Via Electronic Submission: regulations.gov

August 29, 2016

Office of Medicare Hearings and Appeals
Department of Health and Human Services
5201 Leesburg Pike, Suite 1300
Falls Church, VA 22041
Attention: HHS-2015-49 5201

Re: MEDICARE PROGRAM: CHANGES TO THE MEDICARE CLAIMS AND ENTITLEMENT, MEDICARE ADVANTAGE ORGANIZATION DETERMINATION, AND MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION APPEALS PROCEDURES

To Whom It May Concern:

The Department of Health and Human Services (HHS) published a request for comments on a proposed rule to amend the Medicare appeals process.[1] The Secretary hopes that by streamlining appeals processes, the Agency can reduce the backlog of appeals pending at the Administrative Law Judge (ALJ) and the Medicare Appeals Council (MAC) levels. The American Association for Homecare (AAHomecare) represents suppliers and manufacturers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). DMEPOS products and services are central to ensuring Medicare meets the challenge of delivering safe, effective and affordable care to the chronically ill and the frail elderly.

AAHomecare commends the Agency on its recent announcement directing contractors not to find new reasons for denying claims they review on appeal. This practice forced suppliers to go to the next level of appeal even though the original issue on appeal had been decided in their favor. Instructing contractors to refrain from making these denials is an important first step towards correcting structural flaws inherent in the audits and appeals processes.[2]

There are other issues that, like this one, contribute disproportionately to the appeals backlog. This is especially true for appeals of DMEPOS claims because of the benefit's unique structure. Medicare pays for most DMEPOS as rentals or recurring purchases of supplies. The appeal of one rental or one purchase

[1] 81 Fed. Reg. 43,790 (July 5, 2016)

[2] Generally regulations use the term "provider" to reference Part A providers like hospitals and home health agencies and the term "supplier to reference practitioners and entities like labs and DMEPOS suppliers. At times we use "provider" to reference entities and practitioners under both parts A and B.

(of reoccurring supplies) claim affects the trajectory of all subsequent claims for the same item because each claim arises from the same set of medical necessity facts. So although each monthly claim represents a new date of services (DOS), the beneficiary's medical necessity and supporting documentation for each claim reference points in time on or before the DOS for the initial claim.

We ask the Agency to be mindful of this unique structure and the specific ways DMEPOS claims contribute to the appeals backlog. Medicare DMEPOS spending is only a small part of the overall Medicare spending, yet at a 2014 provider forum to discuss the appeals backlog, the Office of Medicare Hearings and Appeals (OMHA) officials estimated that DMEPOS claims accounted for 25% of pending appeals.[3] Assuming, without conceding, that the relative proportion of pending DMEPOS appeals is about the same, *i.e*., that it has not dropped, this figure translates to roughly 225,000 appeals. But the DMEPOS benefit accounts for only 1.4% of Medicare spending, suggesting that DMEPOS claims should represent a much smaller proportion of backlogged appeals.[4]

DMEPOS claims account for a disproportionately large share of backlogged appeals because, as we noted, the denial and appeal of the initial claim for an item results in the denial and appeal of all subsequent claims for the item. DME items like continuous positive airway pressure (CPAP) devices and hospital beds typically have a 13-month rental period, after which a beneficiary receives title to the item. Beneficiaries who use a CPAP will also need to purchase supplies for their device for as long as it is medically necessary. Oxygen equipment rents for 36 months. Then Medicare pays for content refills for another 24 months before a new rental cycle begins. And the program pays for ventilators as continuous rentals, *i.e*., for the duration of the beneficiary's medical necessity.

If a contractor denies the initial claim for a CPAP device that denial calls into question all claims for the months remaining in the rental period and all purchase claims for supplies. Suppliers find themselves submitting and appealing claims for the 12 months remaining in the rental period and purchase claims for supplies or they risk losing the right to submit the claims under Medicare timely filing rules. Each appealed claim works its way through the appeal levels independent of the others.

