



Via email to [secretary@hhs.gov](mailto:secretary@hhs.gov)

June 18, 2018

The Honorable Alex M. Azar, II  
Secretary  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S. W.  
Washington, D. C. 20201

**RE: President's Budget 2019**

Dear Secretary Azar:

The American Association for Homecare (AAHomecare) would like to take this opportunity to provide comments to Department of Health and Human Services (HHS) on the recently released President's Budget.

AAHomecare is the national association representing the interests of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. AAHomecare members include a cross section of manufacturers, suppliers and other industry stakeholders that assist, make or furnish DMEPOS items that beneficiaries use in their homes. Our members are proud to be a part of the continuum of care that assures that Medicare beneficiaries receive cost effective, safe and reliable home care products and services.

On February 19, 2018, the HHS published [Fiscal Year 2019 President's Budget in Brief](#). AAHomecare identified seven proposals within the Brief that would impact the DMEPOS industry and have developed a response to each of these proposals.

The key issues are separated into specific recommendations to DMEPOS and the appeals process. These are summarized below and then discussed in more detail.

**1. Address overutilization and billing of DMEPOS by expanding Prior Authorization.**

AAHomecare supports the expansion of the prior authorization program, however, we encourage CMS to continue to review and improve the program and consider the unique requirements for different product categories.

**2. Reform and expand durable medical equipment competitive bidding.**

Competitive bidding should not be expanded into rural area. Several studies have detailed out challenges and issues with access to care for Medicare beneficiaries both in and outside of competitive bidding areas. In addition, CMS has recognized the reduction in number of suppliers in a recently released IFR. Expanding competitive bidding will only further deteriorate access to care issues. AAHomecare has supported reform to the current program and has submitted several proposals to CMS and HHS.

**3. Address excessive billing for durable medical equipment that requires refills or serial claims.**

The budget proposal seeks to add an additional layer to the oversight of beneficiaries who rent durable medical equipment and receive on-going accessories and supplies. CMS and the DME MACs have many mechanisms in place today on how the industry monitors these activities. Adding additional requirements would be costly to the Medicare program and delay access to care for Medicare beneficiaries.

**4. Eliminate the unnecessary requirement of a face-to-face.**

AAHomecare supports the elimination of the face-to-face requirement as required in the ACA. Medicare policies already require a clinical examination prior to receipt of equipment and supplies. As such, there is no need for an additional face-to-face requirement.

**5. Increase the minimum amount in controversy required for an adjudication to the Administrative Law Judge to the Federal District Court amount in controversy requirement.**

The industry has serious concerns about this proposal based on the fact that DMEPOS appeals are currently and have been for many years approximately 50% of the backlog at the ALJ level.

**6. Establish a post-adjudication user fee for the third level and the fourth level of appeals.**

As the health care sector with the largest volumes of appeals with the lowest average dollar value, AAHomecare is concerned that a fee associated with an appeal will unfairly target the DEMPOS industry.

**7. Require a good-faith attestation on all appeals.**

The requirement for suppliers to sign a good faith attestation is an attempt to discourage the filing of appeals. HHS needs to address the root causes of the appeals backlog issue and provide the additional resources to process appeals in the mandated timeframe.

In conclusion, AAHomecare requests Secretary Azar evaluate the President's Budget in detail to ensure those items specifically affecting the DMEPOS industry be reviewed prior to any implementation. The industry welcomes the opportunity to meet with HHS and CMS to further discuss these comments further. Thank you for your time and consideration.

