the DMEPOS provisions in the Proposed Rule and welcomes continued dialogue and to provide additional information. I may be reached at mike.isaacson@vgm.com.

Sincerely,



Michael Isaacson

Senior Vice President, Government & Regulatory Relations