We have reservations about some provisions in the proposed rule because they raise serious procedural questions. The proposal to give the Departmental Appeals Board (DAB) discretion to determine when a final decision of the MAC is precedential duplicates the Agency's authority to issue CMS Rulings and raises questions about the legitimate scope they should have. We also question the proposal to delegate to "attorney adjudicators" the authority to render decisions that ALJs currently make. While the use of delegates in this capacity might have some merit, we question whether they will receive adequate training, the extent of their authority and how the Agency will address the procedural issues this proposal would create. And the proposed rule is rife with confusing and difficult to track word changes that would transfer authority from ALJs to attorney adjudicators or to OMHA. Our concerns are that these changes would dilute ALJs authority to make *independent* decisions as Congress explicitly authorizes them to do.

We also believe the current backlog is rooted in structural flaws deeply entrenched in CMS' audit and payment policies. While we do not want to diminish our concerns about the proposed rule, our comments

[3] Office of Medicare Hearing and Appeals, OMHA Appellant Forum (February 12, 2014) http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/index.html

[4] Assuming DMEPOS appealed claims are in direct proportion to DMEPOS' share of Medicare spending, only about 12,500 DMEPOS appeals, or 50% less than OMHA's estimate, would contribute to the backlog.

also address overarching issues that are key to fixing these flaws. "Fixes" for these problems are straightforward and would be highly cost effective in light of the inordinate expense to the program and appellants the current system has wrought.

BACKGROUND AND DISCUSSION

As you know, OMHA informed providers in 2013 that it was experiencing delays of as much as 24 months in adjudicating appeals.[5] This was a stunning announcement inasmuch as the Social Security Act (SSA) requires ALJs to resolve appeals within 90 days.[6] Since then, the backlog has grown worse. OMHA projects that at current disposition rates, it would take 935 days to resolve an appeal filed today.[7] These delays have caused financial disruption among providers and suppliers across the spectrum of the Medicare benefit. Many of them, especially AAHomecare members, are small businesses that simply cannot afford to carry Medicare debt for the amount of time it takes to resolve claims on appeal.

The genesis of the crisis rests with misguided Medicare audit practices that focus excessively on literal applications of Medicare coverage and documentation policies in pre or post-payment reviews. These audit strategies, in turn, have resulted in a staggering number of what we consider technical denials. Providers and suppliers attending OMHA sponsored forums validated our concerns when they too attributed the backlog to an increase in the volume of audits and the consequent technical denials which they had to appeal. Providers cannot afford to forego the amount of compensation the unpaid claims represent.[8]

Providers and suppliers at these forums also underscored the urgency of reforming the Medicare audit and appeals process. We agree with this consensus and support efforts to streamline appeals. But the proposed rule does not address flaws inherent in the system that led to the crisis in the first place. In response to invitations for comments from OMHA and the Secretary, AAHomecare has made practical recommendations for changes we believe would reduce the backlog. We reiterate and expand on them in these comments. Briefly, Medicare should:

1. Provide an opportunity for a telephone hearing in place of the on the record Qualified Independent Contractor (QIC) level of appeal.

2. Waive the one year claims filing limit for DMEPOS claims on appeal.

3. Require claim processing contractors and appeal adjudicators to give precedent to DMEPOS claims and appeals determinations for the same item and same beneficiary.

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[5] Letter from OMHA Chief Administrative Law Judge (ALJ), Nancy J Griswold, to Medicare Appellants, December 2013, available at: http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/index.html

[6] 42 USC § 1395ff

[7] OMHA Current Workload. Retrieved on August 26, 2016 at http://www.hhs.gov/omha/Data/Current%20Workload/index.html

[8] See Office of Medicare Hearing and Appeals, OMHA Appellant Forum (February 12, 2014 and October 29, 2014) (providers who commented during the forum emphasized they had increased the number of appeals they were filing because they believed their claims were being improperly denied for technical reasons). http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/index.html

4. Prohibit contractors from repeatedly auditing claims for the same item and same beneficiary.

5. Implement an effective prior authorization procedure for DME, especially for respiratory and mobility devices.

COMMENTS

A. Including the opportunity for a telephone hearing instead of the "on the record" review by the QIC would increase the efficiency of the appeals process by reducing the volume of appeals that go to ALJs.