Sincerely,



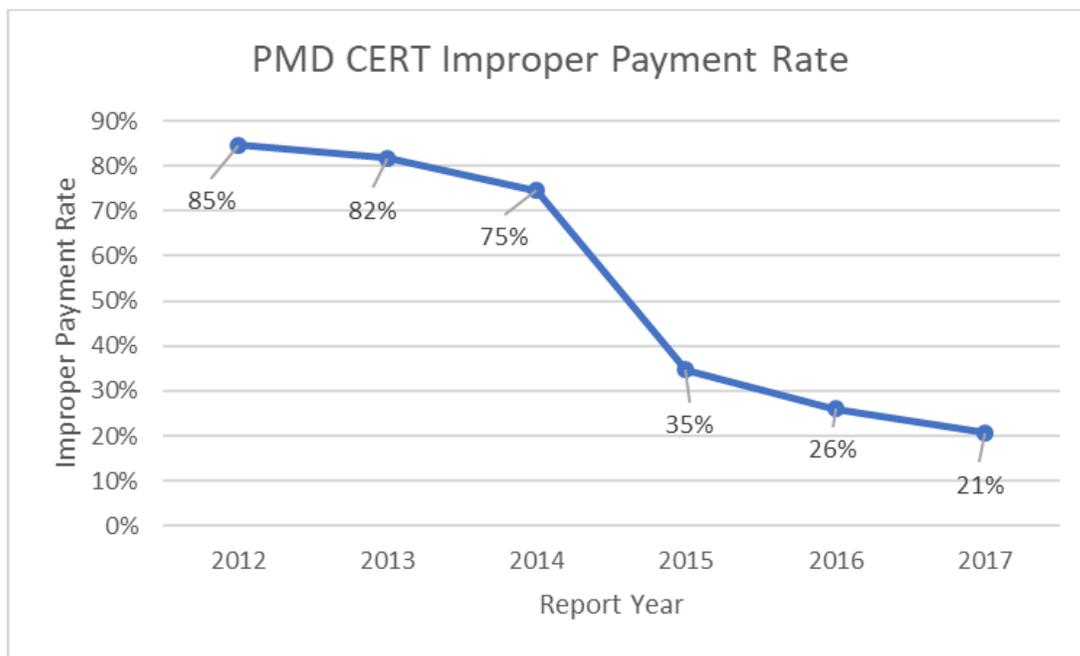
Tom Ryan  
President and CEO  
American Association for Homecare

CC: Deputy Secretary Eric Hargan  
CC: Administrator Seema Verma

*In analysis of the details of the budget items listed above, AAHomecare developed the following to further assist in understanding our concerns as follows:*

- 1. Address overutilization and billing of DMEPOS by expanding Prior Authorization.** This proposal expands prior authorization to additional items and services that are at high risk for improper payments. In FY 2016, CMS finalized a regulation that established a master list of items that are both high-cost and high-risk for improper payments and therefore could be subject to prior authorization. This proposal would expand the number of items on the list subject to prior authorization. [Budget impact not available]

CMS has already implemented a successful prior authorization (PA) pilot program for certain DME items and is in the midst of further expansion of this program. PA is already the preferred method of many other third-party payers, including Medicaid programs. In addition, there has been support for expanding this program by Congress. In previous legislation there was an audit exemption for prior authorized services. Power Mobility Devices (PMD) PA Demonstration has proven to be successful for CMS by reducing improper payments; and the evidence can be seen in CMS' Comprehensive Error Rate Testing (CERT) reports. In the 2012 Medicare Fee-for-Service Supplemental Improper Payment Data report (date of service: 07/01/2010-06/30/2011), CMS reported an 84.6% improper payment rate for PMDs.<sup>1</sup> However, the 2017 report that was published earlier this year showed an improper payment rate of 20.8%.<sup>2</sup> Within a 5-year period, the CERT improper payment rate for PMD was reduced by 75%. You can see the trend in the graph below.<sup>3</sup> The significant drop seen between the 2014 report and 2015 report coincides with the start of the PMD PA Demonstration.



The PMD PA Demonstration has helped CMS reduce improper payments and ensure that the right beneficiary acquires the correct equipment by moving away from a pay and chase model to proactively determining coverage. The benefits to CMS include relief for audit and appeal contractors since prior authorized items have been deemed to meet the medical necessity requirements, these items are excluded from audits and thus the appeals process.

<sup>1</sup> Centers for Medicare and Medicaid Services (2013). Medicare Fee-for-Service 2012 Improper Payments Report.

