Via Electronic Submission: https://www.regulations.gov/

April 25, 2016

Andrew Slavitt
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6058-P
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 [CMS-6058-P]

Dear Acting Administrator Slavitt:

The American Association for Homecare (AAHomecare) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned proposed rule. Specifically, the 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 the CMS' efforts to remove fraudulent suppliers from the CMS programs. We support any and all efforts to deny fraudulent provider and supplier participation in the CMS programs. While we agree with the intentions of the proposal, we would like the CMS to reconsider some of the proposed rule per our suggestions below.

AAHomecare is the national association representing the interest of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) providers. 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.

I. COMMENTS
The following section organizes AAHomecare comments by subject area from the 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.

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Denied, revoked, or terminated disclosures should be required only for fraudulent activities, not any and all. 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 payers. The process of appealing and having the supplier number reinstated can often take months. Due to these situations, the 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 rule does not specify how each type of reported affiliation will impact the enrolling supplier. 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 the 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.

Definition of "uncollected debt."
The threshold for the level of debt that would need to be reported should be greater than $50,000, which is the value of the surety bond a DMEPOS supplier is required to maintain. This is intended to curb fraud and abuse, which aligns with the intention of this proposal.

In addition, when a supplier is adhering to a repayment plan, they should be exempt 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.[1] According to the OMHA website, it is estimated to take 791.4 days for an appellant to receive a hearing.[2] 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.[3] 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.

[1] "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
[2] 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
[3] Ibid.

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.

The "reasonableness" test instituted, which explains what constitutes a sufficient effort by the enrolling supplier to obtain information.

The CMS needs 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.

Factors that would be considered when reviewing disclosed affiliations that pose an undue risk of fraud, waste or abuse.

The proposed rule states that the CMS has the "flexibility to deal with each situation on a case-by-case basis." We are concerned that this statement assigns too much discretionary authority to the CMS and its' contractors. There should be objective measures with clear correlation to consequences to the supplier that determine undue risk.

The 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.

The 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. The 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, the CMS explained a situation where a supplier continues to provide services even though the owner is aware that they are not compliant with supplier standards. Often times suppliers add new locations or consolidate locations to better manage their business. The CMS must be clear to evaluate situations where a supplier is in the process of reorganizing their business and not determine the intent was fraud on the part of the supplier.

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.

The CMS should consider setting the bar differently depending on the reason for the revocation. If the issue is due to technicality (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.

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.
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 suppliers. A onetime delayed change of information by a supplier does not constitute fraud.

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.
AAHomecare concurs with the CMS that when a claim has not been submitted within 18 months, the CMS should automatically terminate the supplier. The 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 that it becomes a requirement.

While ensuring suppliers maintain accurate enrollment information, the CMS should similarly be required to ensure that PECOS records are up to date. Going so far as to establish a time frame where the CMS is required to ensure that online records are up to date and accurate. A 30-day time frame for the 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.

30 minutes for a provider or supplier to report and submit new or changed affiliation information to its Medicare contractor.
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. The 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 suffice for the investigation necessary of 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.

Suppliers are expected to incur additional burden due to the implementation of this proposal.
AAHomecare would like to make a recommendation to the 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 the 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 the 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.

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

AAHomecare requests that the 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. The 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 the CMS to established a proposed rule specific to the surety bond issues from this notice. Such 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.

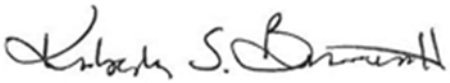
In addition, the CMS should clarify that one bond should cover the requirement for both the Medicare and Medicaid programs for a particular location. Many state Medicaid programs will not accept a supplier's bond if it shows the CMS as the Obligee, and requests suppliers to obtain a second bond showing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

II. CONCLUSION

AAHomecare supports CMS' efforts to remove fraudulent suppliers and continuing the protection of the Medicare Trust Fund.

AAHomecare appreciates the opportunity to submit these comments. We are available to discuss them in greater detail at your convenience.

Sincerely,



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