As we have said, AAHomecare understands the goals of the proposed rule and we believe reforming the appeals process is an important step toward making the system more balanced and efficient. But the procedural changes in the proposed rule affect OMHA's internal operations without changing any of the structural flaws inherent in the current system.

One important issue is that appellants cannot engage directly with an *independent* adjudicator until the ALJ level of review. This is the only appeal level where appellants can produce evidence, respond to the ALJ's questions and give testimony on the record. The broader scope of the ALJ hearing may be the primary reason appellants report high rates of success at the ALJ level of appeal.

Many appeals could be disposed of sooner if appellants had an opportunity to speak with an independent reviewer at an earlier stage. The QIC level is the first time appellants come before an independent reviewer. But QICs are limited to an "on the record" review. The truth is that QICs have proved ineffective in reducing the number of appeals that go on to ALJ hearings, perhaps because of the lack of direct communication between appellants and QIC adjudicators.

A straightforward solution is to replace the QIC on the record reviews with ones that allow appellants to speak directly to reviewers. This type of hearing would allow appellants to respond to questions about medical necessity and documentation the supplier submits with his appeal. Currently CMS and the QIC contractor are conducting a pilot for oxygen and diabetic supply appeals that allow for this type of dialogue. Recent feedback indicates this pilot is proving to be successful.

B. Documentation supporting the initial claim for a DMEPOS item determines the medical necessity of all subsequent claims for the item or supplies.

Medicare suppliers must file claims on behalf of beneficiaries within one year of the claims' DOS.[9] The statutory provision that establishes the timely filing limits also allows the Secretary to create exceptions to this deadline.[10, 11] We recommend expanding the existing exceptions to include one for DMEPOS claims when contractors deny the initial claim in a prepayment audit and the supplier appeals. Ideally, suppliers should be able to suspend claims filing whenever they appeal the initial claim for a DMEPOS item. Suppliers cannot do this today because of Medicare timely filing limits.

[9] §6404 of the Affordable Care Act (ACA), Pub. L. 111- 148 (2010).
[10] *Ibid*.
[11] See 42 CFR § 424.44

Again, Medicare pays for DMEPOS over a period of 13 months or longer (36 months for oxygen) and an even longer period for related supplies or accessories, which, for oxygen, can be an additional 24 months after the initial rental period. Some DMEPOS items like diabetic test strips, urological supplies or enteral nutrients are recurring purchases. And Medicare pays for a ventilator for as long as the beneficiary needs it. For rental DME and purchased items, each month's rental or purchase is a new claim with a new DOS that arises from the same medical necessity facts and is supported by the same documentation that supports the initial claim.

When contractors do prepayment reviews of initial rental claims, suppliers typically suspend billing for the months remaining in the rental period, pending a determination on the initial claim. If the initial claim denies as not reasonable and necessary, contractors will also deny claims for the remaining rental months because a finding of medical necessity for these claims depends on the medical necessity for the initial claim. Suppliers that appeal the initial claim must nonetheless submit and appeal claims for the remaining rental months, even though these appeals will not succeed, to avoid a timely filing bar. They pursue this futile cycle of claims submission and appeals because by the time they succeed on the merits of the initial claim, Medicare's one year timely filing limit bars them from submitting claims for the remainder of the rental period.

This piecemeal approach wastes time and resources for suppliers and OMHA. But these redundant appeals can be easily avoided if suppliers could hold back claims for the remainder of the rental cycle until the appeal on the initial claim is resolved. We understand the Agency must publish a proposed rule to create this exception and encourage the Secretary to initiate rulemaking to accomplish this.

C. Because each DMEPOS claim depends on the medical necessity determination of the initial claim for the item, a determination affirming medical necessity for the initial claim can and should serve as precedent for each subsequent rental or purchase claim for the same item and beneficiary.

Limiting contractors' ability to repetitively audit claims for the same DMEPOS item for the same beneficiary will reduce redundant and unnecessary appeals.