<sup>2</sup> Centers for Medicare and Medicaid Services (2018). Medicare Fee-for-Service 2017 Improper Payments Report.

<sup>3</sup> Data is retrieved from the annual CERT Reports on Centers for Medicare and Medicaid Services' Comprehensive Error Rate Testing (CERT) website, last accessed on March 7, 2018: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports.html>

While CERT audits may still occur, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs), Recover Audit Contractor (RAC), and Supplemental Medical Review Contractors (SMRCs) no longer audit these claims for medical necessity.

AAHomecare supports the expansion of the PA program, however, we encourage CMS to continue to review and improve the program and consider the unique requirements for different product categories. Here are some issues to consider:

- The current PA program CMS administers determines inclusion based on the price of the equipment/service and historical improper payment rates. We advise HHS to consider the longevity of the service. For example, aerosol medications, infusion medications, enteral therapy, urological and ostomy supplies tend to be needed on a long-term basis, often until the patient expires. If these types of service could be prior approved, it could alleviate large volumes of audits for beneficiaries that have a chronic illness who have long-term need.
- Product categories in total should be considered for prior approval. While oxygen concentrators are on the PA master list, not all oxygen equipment is listed. If a beneficiary received a prior approval for oxygen therapy, then all items should be approved and eliminated from the audit and appeal cycle. The timing of the authorization process is a critical factor in determining which product categories should be considered. While a ten-day turnaround time may work for PMDs, it will not work for many items that are needed quickly. The industry is very supportive of a PA process that is efficient, electronic and timely. Given most issues related to the PA process lie with the prescriber and their records, consideration should be given to requiring the prescriber to obtain the authorization prior to writing an order and sending to a supplier. In similar situations, the ordering physician for an MRI seeks the authorization, not the imaging facility or the patient, and the surgeon's office seeks the authorization for a surgery, not the facility or the patient. These situations, as with DMEPOS, it is the prescriber's records and recommendation that are needed for an authorization to be issued.
- The current PA program for the two group 3 PMD codes does not allow for the notification of the prescriber on a PA decision. AAHomecare advocated for the prescriber to receive notification and CMS has allowed a change to the process if the prescriber requests a copy of the decision letter at the time the PA is requested. For the PMD PA demonstration, the correspondence has improved prescriber education on documentation requirements and has been imperative to the success of the Demonstration.
- Consideration must be given in any expansion of the PA process to allow for same day approvals for items that are orders on a hospital discharge. The current demonstration and PA process work well for items or services that are not needed immediately, however this process will not work for same day services.
- The DMEPOS industry is supportive of a PA process that continues to be **prior** to a service being rendered. A preclaim review or a system where an authorization is not needed for the first 30 days will not work for the DMEPOS industry.
- The expansion of PA should exempt any claims for items that receive prior authorization from subsequent routine audits, unless probable fraud and abuse is suspected. This would dramatically reduce the burden placed on the Medicare audit and appeals system by redirecting the focus of audits to criminal activities rather than lawful suppliers.

- 2. Reform and expand durable medical equipment competitive bidding.** This proposal eliminates the requirement under the durable medical equipment competitive bidding program that CMS pay a single payment amount based on the median bid price, and instead, pay winning suppliers at their own bid amounts. Additionally, this proposal expands competitive bidding to all areas of the country, including rural areas. Expanding competitive bidding to rural areas will set prices for items and services in rural areas based on competitions in those areas rather than on competitions in urban areas. In the event that in a rural area less than two suppliers submit bids, CMS will use a reference price from other, similar rural areas. [\$6.5 billion in savings over 10 years].

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directs CMS to “determine a single payment amount (SPA) for each item or service in each competitive acquisition area” based on bids submitted and accepted for such items. The President’s budget has proposed replacing the current “median price” payment method with paying contract suppliers the amount they submitted on their bids. CMS’ current median price method reimburses half of all winning bidders more than the estimated costs reflected in their bids while the other half gets reimbursed below their costs. CMS adopted the median price methodology with no apparent justification except to achieve the lowest possible CBP prices. But this payment method is only one component of a program designed to force prices down to the lowest possible level. Median pricing makes a bad bidding design worse by forcing responsible suppliers to accept contracts below their costs. Switching from SPAs to bidders’ winning bid amounts, however, does not fix these underlying fundamental flaws.

