AAHOMECARE
American Association for Homecare

DMEPOS Related Proposals from CMS-1828-P

On July 5, 2025, the Centers for Medicare & Medicaid Services (CMS) published the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) Rate Update Proposed Rule (CMS-1828-P) in the Federal Register. The proposed rule includes updates related to the HH Quality Reporting Program, the HH Value-Based Purchasing Expanded Model, and several provisions affecting the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) sector, specifically the Competitive Bidding Program, accreditation requirements, and prior authorization policies.

CMS is accepting public comments on the proposed rule through August 29, 2025.

Below is a summary of the proposals relevant to the DMEPOS industry.

DMEPOS Competitive Bidding Program Proposals

Following is a summary of CMS's proposed regulatory changes to the DMEPOS Competitive Bidding Program (CBP). There are many parts of the regulations that CMS is not proposing to change (e.g., lead item bidding), found at 42 C.F.R. §414.400 et seq.

1. Payment and Product Scope Changes

a. Potentially Adding Class II CGMs and Insulin Pumps to CBP

- **Proposal:** Change the payment category for Class II CGMs and insulin pumps to Frequently and Substantial Servicing (FSS) for CBAs and non-CBAs.
    - Payment will change to continuous monthly rental, where the supplier will own the Class II CGM receiver and insulin pump.
    - Supplies will be included in the monthly rental rate.
    - CMS notes the change is due to evolving technology and supporting beneficiaries in getting the newest technology.
- **Proposal:** Class II CGMs and insulin pumps might be phased into a national CBP.
    - CMS introduces national CBP based on the fact that the majority of supplies are shipped to the beneficiaries and supplies are rarely picked up from a physical location.
    - There is no difference between the cost of shipping to an urban area vs rural area.
    - CMS notes the structure applies as long as Class II CGMs remain covered under Medicare Part B.
- **Proposal:** Insulin pumps used with Class III CGMs would be excluded from CBP because they are Class III devices (excluded by law).
- **Proposal:** Payment for Class III CGMs used with insulin pumps will not exceed the payment rate for Class II CGMs + insulin pumps under CBP. CMS will adjust the Class III CGM + Insulin pump to the CBP rate.
    - To prevent suppliers from being incentivized to provide Class III CGMs, which are less accurate than Class II CGMs

    - CMS expects the Class II CGM + insulin pump rate will be 15% less than the current Class III CGM + insulin pump rate.
- **Proposal:** National CBP will be phased in for future competitions and the payment rental rates will be phased in.
- **Proposal:** Fee schedule for rural and non-rural areas for Class II CGMs + insulin pumps would be based on the rental SPAs from CBP.
- Example of bid limit for monthly rental for Class II CGM and supplies is sum of (average purchase price for Class II CGM receiver ÷ 60) + monthly payment for supplies:
    - Example: Class II CGM monthly rental bid limit would be $272.69 based on:
        - A4239 monthly payment is $267.92
        - E2103 payment is $286.03 ÷ 60 = $4.76
- **Proposal:** Bid limit for insulin pumps and supplies and accessories under subpart B non-rural rate for 1 month + (rental total ÷ 60)
    - Example: The bid limit would be $226.22 ($100.79+$30.42+$95.04)
        - A4224 payment rate is $25.19 ($100.79/monthly)
        - A4225 payment rate is $3.38 ($30.42/monthly)
        - Insulin infusion pump over 13 months is $5,702.34 ($95.04/monthly)
- **Proposal:** Grandfathered suppliers that do not have a contract in the CBA can continue servicing their patients, but they will need to accept the monthly rental SPA.
- **Proposal:** Class II CGM receivers and insulin pumps owned by the beneficiary prior to the CBP can continue to be owned by the beneficiary. Supplies/accessories will be paid separately based on the SPA. The beneficiary will have a choice at the start of the new round to transition to a rental at any time.
    - This is intended to be a temporary transition.
- **Proposal:** Suppliers will be allowed to bill up to 3 months in advance, as they can now for CGM supplies.
- **Proposal:** Calculate what the Class II CGM payment rates would have been in 2015 in order to compare the unadjusted fee schedule amounts for insulin pumps from 2015 for the purposes of calculating non-lead item SPAs for insulin pumps.
    - CMS would use the 2025 fee schedule for Class II CGM and remove the fee schedule update from 2016-2025 to obtain the 2015 price.
- Other notes:
    - Not proposed, but CMS notes that Class II CGM and insulin pumps would likely be in the same bidding category with Class II CGMs being the lead item.