CMS does not allow claim adjudications to serve as precedent for related claims for the same item and beneficiary. And the Agency does not plan to change this position despite the proposal to allow the DAB chair to designate certain MAC decisions as precedent for future adjudications. Favorable medical necessity determinations on individual claims do not create precedent for claims for the same item and same beneficiary. But maintaining this policy for DMEPOS claims is short sighted, and we recommend that the Secretary change it.

This recommendation is closely related to our recommendation for extending timely filling and claim submission limits for appealed DMEPOS claims and rests on the same underlying rationale. We also recommend that CMS limit contractors' ability to repetitively audit claims for the same DMEPOS item for the same beneficiary.[12] Again, because DMEPOS claims for rented DME and purchased supplies arise from the same set of medical necessity facts, each claim for a new rental month (for the same item and beneficiary) depends on the medical necessity determination of the initial claim for the item. CMS'

[12] Section F. below discusses our concerns with the proposal to accord precedential value to some final MAC decisions.

contrary views lead to unnecessary appeals of claims that share the same underlying medical necessity facts and documentation.

Contrast DMEPOS claims with claims for other covered services where each claim represents a finite encounter supported by unique medical necessity facts. Each physician visit, for example, must have its own medical necessity. A beneficiary's encounter with his doctor in January will have medical necessity documentation that is different from a new encounter the following March. Similarly, gall bladder surgery in June likely would not be supported by the medical necessity of gall bladder surgery on the same beneficiary the preceding February. There must be a specific set of facts, like the presence of an infection or the regrowth of a tumor, to support medical necessity for a second procedure. So for these types of services, CMS' view is correct: each claim must stand on its own.

A concentrator or power wheelchair is a single covered item analogous to a single episode of care for physician services. The difference is that while Medicare pays for one physician visit at a time, Medicare makes monthly payments for a single item of DME over a span of 13 or 36 months and for recurrent purchases of supplies. Each rental or purchase claim arises from and depends on the same medical necessity facts that support medical necessity for the initial claim. For DMEPOS items, CMS' view does not withstand analysis. Medicare cannot review a DME rental claim or a claim for recurring purchases of supplies standing alone: each claim is inextricably tied to the initial claim for the item and to each other.

Adopting these policies would pose a very low program integrity risk for the Agency. But they would greatly improve the overall efficiency of appeals by reducing the number of redundant appeals of DMEPOS claims for the same item. AAHomecare would be happy to meet with CMS to elaborate on these recommendations and assist the Agency in adopting them.

D. Prior authorization procedures for DMEPOS, especially for respiratory and mobility devices, would reduce the number of DMEPOS claims on appeal.

AAHomecare urges the Secretary to implement prior authorization procedures for DMEPOS, especially for respiratory and mobility devices. Effective prior authorization procedures would improve the appeals process for all providers and suppliers by reducing the large volume of initial DMEPOS claims suppliers take to appeal. An effective prior authorization program would:

- Establish medical necessity for a DMEPOS item before the beneficiary receives the item.
- Include expedited procedures in case a referral source determines a beneficiary needs an item the same day.
- Rely on electronic communication that includes model documentation forms to facilitate the transmission of medical necessity documentation.
- Ensure beneficiaries have timely access to DMEPOS items subject to prior authorization.
- Allow a beneficiary, physician or supplier to initiate a request for prior authorization.
- Ensure that the ordering practitioner knows when he or she must submit records supporting a request or whether there are missing or deficient records he must supplement.
- Establish the beneficiary's medical necessity for the DMEPOS item for as long as he or she needs the item even if the beneficiary moves or changes suppliers.

- Establish a beneficiary's medical necessity for supplies, accessories and repairs of base DME with an affirmative prior approval for as long as the beneficiary needs the base equipment even if the beneficiary moves or changes suppliers.

AAHomecare is aware that implementing an effective prior authorization procedure is a big undertaking, but we can think of very few policies that could reduce Medicare's administrative costs as quickly. We encourage the Secretary to move forward promptly on prior authorization and to introduce prior authorization for respiratory and mobility devices before other DMEPOS items.