Aside from establishing the SPA at the median of bids at or below the clearing price, CMS’ bid design artificially drives prices down by:

- Using composite bids weighted by the bid item’s utilization, allowing bidders to game the bidding by bidding higher on low utilization base equipment like wheelchairs or CPAPs while bidding lower on higher utilization items like CPAP tubing and masks or replacement parts for wheelchairs.
- Defining bidding according to broad product categories, exacerbates pricing distortions inherent in composite bidding. Because bidders agree to furnish every HCPCS in a product category, broad product categories encourage lowball bids from suppliers that furnish only some of the many products in the category and have no intention of furnishing the others.
- Manipulating capacity determinations, and by extension clearance prices, by limiting suppliers’ capacity in a CBA to 20% and reserving the right of adjusting bidders’ self-reported capacity up or down based on its assessment of the bidder’s financial ability to grow capacity instead of using transparent criteria like a supplier’s claims history and experience with bid products in a CBA. Economists who are auction experts have criticized this payment method and have told Congress and CMS that CMS should instead adopt the “clearing price” as the payment level because that represents the lowest bid where supplier capacity is presumed to meet expected beneficiary demand in a bid area.<sup>4</sup> Economists and suppliers have further criticized the median price methodology because it guarantees low ball bidders a contract while placing responsible bidders in the untenable position of getting paid below their bid price.

The proposal to pay each winning bidder its own bid amount seems to address concerns that SPAs give low ball bidders a windfall at the expense of responsible suppliers. In reality this proposal perpetuates CBP design flaws that systematically drives prices down in a CBA. AAHomecare does not support this proposal without comprehensive reforms to CBP. Therefore, absent any larger structural reforms of the bid program, the only logical change to bid prices is to establish the bid price at the clearing price.

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<sup>4</sup> Peter Cramton, 2012. "Letter from 244 Concerned Auction Experts on the Medicare Competitive Bidding Program," Papers of Peter Cramton 111to, University of Maryland, Department of Economics - Peter Cramton, revised 2012.

Under the Medicare Modernization Act, Congress originally prohibited CMS from running CB programs in areas outside the current 100 highly populated metropolitan areas because Congress recognized that bidding was simply inappropriate in rural areas due to limited number of suppliers and potential access issues.<sup>5</sup> Instead, Congress directed the Secretary to use information obtained from CBP to adjust payment amounts for competitively bid items in areas outside CBAs. CMS implemented this authority issuing rules to create adjusted fee schedules using average regional SPA amounts from CBAs. After a brief phase-in, CMS fully implement the new rates January 1, 2017. In many cases, reimbursement dropped by as much as 75% compared to the old, unadjusted rates.

As a result of these extraordinary payment cuts in rural areas, beneficiaries in areas outside of CBAs have seen decisive drops in access to DMEPOS. Expanding CBP to these rural areas will only intensify access hurdles for beneficiaries living there. Given the well-known structural flaws of CBP and the special demographic and economics of areas outside CBAs, expanding CBP could exacerbate the access issues these beneficiaries face. We recognize and are very concerned about deteriorating access to DMEPOS in areas outside CBAs. But expanding CBP to these areas will not increase, and could very well aggravate, access for beneficiaries there. The controlling statute, 42 USC §1395m(a)(F), *requires* CMS to use information from CBAs to adjust prices for “covered items” furnished on or after January 1, 2016 in areas outside CBAs. The statute states:

*The Secretary may (and, in the case of covered items furnished on or after January 1, 2016, ... shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under [the unadjusted fee schedules] for an area that is not a competitive acquisition area ... [.]*