b. CMS States It Has Authority to Add Medical Supplies Product Categories to CBP

- **Proposal:** Clarifying the definition of "medical equipment items" to include ostomy, tracheostomy, and urological supplies.
    - Although CMS believed the section of the Act that defines items that can be included in the Medicare DMEPOS CBP was ambiguous, it no longer believes it is and is interpreting the section as providing CMS the discretion to include or exclude the medical supplies.

  - CMS highlights the increased utilization, high payment rates, and high improper payment rates as reasons to qualify the supplies to be included to be CBP.
- **Proposal:** Medical equipment, including ostomy, tracheostomy, and urological supplies are purchase items for which the SPA is calculated based on the bids submitted and accepted.

c. Remote Item Delivery Competitive Bidding Program (RID CBP)

- **Proposal:** "Remote item delivery item" to be defined as *"an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person."*
- **Proposal:** Contract suppliers are responsible for furnishing mail and non-mail order items under RID CBP. If a patient decides to pick up supplies from a supplier, they would need to go to a contracted supplier.
- **Proposal:** Create one national RID CBP or regional RID CBP that includes several CBAs in one region.
  - CMS is soliciting comments.
  - The program is similar to the national mail-order program, but would include items that are not typically picked up by the beneficiary at a supplier location.
  - The items included are based on historical utilization and how beneficiaries are currently typically receiving the items.
- **Proposal:** Set bid limit to the 2015 fee schedule specific to the area of service instead of using the average 2015 fee schedule.
- **Proposal:** Bids for OTS back and knee braces included in future RID CBP to not exceed the average of the non-rural fee schedule amounts that would otherwise apply.
  - OTS back and knee braces were bid in the most recent CBP round, was included in over 100 CBAs, but did not move forward in all CBAs.
- **Proposal:** Create a "fail-safe" to ensure that the bid limit would never exceed the unadjusted fee schedule (2015 fee schedule).
- **Proposal:** Add items from Table 45 to RID CBP.

TABLE 45: CATEGORIES OF ITEMS FURNISHED FROM REMOTE SUPPLIER LOCATIONS

Category	2024 Allowed Charges for the Category	Lead Item	Average Distance[88] (Lead Item)
Class II Continuous Glucose Monitors	$1,945 million	A4239	813 miles
Urological Supplies[1]	$1,214 million	A4353	784 miles
Ostomy Supplies[1]	$436 million	A5057	758 miles
Insulin Pumps	$151 million	E0784	679 miles
Off-the-shelf Knee Braces	$138 million	L1852	1047 miles
Off-the-shelf Upper Extremity Braces	$127 million	L3916	1049 miles
Off-the-shelf Back Braces	$126 million	L0651	976 miles

[1] Urological supplies and ostomy supplies categories have 9 overlapping HCPCS codes at $16 million

**Table provided in the proposed rule.*

- For OTS back and knee braces, CMS is soliciting comments on whether all HCPCS codes it is recommending be included in the RID CBP are not suited for mail order and if they should be furnished only as non-mail orders.

  - An alternative approach would be to exclude codes with a national average delivery distance of less than 100 miles from the initial competition and only include them in future nationwide or regional competitions if their average delivery distance increases to over 100 miles. Under this approach, contract suppliers would not be required to furnish these items; however, CMS is concerned about the potential impact on beneficiary access.
- **Proposal:** In situations where beneficiaries lose or are temporarily without their supplies that are included in RID CBP, suppliers would continue to have the beneficiary be responsible for the replacement supplies and have them sign an Advance Beneficiary Notice (ABN).
  - CMS expects this to be a rare occurrence.
  - This is currently how replacement supplies are handled.
  - Beneficiaries can utilize the appeals process to potentially get the replacement supplies covered by Medicare.
- **Proposal:** Phase in the RID CBP and non-CBA rates based on RID CBP competitions.

