



**Via Electronic Submission: <https://www.regulations.gov/>**

October 2, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-6058-FC,  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process [84 Fed. Reg. 47794, September 5, 2019, CMS-6058-FC]**

Dear Administrator Verma:

The American Association for Homecare (AAHomecare/AAH) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned final rule. AAHomecare is the national association representing the interest 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 part of the continuum of care that assures that Medicare beneficiaries receive cost effective, safe and reliable home care products and services.

Specifically, this rule implements a provision of the Affordable Care Act that requires Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers and suppliers to disclose any connection to a provider or supplier with a history of fraud, waste, or abuse. This provision allows the Secretary to deny

enrollment to a provider or supplier based on affiliation to a fraudulent provider or supplier. AAHomecare is a strong supporter of CMS' efforts to remove fraudulent suppliers from CMS' programs. We support any and all efforts to deny fraudulent provider and supplier participation in CMS programs. While we agree with the intentions of the proposal, we would like CMS to reconsider some of the final rule per our suggestions below.

## **COMMENTS**

The following section organizes AAHomecare's comments by subject area from the proposed and final rule.

**CMS PROPOSAL: If an affiliated supplier had their enrollment denied, revoked or terminated, this must be reported regardless of the reason for the denial, revocation or termination. The proposed rule indicated denied, revoked, or terminated disclosures should be required only for fraudulent activities, not any and all.**

**AAH PROPOSED RULE:** For the DMEPOS industry, it is common to have supplier numbers revoked due to technical misunderstandings by the National Supplier Clearinghouse (NSC) and/or Medicaid programs. The process of appealing and having the supplier number reinstated can often take months. Due to these situations, CMS needs to establish clear guidance on what types of affiliation will result in a supplier having at risk their ability to participate in the Medicare and/or Medicaid programs. The DMEPOS industry seeks clear guidance on how different infractions will impact their supplier number(s). The rule is also unclear on how a reported affiliation that results in a termination would be applied to other National Provider Identifiers (NPIs) associated with the enrollee. AAHomecare recommends CMS to report affiliation based on NPI.

Acquisitions occur frequently in the DMEPOS industry. As such the challenges for a purchasing entity to effectively research and report past affiliations of the purchase are difficult to overcome, especially when the purchased entity has many NPI numbers. An example of this is a selling organization that has debt to Medicare or Medicaid at the time of the acquisition or pre-sale for 5 years. Often times overpayment letters are sent post-sale to the last address of the selling entity. The buying entity could not have been expected to know that an overpayment letter was to be issued to the selling entity.

***CMS FINAL RULE RESPONSE: "Denials and revocations pursuant to § 424.519 will be applied no differently than how other denials and revocations are currently applied. As for the commenter's recommendation, affiliations will be reported in accordance with the requirements of this rule irrespective of the particular NPI enumeration involved."***

***AAH FINAL RULE COMMENTS: We continue to recommend that CMS consider our issues and concerns related to what a purchaser could have reasonably been expected to know in an acquisition.***

**CMS PROPOSAL: Require providers and suppliers to disclose affiliation with a provider or supplier that has uncollected debt.**

**AAH PROPOSED RULE RESPONSE:** When a supplier is adhering to a repayment plan, they should be exempting from being required to report as an uncollected debt. We agree on the 5-year look back period for disclosable events is appropriate.

The current backlog of the appeal process must be factored into considerations for the reporting of debt. In Fiscal Year 2015, OMHA reported 240,371 appeals were received at the ALJ.<sup>1</sup> According to the OMHA website, it is estimated to take 791.4 days for an appellant to receive a hearing.<sup>2</sup> These numbers show there are thousands of suppliers who are in repayment, the overpayment processes due to the fact that suppliers are required to refund the Medicare program at the conclusion of the second level of appeal while waiting for an ALJ hearing. OMHA data shows that 30.1% of appeals have been overturned so far at the ALJ level in FY2016 and this number was as high as 53.2% in FY2012.<sup>3</sup> We believe it will stay true to the efforts to curb fraud, abuse, and waste if the disclosure requirement only applied to suppliers that have exhausted all levels of appeals.

***CMS RESPONSE:*** *CMS is “not exempting debts that are being either repaid or appealed from disclosure.”*

***AAH COMMENTS:*** *We encourage CMS to evaluate our comments on the proposed rule.*

**CMS PROPOSAL:** Set “reasonableness” standard, which would require certain information to be disclosed only if the supplier should have reasonably known of the information. CMS also solicited feedback on establishing a “reasonableness” test, which would clarify what constitutes a sufficient effort by the enrolling supplier to obtain information.