In the Medicare Modernization Act, Congress specifically limited CMS’ authority to conduct bid program in densely populated metropolitan areas.<sup>6</sup> This is because Congress understood that bidding requires a large number of participants to compete in the bid program, and a large enough number of contract providers to serve the population. In more rural areas, there are typically very few providers. For example, in South Dakota, there are 30 traditional DME suppliers to serve the entire state, an area of over 78,000 square miles.<sup>7</sup> There are already demonstrated access issues in states such as North Dakota and there are simply enough potential suppliers to participate in a bid program. Finally, auction experts agree that a rational bid program not only requires existing entities to participate in the bid program, but that the real competition comes from new entrants.<sup>8</sup> In rural areas, there has been a sharp decline in DME suppliers over the last several years due to increased costs of serving these areas. It is highly unlikely that bidding in rural areas would attract enough new suppliers to provide the necessary competition.

The Administration further proposes to use a reference price from other, similar rural areas if in a particular rural area there are less than two suppliers submitting bids. Congress has already required CMS to use a reference pricing methodology when it required (in the 21<sup>st</sup> Century Cures law) CMS to redraft its regulation that defines how CMS calculates prices in non-bid areas based upon bidding in metropolitan areas. Therefore, Congress should reject the Administration’s proposed alternative methodology, because it directly skirts Congress’ outstanding mandate for CMS to fix the pricing methodology in non-bid areas.

CMS should not conduct bidding in areas outside the 100 metropolitan areas that Congress originally authorized because it will accelerate the deterioration of access. CMS must amend the rules creating adjusted fee schedules using notice and comment, following Congress’ instructions in 42 USC §1395m(a)(G) which mandates CMS to: solicit and

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<sup>5</sup> Social Security Act/SSA 1847(a)(1)

<sup>6</sup> Social Security Act/SSA 1847(a)(1)

<sup>7</sup> AAHomecare analysis based on data retrieved from PDAC.

<sup>8</sup> See Testimony of Peter Cramton Before House Small Business Committee, Subcommittee on Healthcare and Technology, September 11, 2012: <http://www.cramton.umd.edu/papers2010-2014/cramton-house-small-business-hearing-comments-17-sep-2012.pdf>

take supplier input, consider the highest amount bid by a winning bidder in a CBA, and compare economic and demographic differences between CBAs and non-CBAs with respect to average travel distances, the volume of items and services and number of suppliers.

**3. Address excessive billing for durable medical equipment that requires refills or serial claims** This proposal uses Medicare demonstration authority to test whether using a benefits manager for serial durable medical equipment claims results in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring beneficiaries were receiving the correct quantity of supplies or services for the appropriate time period. [Budget impact not available]

CMS currently requires DMEPOS suppliers to follow very stringent guidelines for replacing consumable and non-consumable supplies that ensure the beneficiary is in need of the refills. The current requirements are as follows:

*For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between you and the beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by you or the beneficiary is not sufficient. The refill record must include:*

- *The beneficiary's name or authorized representative, if different than the beneficiary*
- *A description of each item that is being requested*
- *Date of refill request*
- *For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.)—you must assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.*
- *For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., positive airway pressure and respiratory assist devices' supplies)—you must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. You must document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).*

*This information must be kept on file and be available upon request.<sup>9</sup>*

The above instructions make it very clear that the supplier and the beneficiary concur on what they have and what the needs are. Current audit processes ensure that suppliers are following the CMS requirements for supplies.

In addition, CMS has issued stringent guidance on the time frames for beneficiary contact and the timing of shipping or delivering refill supply orders. Here are the current requirements:

- *For all DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use.*
- *For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must*

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<sup>9</sup> Centers for Medicare and Medicaid Services, Face-to-Face Encounter Requirement for Certain Durable Medical Equipment, Updated 09/09/15, accessed on 05/09/2018: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html>

*take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.<sup>10</sup>*

The above instructions clearly outline the requirements for contacting beneficiaries, ensuring a need and the time frames for placing the order and delivering to a beneficiary.

Beneficiaries that have monthly rentals of durable medical equipment are required to sign a document that the patient is responsible for notifying a supplier when the equipment is no longer needed. As in any business transaction, both parties have rights and responsibilities.