2. Changes to Winning Bid Calculation and Contracts

a. Changes to Calculating Winning Bids: 75th Percentile and 25% Reduction in Number of Contract Winners

- **Proposal:** Change the winning bid from the maximum winning bid to the 75th percentile of winning bids and reduce the number of contract winners by 25% from previous rounds. For future rounds, the number of contracts would be adjusted based on Medicare fee for service enrollment changes.
  - By limiting the number of winning contractors, the winning bid would be closer to the median bid.
  - CMS believes Round 2021 failed because CMS did not limit the number of contracts.
    - If the Round 2021 had moved forward, CMS estimated it would have resulted in a $1.2B increase in payments to contract suppliers.
    - CMS also notes, *"…industry consultants created and distributed information encouraging bidding entities to submit very low estimates of their capacity to furnish items if awarded a contract in order to significantly overinflate the total number of contracts awarded and drive up the maximum winning bids and SPAs."*
  - *"This option partly addresses the criticism provided by DMEPOS suppliers, manufacturers, and certain economists about paying contract suppliers less than their bid amount. However, as noted previously, the fact that 92 percent of suppliers accepted contracts at the median bid rates, and these amounts were proven to be adequate for items and services to be furnished with no negative impact on health outcomes, indicates that this criticism may be unfounded."*
- **Proposal:** CMS will evaluate the composite bid by: (1) determining how many contract suppliers are needed; (2) listing all the bids from lowest to highest; (3) choosing the required number of suppliers while making sure each bidder meets the eligibility requirements.
- CMS considered other options but is not proposing:
  - "Median bid"—Median winning bid of all bidders

- "Maximum bid"—reduce contracts by 50% below past rounds
- CMS contracted with the Research Triangle Institute (RTI) that simulated the different options using the R2RC and R1 2017 information
    - RTI identified the number of suppliers that furnished at least 5% of the total utilization under each round and doubled to generate the target number of contract winners.
    - SPAs for lead items calculated based on 75th percentile of winning bids.
    - If 75th percentile fell between 2 bidders, the SPA was determined using the 75th percentile between the two bids, rounded to the nearest cent.

TABLE 40: EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING ON ONE SUPPLIER

Winning Contract Suppliers	Bid Amount
1	$4.00
2	$5.00
3	$5.25
4	$5.50
5	$6.00
6	$6.50
7	$7.00
8	$7.50

The 75th percentile falls directly on the sixth winning supplier (8 X 75 percent = 6), resulting in the SPA of $6.50.

TABLE 41 EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING BETWEEN TWO SUPPLIERS

Winning Contract Suppliers	Bid Amount
1	$4.00
2	$5.00
3	$5.25
4	$5.50
5	$6.00
6	$6.50
7	$7.00
8	$7.50
9	$8.00

**Tables provided in the proposed rule.*

- For Table 41, the 75th percentile falls between the 6th and 7th bidder (9*.75= 6.75). The SPA would be calculated based on the 75th percent of the two bids ([$7-$6.50] +$6.50=$6.88)
- Table 42 is an example of the 75th Percentile option for oxygen lead item using the R1 2017 data.

TABLE 42: ROUND 2017 RESULTS COMPARED WITH SIMULATION RESULTS FOR OXYGEN AND OXYGEN EQUIPMENT (LEAD ITEM HCPCS LEVEL II CODE E1390)