**AAH PROPOSED RULE RESPONSE:** Suppliers should only have to disclose past affiliations for persons identified as 5% and greater owners. It is impossible for a supplier to research an entity or organization. The requirement for disclosure should apply only to individuals listed as owners on the 855-S. In the proposed rule, CMS needed to provide clear guidance on the necessary steps for a supplier to complete that would demonstrate they took reasonable effort to research past affiliations. A supplier should only be required to complete steps that are clear and through publicly available searches. For example, a supplier should be required to evaluate the OIG Exclusion List to ensure no owners are currently on the list or have been in the last five years. In addition, DMEPOS suppliers are required to complete a fingerprinting process as part of the enrollment and re-enrollment process, which should suffice to meet the intent of background research on individual owners.

***CMS RESPONSE:*** *“While we believe that public database searches would prove useful in obtaining affiliation data, we do not believe the provider's or supplier's efforts should be automatically restricted to these means. Depending on the particular circumstances involved and recognizing that certain instances might necessitate greater degrees of research, this could require, for instance, a review of internal records and contacting affiliates. Such actions may yield data and information that is not otherwise available via public databases. We note that DMEPOS suppliers are subject to our fingerprinting requirements”*

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<sup>1</sup> “Medicare Appellant Forum- February 25, 2016”, Office of Medicare Hearings and Appeals (OMHA). Retrieved on April 11, 2016. Retrieved from:

[http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/presentations\\_feb\\_25\\_2016.pdf](http://www.hhs.gov/omha/OMHA%20Medicare%20Appellant%20Forum/presentations_feb_25_2016.pdf)

<sup>2</sup> U.S. Department of Health & Human Services, OMHA, Decision Statistics. Retrieved on April 11, 2016. Retrieved from: <http://www.hhs.gov/omha/Data/Current%20Workload/index.html>

<sup>3</sup> Ibid.

*“As previously stated in both this final rule with comment period and the proposed rule, we recognize that various data may be difficult to obtain. We intend to issue subregulatory guidance that will clarify our expectations regarding the level of effort that is required in securing the relevant affiliation information.”*

**AAH COMMENTS:** We agree that it would be appropriate to issue subregulatory guidance on what would be deemed to be reasonable efforts to meet this requirement.

**CMS PROPOSAL:** Factors that would be considered when reviewing disclosed affiliations that pose an undue risk of fraud, waste or abuse. The proposed rule stated that CMS has the “flexibility to deal with each situation on a case-by-case basis.”

**AAH PROPOSED RULE RESPONSE:** We are concerned that this statement assigns too much discretionary authority to CMS and its’ contractors. There should be objective measures with clear correlation to consequences to the supplier that determine undue risk.

*CMS RESPONSE: We appreciate the commenters’ concerns and will include pertinent information regarding the reason(s) for the undue risk determination in the denial or revocation letter sent to the provider or supplier. Such information would be in the revocation or denial letter itself, not a pre-revocation or pre-denial notice, as suggested by one commenter. Furthermore, as we stated in the proposed rule, the determination of undue risk will be so dependent on the individual facts and circumstances involved that it is difficult to identify examples of what would and would not constitute an undue risk or to clearly define the term “undue risk.” Every case is different, and we must retain the discretion to address each based on its own merits and facts. In addition, we do not believe our factors are overly broad; we believe they are fairly specific, while simultaneously containing a measure of flexibility to deal with particular circumstances.*

**AAH COMMENTS:** We recommend that CMS be as transparent as possible when evaluating what is determined to be “undue risk.”

**CMS PROPOSAL:** CMS will revoke a supplier’s Medicare enrollment if they billed for services from a location that it knew or should have known did not comply with Medicare enrollment requirements.

**AAH PROPOSED RULE RESPONSE:** CMS should take action to revoke all of a suppliers NPIs in situations where an owner is convicted of fraud in a court of law. CMS has the ability to crosswalk owner listings across entities that are enrolled in PECOS and should use its’ own data to determine where owners are listed on many supplier/provider applications. In the proposal, CMS explained a situation where a supplier continues to provide services even though the owner is aware that they are not in compliance with the Medicare DMEPOS supplier standards. DME suppliers often add new locations or consolidate locations to better manage their business. CMS must clearly evaluate situations to distinguish where a supplier is in the process of reorganizing their business from situations where there was fraudulent intent was fraud on the part of the supplier.