CMS currently requires suppliers to document continued use as follows:

*Continued use describes the ongoing utilization of supplies or a rented item by a beneficiary.*

*Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.*

*Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:*

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies.*
- Supplier records documenting the request for refill/replacement of supplies in compliance with the REFILL DOCUMENTATION REQUIREMENTS section. This is deemed sufficient to document continued use for the base item, as well.*
- Supplier records documenting beneficiary confirmation of continued use of a rental item.*

*Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.<sup>11</sup>*

The above instructions clearly outline the requirements for ensuring the equipment continues to be needed.

The concept of a benefit manager to serve as a 'middle man' between a supplier and a Medicare beneficiary would impact the ability to ensure access to needed equipment, accessories, and supplies. The current process of contact, documentation, order fulfillment, and shipping are tightly managed and to insert another point of contact would slow down the process and cause confusion for beneficiaries.

In addition, on-going rentals for oxygen concentrators (E1390) alone average 659,385 patients per month based on Medicare claims allowed units for 2016.<sup>12</sup> It is inconceivable for any number of benefit managers to be able to contact Medicare beneficiaries to ensure on-going rentals are needed.

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<sup>10</sup> CGS, JD DME, Items Provided on a Recurring Basis and Request for Refill Requirements-Revised-August 2012, accessed on 05/09/2018: <https://www.cgsmedicare.com/jc/pubs/news/2012/0812/cope19798.html>

<sup>11</sup> Noridian Healthcare Solutions, DME Jurisdiction D, Continued Use/Continued Need, accessed on 05/09/2018: <https://med.noridianmedicare.com/web/jddme/topics/documentation/continued-need>

<sup>12</sup> 2016 Claims retrieved through FOIA request.

If the concept of the benefit manager is to ensure suppliers are providing equipment and supplies as needed, it is a duplicative effort and an additional expense to the Medicare program. The current audit and oversight activities should be the mechanism with which suppliers are held accountable. In looking at the 2017 CERT improper payment rate, the root cause of insufficient documentation errors, of that less than 24% were due to records of the supplier, the remaining 76% were due to prescriber records.<sup>13</sup> It would seem more focus on prescriber patterns and processes is warranted.

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<sup>13</sup> Centers for Medicare and Medicaid Services (2018). Medicare Fee-for-Service 2017 Improper Payments Report.

- 4. Eliminate the unnecessary requirement of a face-to-face Provider Visit for Durable Medical Equipment** Currently, physicians must document a beneficiary's face-to-face encounter with a physician or non-physician practitioner as a condition for Medicare payment for a durable medical equipment order, which can be overly burdensome on providers and suppliers. This proposal enables CMS not to impose this face-to-face requirement on all providers. [No budget impact]

AAHomecare requests additional information on the inclusion of eliminating the unnecessary requirement of a face-to-face for DME. Currently CMS has not enforced the requirement for a face-to-face despite the effective date of 10/1/13. The last update on CMS' website was on September 30, 2015, indicating, "CMS will not start actively enforcing or expect full compliance with the DME face-to-face requirements until further notice."<sup>14</sup>

The industry requests additional information on this item in the budget. While CMS may not be enforcing to date, various local coverage determinations (LCDs) do require a clinical evaluation/face-to-face visit. Should this item come to fruition, it will not eliminate the requirement based on LCDs.

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<sup>14</sup> Centers for Medicare and Medicaid Services, Face-to-Face Encounter Requirement for Certain Durable Medical Equipment, Updated 09/09/15, accessed on 05/09/2018: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetofaceEncounterRequirementforCertainDurableMedicalEquipment.html>

5. **Increase the minimum amount in controversy required for an adjudication to the Administrative Law Judge to the Federal District Court amount in controversy requirement (\$1,600 in the calendar year 2018 and updated annually). Appeals that do not meet this threshold would be adjudicated by a Medicare magistrate. This proposal increases the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is \$1,600 in calendar year 2018 and updated annually. This adjustment will allow the amount at issue to better align with the amount spent to adjudicate the claim. Appeals not reaching the minimum amount in controversy will be adjudicated by a Medicare magistrate. [No budget impact]**

This proposal would delegate Medicare Magistrates the authority to render decisions that ALJs make. While there may be merit to using ALJ surrogates in some instances, AAHomecare has serious concerns about this proposal and does not support it.