CBA	2017 # of Contracts	2017 SPA	75th # of Contracts	75th SPA	Reduction in # of Contracts	Reduction in SPA
Charlotte-Concord-Gastonia, NC	21	$79.00	14	$72.33	33%	8%
Chester, Lancaster & York Counties, SC	15	$70.04	11	$70.00	27%	0%
Cincinnati, OH	21	$79.00	12	$76.21	43%	4%
Cleveland-Elyria, OH	25	$78.00	16	$77.42	36%	1%
Covington-Florence-Newport, KY	18	$72.45	11	$69.81	39%	4%
Dallas-Fort Worth-Arlington, TX	31	$76.48	22	$72.90	29%	5%
Dearborn, Franklin, Ohio & Union Counties, IN	15	$74.92	9	$70.09	40%	6%
Kansas City-Overland Park-Ottawa, KS	18	$79.23	12	$73.91	33%	7%
Kansas City, MO	19	$78.53	13	$73.91	32%	6%
Miami-Fort Lauderdale-West Palm Beach, FL	29	$90.01	16	$82.99	45%	8%
Orlando-Kissimmee-Sanford, FL	23	$79.20	12	$72.00	48%	9%
Pittsburgh, PA	28	$77.50	20	$70.71	29%	9%
Riverside-San Bernardino-Ontario, CA	21	$79.22	13	$70.77	38%	11%

**Table provided in the proposed rule.*

- CMS is aware that the simulation is based on previous rounds and it may not reflect bidding behaviors for future rounds, but believes this would still result in savings while maintaining beneficiary access.

b. Changes to Contract Award Threshold

- **Proposal:** Adjust the number of contracts awarded to double the number of contract suppliers that previously furnished at least 5% of the items or services needed in the competition.
    - CMS has historically used a number of contracts in excess of projected demand to ensure beneficiary access.
    - Under Round 2 Recompete (R2RC) and Round 1 2017 (R1 2017), only 28% of contract suppliers accounted for at least 5% of the total items and services furnished by contract suppliers in each competition.
- **Proposal:** At least 2 suppliers per competition.
    - Regulations today requires at least 5 suppliers.
- **Proposal:** If fewer suppliers bid than the target number of contracts, CMS would still move forward with the competition so as long as there are at least two winners and there are no major concerns about meeting demand.
    - In these scenarios, CMS will monitor access and implementation.
- **Proposal:** For product categories that were included in previous rounds, the number of contract suppliers cannot be more than two times the number of suppliers that furnished at least 5% of the total services for the lead item in the CBA. The number can be adjusted based on enrollment in the CBA since 2018 or 2023.
- **Proposal:** For new product categories, the number of contract suppliers should not exceed 125% of the number of suppliers that furnished at least 3% of the total utilization of the lead item in the product category and CBA during the most recent calendar year prior to bidding.
- CMS maintains that, "One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market" (72 FR 18036).

c. Changes to Lead Item Bid Ceiling Rules

- **Proposal:** For product categories that have already been included in previous rounds of 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 competition, the bid amount cannot exceed the lesser of (1) the most recent SPA for the item increased by the CPI updates since then, or (2) the unadjusted fee schedule amount for the item.
- **Proposal:** 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.
- **Proposal:** For new product categories to CBP, the lead item bid cannot exceed the 2015 unadjusted fee schedule.

d. Changes to Lead Item to Non-Lead Item Ratio

- **Proposal:** Change the ratio of lead item to non-lead item by area.
    - Under current regulations, the ratio is based on the average national ratio.
        - For example, under the proposal, for a CPAP category in Miami, the ratio of the CPAP device (lead item) to all supplies (non-lead items) would be specific to the unadjusted rates that were used in Miami, i.e., Florida 2015 rates.

e. Inflation Adjustment to SPAs

- **Proposal:** Apply inflation adjustments to the SPA during the second and third year of the contract equal to the CPI-U for the 12-month period ending 6 months prior to the beginning of the respective second and third year. The updated rate cannot be more than the unadjusted rate or 110% of the adjusted rate. (Current regulations provide for no CPI update during the contract period.)

f. Contract Award Determinations

- **Proposal:** Not award contracts if the total payments under the CBP would end up being higher than what Medicare would otherwise pay.
    - The largest decrease in prices occurred with the first round—20%-50% savings.
    - CMS credits the CBP price reductions with effectively reducing improper utilization (based on beneficiaries not reporting access issues).
        - Evidence suggests a 10%-20% reduction in fraud, waste, and abuse due to the implementation of CBP.
- **Proposal:** For items not previously included in a bid program (e.g., CGMs) - The first time a competition is conducted after 2023, the number of contract suppliers selected to furnish items and services is at least 2, but no more than 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, and rounded to the nearest whole number.