E. Delegating to attorney adjudicators authority to make decisions that ALJs make raises important questions about their experiencing and training, their scope of authority and Secretary's authority to adopt this rule.

The proposed rule would delegate to attorney adjudicators the authority to render decisions that ALJs make. While there might be merit to using ALJ surrogates in some instances, AAHomecare has serious concerns about this proposal and does not support it.

The proposed rule makes distinctions between *hearings*, which the Agency says only ALJs can conduct, and *decisions* which the Agency believes can be delegated to surrogates. But the Agency's reliance on these distinctions is misplaced. First we doubt the Agency can deploy attorney adjudicators to make decisions Congress explicitly authorized ALJs to make. Both the Administrative Procedure Act (APA) and Medicare provisions of the SSA give ALJs judicial *independence* to render decisions. And Congress *explicitly* required the Secretary to ensure their independence when ALJs became part of the Agency.[13]

Other Medicare appeals adjudicators do not have judicial independence to the extent of ALJs. Attorney adjudicators would be Agency employees whose workloads and assignments would presumably be under the Agency's control. And the MMA does not distinguish between ALJ hearings and decisions, so there is no support for the rationale advanced for engaging attorney advisors. Based on the type of hearings parties request. More importantly, the Medicare appeals statute does not include references to attorney adjudicators nor does it contemplate that anyone other than statutorily authorized ALJs will make decisions at the ALJ level of appeal, raising legitimate questions about the Agency's authority to adopt this proposal.

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 she delegates to contractors to make decisions, including questions about whether items or service "reasonable and necessary." And the DMEPOS benefit rules makeup an especially intricate subset of Medicare program rules. So assuming without conceding that the Agency has authority to engage attorney advisors, the Agency must be very specific about the steps it will take to ensure they remain independent and are appropriately qualified and trained for the roles they assume.

The Agency must also establish rules for how it will divert appeals to these surrogates. The proposal to use amount in controversy limits for determining their jurisdiction has the potential to steer most

[13] Section 931(a) (2) of the Medicare Modernization Act (MMA), Pub. L 108-173 requires the Secretary to identify steps she will take to ensure the independence of ALJs.

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.

The proposed rule is also replete with confusing word changes that are difficult to follow and understand. They mostly substitute the term "ALJ" for "attorney adjudicator" or "OMHA" throughout the regulation. As we have noted, we do not endorse delegating authority from ALJs, who must have judicial independence, to attorney adjudicators, who are Agency employees. AAHomecare also disagrees with transferring control of ALJs' workload from ALJs to OMHA as the proposed wording changes would do. Again, ALJs were designated by Congress to render independent Medicare appeals decisions. AAHomecare would not support regulatory changes with the potential to dilute ALJ independence.

F. Designating certain final MAC decisions to serve as binding precedent in future claim adjudications and appeals raises questions about the legitimate reach of these decisions on contractors and parties to proceedings.

The proposed rule would authorize the chair of the DAB to designate some final MAC decisions as precedent for future appeals and claims adjudications. Precedential decisions would be binding on all contractors and ALJs to the same extent as CMS Rulings. AAHomecare understands agencies have discretion to determine how to develop policies and rules, but that the Secretary might have some latitude to adopt this proposal may not be the best rationale for adopting it. Our concerns focus on the policy's potential to erode the independence of ALJs' decision making and questions about the legitimate scope of precedential decisions.

As we noted, this proposal is different from AAHomecare's recommendation for CMS to allow favorable determinations on a DMEPOS claim to serve as precedent for other claims for the same item and same beneficiary. This proposal would designate some final MAC decisions as precedent, binding on parties to future claims adjudications or appeals. In this respect, the policy would duplicate the Agency's authority to issue Administrator Rulings, potentially giving rise to conflicts between precedential MAC decisions and CMS Rulings, which the administrator could presumably use to overrule MAC precedents.