The proposal to use amount in controversy will steer most, if not all, DMEPOS appeals away from ALJs. Reimbursement for one monthly DMEPOS rental or purchase claim is very modest. These claims will be much smaller than those for inpatient stays, or in some cases, even a single physician visit. Adopting an amount in controversy approach has the potential to deprive most suppliers the opportunity to appear before ALJs.

There are also important practical issues about how the Agency might implement this proposal. One important concern is the caliber of the experience and training these individuals will have. Medicare is itself a complex statutory scheme rendered even more complicated by the breadth of the Secretary's discretion and the discretionary authority he delegates to contractors to make decisions, including questions about whether items or service "reasonable and necessary." The DMEPOS benefit rules makeup an especially intricate subset of Medicare program rules. The Agency must be very specific about the steps it will take to ensure magistrates remain independent and are appropriately qualified and trained for the roles they assume.

**6. Establish a post-adjudication user fee for the third level of appeals at the Office of Medicare Hearings and Appeals (OMHA) and the fourth level at the Departmental Appeals Board. This proposal establishes a post-adjudication user fee for all unfavorable Medicare appeals, other than beneficiary appeals, at the Office of Medicare Hearings and Appeals, the 3rd level of appeals, and the Departmental Appeals Board, the 4th level of appeals. The user fee amount will support a portion of the administrative costs required to adjudicate appeals. [No budget impact]**

AAHomecare is not in favor of a filing fee. Suppliers file appeals because they believe the claim was denied in error. This would be a duplicative punishment since the supplier is already not paid for services rendered or had the payment recouped and in some cases is paying interest charges. The current estimated wait time at the ALJ is 1,214 days, which means suppliers are waiting over three years to receive payment.<sup>15</sup> In an effort to reduce the ALJ backlog, CMS developed two programs to reduce DME appeals: the QIC Telephone Demonstration, which has resulted in a 64% overturn rate and the serial appeals initiative, which has overturned 75,000 claims.<sup>16,17</sup> These numbers showcase that suppliers should not have had these claims denied in the first place. HHS should not be discouraging suppliers from appealing on denied claims especially when there is strong evidence that support suppliers' efforts.

It would also appear that this proposal has the potential to disproportionately target the DMEPOS industry as the industry continues to be 50% of backlogged appeals according to OMHA.

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<sup>15</sup> <https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html>

<sup>16</sup> Reported by C2C Innovative Solutions at Medtrade Spring 2018.

<sup>17</sup> Reported by C2C Innovative Solutions at Medtrade Spring 2018.

**7. Require a Good-Faith Attestation on All Appeals.** This proposal requires all appellants to include in their initial appeal filing an attestation that they are submitting their appeal under a good-faith belief that they are entitled to receive Medicare reimbursement. This proposal also authorizes the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith. [No budget impact]

If adopted, the requirement will effectively take away appeal rights in many instances. There are several concerns the industry has, such as:

1. Will there be complimentary language that punishes the CMS contractors for unreasonable/bad faith denials?
2. Will there be guidance on what constitutes an “unreasonable” or “bad faith” attestation?
3. Who makes the decision regarding whether an appeal is “unreasonable” or is filed in “bad faith?”