- Due to there being a higher concentration of suppliers servicing in the area, lowering the threshold to 3% would determine which suppliers meaningfully contributed.
- Past data shows only 28% of suppliers met the 5% threshold in previous CBP rounds.
- Based on 2023 Medicare claims data, CMS estimates there would be 7-10 contracts awarded for RID CBP product categories such as CGMs and braces under this new program.
  - 11 contracts were awarded in the previous diabetes supplies national mail order program, but 5 suppliers provided 92% of the services.

- **Proposal:** Remove the use of supplier-reported capacity to determine the number of contracts to award in a competition. Instead, CMS will determine capacity based on previous rounds of CBP or utilization data.

3. Require Less Financial Documentation in the Bid Submission Process

- **Proposal:** No longer require tax returns, income statements, balance sheets, and cash flows as part of the required financial documentation submission.
  - Part of an effort to reduce the number of documents that are required while providing enough information to confirm that bidders are financially stable enough to participate in CBP.
  - Reduced number of documentations is expected to reduce costs of reviewing the applications and reduce the chances that bids are disqualified due to errors in submissions.
- **Proposal:** CMS will continue to require bidders to submit 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.
- **Proposal:** Because credit bureaus regularly update credit reports with new information, the credit reports used for bid submissions must be finalized close to when the bid window opens. To address this, CMS is proposing to publish the applicable scoring list for each round in the round-specific Request for Bids (RFB) or in a Financial Scoring Methodology Fact Sheet to assist bidders with clear guidance.
- **Proposal:** CMS will no longer use credit scores to consider capacity.
  - For previous rounds, CMS has been using the bidder's credit score and other information to determine if the supplier can provide more than what it has historically provided to beneficiaries.
- **Proposal:** CMS will continue to use the five-tier scoring system in reviewing supplier credit scores, where 12 or higher is passing.
  - The scores are either 4, 8, 12, 16, or 20 points—4 being the worst and 20 being the best.
  - CMS reviewed 19 suppliers (bidders) that were previously reviewed that received a score of 8 and found that 4 of the bidders no longer had active locations in December 2023,

which supports its theory that credit scores have a strong correlation with suppliers' ability to continue services with Medicare.

- **Proposal:** Add a field in the application that would require bidders to add their gross revenue.
    - In previous rounds, CMS determined the size of the supplier by using the bidder's tax return—this was specifically used to ensure that at least 30% of the contract suppliers are small suppliers.
        - Small supplier = gross revenue of $3.5m or less
    - The proposal will assist CMS with determining if the supplier is a small supplier.
        - CMS will review claims data to confirm the accuracy of the submission.
        - Suppliers that falsify their information will be referred to the Office of Inspector General and the Department of Justice for further investigation.
- **Proposal:** 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.
    - Currently, there are four different notifications CMS messages bidders regarding their documentation submission.
    - Under current requirements, if there are any missing documents in a bidder's application by the covered document review date (CDRD), CMS is legally required to notify the bidders of the missing document(s) by the close of the bid window.
    - CMS is prohibited from disqualifying the bid submission.
    - CMS will continue notifying bidders within 90 days of the CDRD on whether covered document(s) are missing or confirm receipt of documents.
    - The supplier will have 10 business days from receiving the notice to submit their missing documents.
- **Proposal:** Give bidders a single, 10-business-day window to fix issues with their bid surety bond by submitting a corrected bond rider. If a bond is found to be incorrect, incomplete, or missing required information, CMS would notify the bidder through the DMEPOS CBP's secure portal. The bidder would then be allowed to submit a corrected bond rider within those 10 business days.
    - CMS would only notify bidders of deficiencies that can be corrected with a bond rider.
    - The 10-day timeframe was used successfully in the Round 2021 bidding process and is expected to run alongside other parts of the bid evaluation.
    - CMS believes that bidders have access to the necessary tools (such as fact sheets and templates) and that it is the bidder's responsibility to meet all bid surety bond requirements.