Importantly, this policy has the potential to erode the independent decision making authority Congress gave ALJs. Judges who render MAC decisions are Agency employees whose workloads and assignments would be under the Agency's control. Unlike ALJs, their judicial independence is not explicitly required under the SSA. Precedential MAC decisions will have the effect of prospective rules, binding on all parties to *future* appeals or claims adjudications. The difference is that public comments usually inform an agency's decision to adopt a rule. While the preamble states that decisions will not have precedential effect until the Agency publishes them in the Federal Register, that alone would be insufficient to inspire public confidence in their integrity, nor would it result in the kind of public accountability rulemaking provides.[14]

[14] Note also that aside from the general rulemaking requirements under the APA, the SSA instructs the Secretary to use rulemaking when she establishes or changes substantive standards affecting individuals and entities' scope of benefits, reimbursement, or their eligibility to furnish services. The statutory provision explicitly applies to rules, requirements and "other statements of policy" issued by the Secretary, other than the issuance of national coverage determinations. The statute states in part:

Many courts affirming agencies' discretion to make precedential decisions based their decisions on the formal nature of an agency's adjudicatory proceedings. The MAC's statutory authority to hear claims appeals does not require it to hold formal hearings. MAC hearings are on the record and they are not subject to the APA's procedural requirements for formal hearings. Other appeals policies, like not allowing appellants to question contractor representatives who appear at ALJ hearings, also diminish the "formality" of the Medicare appeals process as a whole. And factors completely unrelated to the merits of an appeal, like appellants' skill in communicating and supporting their case before the MAC, could influence the outcome of decisions the DAB designates precedential.

The lack of public comments and the somewhat random factors that might influence the outcome of a MAC appeal suggest the Agency should proceed with care before adopting this proposal. If a precedential MAC decision is decided incorrectly but parties do not appeal it, providers may be without recourse to challenge the precedent. And assuming nonparties could challenge the precedent in federal court, what would be the effect on claims and appeals decided under a MAC precedent that a federal court overrules?

Courts have also upheld a MAC's coverage decision that a specific device was not reasonable and necessary against a challenge the Agency did not follow procedures for issuing NCDs.[15] At least one court upholding the Agency's discretion to make coverage determinations in the course of an adjudication relied on the Agency's assertion that MAC decisions have no precedential effect.[16] We are concerned that the lack of criteria for designating some decisions as having precedential effect could lead the Agency to take to short cuts in making reasonable and necessary determinations, disregarding the procedures Congress established issuing NCDs. In other words, the Agency might avoid the statutory requirements simply by giving precedential effect to MAC decisions that deny coverage for an item or service.

CONCLUSION

AAHomecare agrees that reforms to the Medicare appeals process are essential to ensuring that appeals are fair and serve the interests of providers and beneficiaries. The reforms in the proposed rule do not address CMS audit and appeals policies that are the source of the current backlog. We recommend that the Secretary consider and implement the changes to these policies we recommended above, especially as they relate to the Medicare DMEPOS benefit. AAHomecare does not support the proposal to delegate a portion of ALJs' authority to decide Medicare appeals to attorney adjudicators. We also do not support

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> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 USC § 1395hh (a)(2).

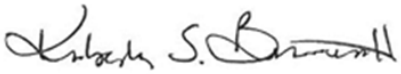
[15] In other words, the MAC's decision determines coverage for an item, not whether a beneficiary's circumstances meet medical necessity coverage criteria.

[16] *Almay v. Sebelius* 749 F. Supp. 2d 315 ((D.MD. 2010), 679 F. 3d 279 (4th Cir, 2012) *affirmed*, 133 S.Ct. 841 (US 2013), *cert. denied.* Earlier decisions also recognize the Agency's discretion to make coverage decisions in the course of an appeal, but these cases were decided well before Congress enacted specific procedural requirements the Secretary must use for making national coverage determinations (NCDs).

the proposal to allow the DAB to designate some final MAC decisions to serve as binding precedent. We believe these proposals would undermine the independence of ALJs' decision making and present legitimate questions about the Agency's authority to adopt them.

Thank you for the opportunity to submit these comments. Please feel free to contact me if I can answer any questions about our comments above.

Sincerely,



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