*CMS RESPONSE: “We appreciate this comment and note that several of our finalized provisions will permit CMS to expand a revocation to a provider’s or supplier’s other locations and enrollments.”*

**AAH COMMENTS:** We agree with CMS’ response.

**CMS PROPOSAL:** Suppliers that have conducted harmful practices towards the Medicare program would be exempt from participation for 3 years to 10 years depending on the action.

**AAH PROPOSED RULE RESPONSE:** CMS should consider setting the bar differently depending on the reason for the revocation. If the issue is due to a technicality (an example is a site survey that finds a supplier not in compliance and the supplier is appealing), then 3 or 5 years would be an appropriate exemption period. If an owner of the supplier is found guilty of a felony, then a 10-year exemption would be more appropriate.

**CMS RESPONSE:** *“We appreciate the commenter’s suggestions and examples. As previously stated, however, each case may differ widely. We must have the flexibility to consider every situation on its own merits rather than be compelled to impose certain reenrollment bar lengths for particular actions.”*

**AAH COMMENTS:** We urge CMS to be transparent and set clear guidelines on bar lengths.

**CMS PROPOSAL:** Revocation of a physician, non-physician practitioner, physician group or non-physician practitioner group if the supplier fails to report either of the following: a change of ownership, final adverse action or practice location within 30 days of the change or any other change in enrollment data within 90 days of the change.

**AAH PROPOSED RULE RESPONSE:** On rare occasions, a supplier may inadvertently miss a 30 or 90-day timeframe for reporting changes on the 855S. Suppliers should be afforded the opportunity to correct without revocation when it is an oversight. Revoking Medicare enrollments should be applied only to egregious situations. A one time delay in change of information reporting by a supplier does not constitute fraud.

**CMS RESPONSE:** *“We note that we already have the authority to revoke providers and suppliers under § 424.535(a)(1) for failing to timely report changes of information under, as applicable, §§ 424.516(d), 410.33(g)(2), and 424.57(c)(2). Our revision to § 424.535(a)(9) simply establishes a dedicated paragraph in § 424.535(a) to address all information changes, not merely those in § 424.516(d)(ii) and (iii). In other words, we have always had general authority to revoke for failing to report changes, and this rule expands upon that existing authority. The expansion of § 424.535(a)(9), however, is focused largely on significant cases of non-reporting, and we will carefully consider several factors, such as the data’s materiality, in determining whether a revocation is appropriate. Yet we must emphasize that we still retain the right to revoke under § 424.535(a)(9) for any failure to timely report informational changes.”*

**AAH COMMENTS:** We concur with the language of the final rule.

**CMS PROPOSAL:** Supplier must complete a new CMS-855 form when a supplier has not submitted a claim for at least 18 months, a supplier previously failed to report changes to enrollment information in a timely manner, or existing enrollment data cannot be viewed.

**AAH PROPOSED RULE RESPONSE:** AAHomecare concurs with CMS that when a claim has not been submitted within 18 months, CMS should automatically terminate the supplier. CMS should consider requiring suppliers to maintain all enrollment records electronically via PECOS. This requirement would offer a simple way for suppliers to periodically review their enrollment records to ensure their accuracy.

While in the past maintaining records via PECOS has been voluntary, it would make sense at this point in time with this proposed rule for it to become a requirement.

While ensuring suppliers maintain accurate enrollment information, CMS should similarly be required to ensure that PECOS records are up to date on a timely basis. Going so far as to establish a time frame where CMS is required to ensure that online records are up to date and accurate. A 30-day time frame for CMS and its contractors to complete updates when submitted would allow for more accurate records. It would appear this proposed rule and the final will require changes to the 855 applications themselves and this would be a good time to be sure the maintenance of PECOS records meets all requirements. Suppliers often complain that the PECOS records do not reflect the most current information that has been submitted.

As noted previously, revocation due to untimely reporting should only be applied to egregious suppliers.

**CMS RESPONSE:** *“We appreciate these suggestions and observations and will consider them as we continue our efforts to further strengthen Medicare program integrity.”*

**AAH COMMENTS:** We appreciate CMS’ considerations of our recommendations to the proposed rule.

**CMS PROPOSAL:** 30 minutes for a provider or supplier to report and submit new or changed affiliation information to its Medicare contractor.