4. Technical Changes

a. Surety Bonds

- **Proposal:** Codify bid surety bonds into law.
    - CMS is correcting a technical error in the law.

b. Definition Changes to Streamline Regulation Text

- **Proposal:** Change the following definitions to streamline regulation text, rather than continuing to write out "competitive bidding area and product category combination":
    - Adjusted fee schedule: the payment amount established for the item under Subpart C of this part, with the application of § 414.105; Subpart D of this part, with the application of § 414.210(g); or Subpart Q of this part, with the application of § 414.1690.
    - Unadjusted payment amount: the payment amount established for the item under Subpart C of this part, without the application of § 414.105; Subpart D of this part, without the application of § 414.210(g); or Subpart Q of this part, without the application of § 414.1690.
- **Proposal:** Add a definition for "Competition" under § 414.402 to mean *"a competitive bidding area and product category combination where bids are submitted by suppliers in an attempt to be awarded contracts for furnishing competitively priced items and services within the product category in the competitive bidding area. The contracts must be recompeted not less often than once every 3 years. We are soliciting comments on this proposal."*

5. Termination Clause for Contract Suppliers Impacted by Public Health Emergency (PHE)

- **Proposal:** If CMS determines that a contract supplier is not able to provide due to being impacted by a public health emergency (PHE), CMS has the option to unilaterally terminate or modify each impacted CBP contract to allow for any DMEPOS supplier to step in to furnish needed services in the PHE-impacted area.
    - The PHE-impacted area can be the entire CBA or certain parts of a CBA.
- **Proposal:** if the PHE-impacted area encompasses all CBAs a supplier has contracts in, CMS can unilaterally terminate the supplier contract. If the PHE-impacted area only encompasses a portion of the supplier contracted areas, CMS can unilaterally modify the contract to remove the contracted supplier's obligation to provide the services and also CMS' obligation to pay for the services under the CBP supplier contract.
- **Proposal:** After a termination or modification takes effect, the payment rate will revert to the Medicare fee-for-service fee schedule.
    - Medicare-enrolled DMEPOS suppliers that do not have a contract are not required to furnish to beneficiaries and are not required to accept assignment unless they are already registered as participating suppliers.
- **Proposal:** The criteria for terminating or modifying contracts would require the following criteria: (1) PHE is declared by the Secretary; (2) CMS identifies evidence that there are DMEPOS access issues within a CBA; (3) CMS identifies that awarding additional contracts would not eliminate the access issues; (4) CMS identifies that terminating or modifying supplier contracts that would allow for other suppliers to provide would alleviate the access issues.
- Background:

- Under current regulations at 42 CFR §414.422, contract suppliers are required to furnish items and services to all residents and visitors within a Competitive Bidding Area (CBA) for which they hold a contract.
- In 2006, CMS proposed adding a clause allowing unilateral contract termination for convenience. However, CMS did not finalize this proposal in the 2006 final rule (71 FR 25682) due to public comment.
    - CMS has never identified a situation where all contract suppliers in a competition were unable to meet beneficiary demand, even during a public health emergency (PHE).
        - CMS attributes this to the fact that not all contract suppliers are physically located within the affected CBA.
        - Suppliers are required to have contingency plans in place to ensure continued service during emergencies and disasters, and CMS has found that suppliers generally resume operations promptly.
- Despite this, CMS remains concerned that during a PHE, contract suppliers may be unable to fulfill their contractual obligations within the CBA. If CMS determines that, due to a PHE, contract suppliers cannot furnish items and services to affected beneficiaries, CMS believes it would be prudent to have authority to unilaterally modify or terminate applicable contracts. This would include removing the requirement to furnish items and services within the PHE-impacted area from the scope of the CBP.

Changes to Accreditation Policies and Accrediting Organizations

The following is a summary of CMS's proposed regulatory changes to the DMEPOS accreditation policies and changes to the accrediting organization requirements that may impact DMEPOS suppliers. Throughout the section, CMS highlights the heightened risk of fraud, waste, and abuse by DMEPOS suppliers. CMS also proposes changes to the enrollment and oversight of Accrediting Organizations (AO), where some of the changes may impact DMEPOS suppliers.