By comparison, Federal Rule of Civil Procedure 11, which pertains to a lawsuit in federal court, says<sup>18</sup>:

*By presenting to the court a pleading...an attorney...certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances: (1) it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) the claims, defenses, and other legal contentions are warranted by existing law or by a non-frivolous argument for extending, modifying, or reversing existing law or for establishing new law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the denials of factual contentions are warranted on the evidence, or, if specifically so identified, are reasonably based on belief or a lack of information.*

The Rule further states<sup>19</sup>:

*If, after notice and a reasonable opportunity to respond, the court determines that Rule 11(b) has been violated, the court may impose an appropriate sanction on any attorney...that violated the rule or is responsible for the violation.*

In federal court, a determination of “bad faith” can only be made after the adverse parties argue to, and present evidence before, a federal judge or federal magistrate. The judge/magistrate will consider the evidence and apply it to the guidelines set out in Rule 11. Only after taking these steps might the judge/magistrate levy sanctions. And so, the question is this: If the attestation requirement is adopted for the administrative appeals process, will the same types of safeguards be given to the suppliers?

Due to the administrative appeals process giving great deference to CMS and its contractors, and in light of the potential exposure to civil monetary penalties, if the proposed requirement goes into effect, many DME suppliers will elect not to pursue appeals. In addition, this may impact the access to care for Medicare beneficiaries because suppliers may decide not to provide services due to the cost and administrative burden such a change will have on suppliers.

Often, denials are technical in nature, many being minor documentation errors even though the patient clearly needs the equipment and the medical records support the patient's need for the equipment. In other instances, CMS

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<sup>18</sup> Fed. R. Civ. P. Rule 11(b).

<sup>19</sup> Id. at 11(c).

contractors deny claims because the contractors assert that there is insufficient documentation showing medical necessity. The determination of “medical necessity” is often subjective in the mind of the CMS contractor; because of this subjectivity, if a claim is decided because of “lack of medical necessity,” it is difficult for the supplier to prevail on appeal. In one case, a DME supplier appealed the denial of over 150 claims. On appeal, only a handful of the claims were allowed. Because this was an “extrapolated” audit (i.e., the CMS contractor extrapolated the percentage of claims denied to a much larger universe of claims), this supplier had no choice but to appeal. In this example, most of the patients medically needed the equipment but the physicians failed to sufficiently document the medical record to support the medical need. If the proposed requirement was in effect, as a result of the low success rate it would not be a stretch to see the government making an argument “after the fact” that the appeal was “unreasonable” and/or made in “bad faith.”

Further, in order to stop recoupments (arising out of post-payment audits) at the redetermination and reconsideration levels, the supplier must file its appeal within 30 days at redetermination and then at approximately 45 days at reconsideration. If the proposed requirement is in effect, then suppliers will be required to weigh the effects of (i) filing an appeal early to avoid recoupment or (ii) filing an appeal later (resulting in recoupment) in order to build a case against a “bad faith” or “unreasonableness” assertion by the government. The certification requirement is an additional burden that will result in many suppliers being subjected to recoupment while they obtain additional documentation to reduce the risk of the government asserting an “unreasonableness” and/or “bad faith” claim against the supplier.

The DME industry has observed favorable results from appeals gradually decline. In Fiscal Year 2012, the number of fully favorable decisions at the ALJ level was 53.2%.<sup>20</sup> That dropped to 31.1% in Fiscal Year 2018.<sup>21</sup> Adding additional burdens to the appeal process will decrease the number of appeals being filed.

If the supplier is unsuccessful at the reconsideration level, then they can appeal to an ALJ. Between the time of the reconsideration decision and the ALJ decision, the CMS contractor can recoup the denied claims. This might not be a severe burden to the supplier if the ALJ would render its decision within 90 days as it is required by law. However, due to the significant backlog of ALJ appeals, it is taking ALJs three to four years to render decisions and even after receiving an ALJ’s favorable decision, a supplier must continue to wait for the DME MAC to remit payment on the claim. This is a severe burden to suppliers. The solution to the appeal backlog is not discouraging appeals. Instead, HHS needs to provide the additional resources needed to process appeals. CMS has increased its audits without committing the additional resources to the appeal process. This is a flawed process that unfairly prejudices suppliers.

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<sup>20</sup> Department of Health and Human Services, Office of Medicare Hearings and Appeals, Decision Statistics. Accessed on June 7, 2017: <https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html>

<sup>21</sup> Ibid.