**AAH PROPOSED RULE RESPONSE:** The estimated 30-minute timeframe may be appropriate for the update process itself to be completed electronically; it may take longer if the process remains on paper, particularly with state Medicaid programs. CMS should require all state Medicaid programs implement an electronic solution for enrollment information in order for suppliers to be able to complete in a 30-minute timeframe.

A 30-minute timeframe will not be sufficient for a supplier to investigate past affiliations. Until the supplier community is made aware of the steps that must be taken for each enrollment record, a timeframe and thus a cost cannot be applied. The investigation of past affiliations could take 30 days or more depending on the requirements.

**CMS RESPONSE:** *CMS is not finalizing the 30-minute timeframe.*

**AAH COMMENTS:** We appreciate CMS’ considerations of our comments on the potential burden and the decisions to not finalize this proposal.

**CMS PROPOSAL:** Suppliers are expected to incur additional burden due to the implementation of this proposal.

**AAH PROPOSED RULE RESPONSE:** AAHomecare would like to make a recommendation to CMS related to the processing of 855S applications. Currently the effective date of a supplier number can be a challenge when the 855S applications are processed. AAHomecare recommends that the effective date be the date the supplier meets accreditation and licensure requirements for a particular location. Currently the effective date can be the date the application is processed by the contractor. As this rule in final form may

significantly increase the volume of 855S applications received, we would like to ensure that any delays due to volumes are considered.

In addition, AAHomecare recommends that CMS and its contractors have a defined timeframe in which various processes related to the applications have to be completed. As an example, a new application should be processed within 60 days, a change of information and change of ownership should be processed in 90 days, etc. Currently these time frames are at the discretion of the contractor. As we strive for more efficiency, it is imperative that suppliers, contractors and CMS have established timeframes to follow. This will work towards resolving any issues related to lost billings as a result of the final rule implementation. This process should also be applied to Medicaid programs. Some state Medicaid programs take up to 9 months to process a simple change of address. In addition, suppliers are not usually notified that their application has been processed and approved. State programs should be required to send notifications when an application has completed processing.

***CMS RESPONSE:*** *CMS believes the comments on the effective date of the supplier number and the recommendation of a defined timeframe for processing applications are outside of the scope of this final rule. CMS understands the concerns about workload and will take steps to ensure applications are processed promptly.*

***AAH COMMENTS:*** *We encourage CMS to evaluate our comments on the proposed rule related to timeframes and requirements for performance for contractors as well as the supplier community.*

**CMS PROPOSAL:** **When a surety fails to make a payment, CMS has the discretion to reject all of the surety's existing bonds with Medicare-enrolled DMEPOS suppliers.**

**AAH PROPOSED RULE RESPONSE:** AAHomecare requests that CMS not implement this policy until additional regulatory guidance is issued related to surety bonds based on the following.

Currently surety bond companies do not have any resources to understand the risk they are taking when approving a supplier. CMS needs to create tools to help surety companies understand a supplier's history and also develop a process for issuing claims against the surety bond company before broad brushed changes are made.

Because it is unlikely for a surety bond company to have seen and commented on this proposal, we recommend CMS establish a proposed rule specific to the surety bond issues from this notice. This proposal should also include a process for the filing of a claim against a surety bond company. It may also be valuable to have the GAO complete a study on the entire bond process and guidelines before instituting the type of change this rule is establishing.

In addition, CMS should clarify that one bond should cover the requirement for both the Medicare and Medicaid programs for a particular location. Many state Medicaid programs will not accept a supplier's bond if it shows CMS as the Obligee and requires suppliers to obtain a second bond showing Medicaid as the Obligee. Since the bonds are required to be under the Obligee of CMS, one bond should cover the requirements for both Medicare and Medicaid.

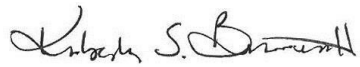
***CMS RESPONSE:*** *CMS is not finalizing this proposal.*

**AAH COMMENTS:** We support CMS' decision to not finalize this proposal.

**CONCLUSION**

AAHomecare supports CMS' efforts to remove fraudulent suppliers and continuing the protection of the Medicare Trust Fund. We appreciate CMS' consideration of our proposed rule comments and opportunity to submit these additional comments. We are available to discuss them in greater detail at your convenience.

Sincerely,



Kimberley S. Brummett, MBA

Vice President of Regulatory Affairs