1. Increase Frequency of Surveys and Reaccreditations

- **Proposal:** Revise to require DMEPOS suppliers to be surveyed and reaccredited at least once every 12 months.
    - Under current requirements, DMEPOS suppliers are surveyed and reaccredited every three years.
    - CMS recognizes this change would be burdensome for DMEPOS suppliers but emphasizes the importance of protecting the Medicare Trust Fund and beneficiaries.
- **Proposal:** CMS proposes to revise § 424.57(c)(22) to clarify and strengthen accreditation requirements for DMEPOS suppliers. Specifically:
    - 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.

- **Proposal:** Require AOs to conduct surveys of all suppliers applying for accreditation or reaccreditation and prohibit AOs from granting accreditation until the survey is completed and the supplier is found to meet all applicable quality standards.
- **Proposal:** All surveys must be unannounced to ensure an accurate evaluation of supplier compliance, but CMS may waive this in limited cases.
    - CMS notes they do not anticipate waiving unannounced visits.
- **Proposal:** CMS may direct AOs to conduct a survey at any time, even between accreditation cycles.
    - CMS notes this change is intended to verify ongoing supplier compliance, not just during initial or renewal cycles.
- **Proposal:** Remove the current regulation that the AO may accredit the new supplier for 3 months after the location is in operation and without a survey.
    - CMS notes that in their view, the current regulation that would allow new supplier locations to operate for 3 months without a vetting of the location presents a serious risk for improper activity.

2. CMS Expanded Revocation Authority on DMEPOS Suppliers

- **Proposal:** Supplier's number can be revoked if the beneficiary attests that they never received the item or service listed in the supplier's claim
    - CMS notes they have recently seen cases where providers have submitted claims for payment that were never provided.

- **Proposal:** Expand the list of situations where CMS may apply a retroactive effective date for a revocation. The effective date would vary based on the reason for the revocation:
    - False or misleading information in the enrollment application—revocation would be the date the application was signed.
    - Failure to timely report a change of ownership and other key changes—revocation would be the day after the date by which the supplier was required to report to CMS.
    - For revocations of any of the supplier's other enrollments under § 424.535(i)—the revocation date of the other location(s) would trigger a revocation.
    - Non-compliance with a condition or standard in § 424.57(b) or (c)—revocation would be the date the non-compliance began.

3. Expansion and Clarification of Stay of Enrollment

- **Proposal:** Expand to apply Stay of Enrollment for rejected revalidations and change of information.

  - CMS notes this is intended to help minimize excessively or unfairly penalizing suppliers for minor instances of non-compliance.
- **Proposal:** Change the start of Stay of Enrollment to 1. Start of the non-compliance or 2. When the application is rejected.
  - Currently the start of Stay of Enrollment is based on the date of the letter.
  - The intention of the change is to activate the Stay of Enrollment earlier.
- **Proposal:** CMS is 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
- **Proposal:** Technical change to remove references to "60-day period" to "CMS assigned stay period"
  - This is intended to further clarify that the stay of enrollment can be active for less than 60 days.

4. Enrollment Documentation Requirements

- **Proposal:** Suppliers are legally responsible for the accuracy and faithfulness of the applications, even if another party completed the applications.
- **Proposal:** CMS to have the right to request additional validating documents if needed to ensure the accuracy of supplier application information.
  - CMS notes this does not necessarily mean the amount of documentation suppliers need to submit will greatly increase.
  - The proposal is intended to strengthen CMS's ability to validate the supplier's ownership and managerial data.
- **Proposal:** The authorized official on the 855s must be the party to sign the liability insurance policy.
  - CMS notes they have seen instances where the employee of the supplier that do not have the authority to act on behalf of the owner have signed the liability insurance.
  - Under current requirements, DMEPOS suppliers must have a comprehensive liability insurance policy of at least $300K.

5. Changes to AO Denials and Terminations

- **Proposal:** AOs would be required to deny or terminate a supplier's accreditation if the following is observed:
  - Lacks required license(s)
  - Is not operational
  - Is an inaccessible location
  - Supplier's Medicare enrollment was revoked due to non-compliance with quality standards and is still under a reenrollment bar
  - CMS directs to have the supplier's accreditation be denied or terminated.
    - AOs must deny/terminate accreditation within 3 business days of CMS's written correspondence
    - AOs must respond in writing to CMS within 5 business days of the action(s) taken

- The proposals are intended to prevent accreditation of high-risk suppliers and ensure that timely action is taken.

6. Changes to Notification Requirements on Complaints

- **Proposal:** Require AOs to report supplier complaints to CMS within 5 calendar days of receiving the complaint.
    - This is a change from the current requirement of reporting monthly.
- **Proposal:** AOs must promptly review the complaint to determine whether the supplier was non-compliant with the quality standards or CMS requirements. If the AO finds that the supplier may not have been compliant, the AO must conduct a survey within 21 days of receiving the complaint.
- **Proposal:** The AO must notify CMS within 10 days of completing a survey that was prompted by a complaint. The AO will need to share the results of the survey and any actions taken or planned to be taken against the supplier.

7. Notification and Impact to DMEPOS Suppliers if Accreditation Organization Contract is Terminated

- **Proposal:** Affected suppliers will be notified of the suspension of the AO's accreditation program and informed 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.
- **Proposal:** Suppliers requiring reaccreditation would need to be reaccredited by their original AO once the suspension is lifted or obtain accreditation from a different AO.

8. Limitations on Accrediting Organizations' Consulting Services

- CMS proposes additional changes to setting parameters on consulting services provided by the AO or its consulting division. This is a follow-up for the February 15, 2024, proposed rule.[i]
- The purpose of the proposals is to maintain the AO to be an objective surveyor as their dual role may lead to bias.
- **Proposal:** There are scenarios when an AO or its consulting division is prohibited from providing consulting services to DMEPOS suppliers:
    - Any new supplier that has not yet completed their initial accreditation survey
    - Supplier that the AO accredits within six months of the supplier's next scheduled re-accreditation survey
    - To a supplier for whom the AO provides accreditation services, when the AO receives a complaint about that supplier.
- **Proposal:** There are scenarios when an AO or its consulting division is permitted to provide consulting services to DMEPOS suppliers:
    - The first 6 months immediately after an accreditation or reaccreditation survey.

- When CMS or another contract receives and is investigating a complaint about the supplier. But consulting services can be provided once the investigation is complete. The consulting services can only focus on the issues that were identified in the investigation.
- Consulting services are provided to suppliers that are not undergoing accreditation by the AO at the time the services are rendered.
- **General education offered by the AO about its accreditation program.**

9. Changes in Majority Ownership (CIMO)

- **Proposal:** DMEPOS suppliers going through a CIMO must enroll as a new supplier and be newly accredited and surveyed.
    - The change will mirror current requirements for Home Health Agencies and hospices.

Prior Authorization Exemptions for Certain DMEPOS Suppliers

The following is a summary of CMS's proposed regulatory changes to prior authorization to clarify and streamline the exemption process for compliant DMEPOS suppliers. This is a follow-up from the 2019 ESRD PPS & DMEPOS final rule[ii] that established authority for CMS to exempt suppliers that demonstrated compliance with Medicare requirements from participating in prior authorization. In the 2019 rule, CMS did not detail the exemption process but has since received requests for clarification.

- **Proposal:** DMEPOS suppliers would be exempt from Prior Authorization If they meet at least 90% provisional affirmation rate during initial or periodic assessments, and are consistently compliant with Medicare requirements (coding, coverage, payment rules).
    - CMS is not setting compliance at 100% compliance to account for unintentional and sporadic errors that are not deliberate can occur.
- **Proposal:** The prior authorization exemption would remain until CMS withdraws it. The withdrawal will be triggered if the supplier's claims reviewed shows they are non-payable, or their non-affirmation rate exceeds 10%.
- **Proposal:** Suppliers will be notified 60 days before an exemption or withdrawal goes into effect.
    - The advance notice is intended to allow suppliers to adjust operations accordingly.

[i] 89 Fed. Reg. 11996 (Feb. 15, 2024)
[ii] 83 Fed. Reg. 56922 (Nov. 14, 2018)