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April 25, 2016

Andy 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: CMS–6058–P; The American Health Care Association’s Comments to Proposed “Program Integrity Enhancements to the Provider Enrollment Process” Rule (81 Fed. Reg. 10,720 (Mar. 1, 2016))**

Dear Mr. Slavitt:

 The American Health Care Association (“AHCA”) appreciates the opportunity to comment on the proposed “Program Integrity Enhancements to the Provider Enrollment Process” rule, 81 Fed. Reg. 10,720 (Mar. 1, 2016) (the “Proposed Rule”). AHCA is the nation’s leading long term care organization. AHCA and our membership of 12,000 non-profit and proprietary facilities are dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation’s frail, elderly and disabled citizens who live in nursing care centers, assisted living communities, subacute centers and centers for individuals with intellectual disabilities and developmental disabilities.

 We commend the Centers for Medicare & Medicaid Services (“CMS”) for continuing to address program integrity vulnerabilities that exist within the federal health care programs, including Medicare and Medicaid. In its preamble to the Proposed Rule, CMS explains that its proposals would help the agency ensure that individuals and entities who pose risks to federal health care programs would be removed from participation in such programs, and potentially barred from participation in such programs for an extended period of time. While AHCA appreciates that some of the proposed revisions are mandated by the Patient Protection and Affordable Care Act (“ACA”), and applauds CMS’ efforts to protect the federal health care programs from fraudulent entities and individuals, we believe that the Proposed Rule would effectively and unjustifiably penalize all providers and suppliers even where there is no risk of fraud, abuse and waste. Specifically, the proposal would:

* Increase the onerous administrative burdens already imposed upon providers and suppliers in regards to the submission of an initial, revalidating or change of information application;
* Introduce additional and unnecessary complexities to already-complicated application and notification processes;
* Further diminish the due process available to providers and suppliers when faced with the sanctions contemplated in the Proposed Rule;
* Potentially severely penalize providers who make inadvertent errors in enrollment submissions without any recourse for such providers;
* Possibly exceed and contravene the statutory authority granted to CMS through the ACA; and
* Allow CMS to pierce to corporate veil and ignore corporate formalities.

 In the following sections of this comment letter, we elaborate upon our concerns regarding the Proposed Rule and in certain instances respond to CMS’ specific requests for comments. We reiterate our support of CMS’ efforts to protect the federal health care programs and express our appreciation to CMS for working with stakeholders to effectively implement various ACA provisions. We hope to work with CMS in this area and stand ready to assist you in developing appropriate policies impacting the long-term care industry.

# **Disclosure of “Affiliations”**

## **Proposed Rule’s Proposals**

 Under proposed 42 C.F.R. § 424.519, the Proposed Rule would require that health care providers and suppliers report (on initial or revalidating Form CMS-855s) “affiliations” with owning or managing employees and organizations that:

1. Currently have uncollected debt to Medicare, Medicaid, or CHIP, regardless of:
	1. The amount of the debt;
	2. Whether the debt is currently being repaid (for example, as part of a repayment plan); or
	3. Whether the debt is currently being appealed.
2. Has been or are subject to a payment suspension under a federal health care program, regardless of when the payment suspension occurred or was imposed;
3. Has been subject to an OIG exclusion or exclusion under the Medicaid or CHIP programs, regardless of whether the exclusion is currently being appealed or when the exclusion occurred or was imposed;
4. Have had their Medicare, Medicaid, or CHIP enrollment denied or revoked, regardless of:
	1. The reason for the denial;
	2. Whether the denial, revocation or termination is currently being appealed; or
	3. When the denial, revocation or termination occurred or was imposed.

For the purposes of the above, CMS proposes, at 42 C.F.R. § 424.519(b), to define “uncollected debt” as applying to the following:

1. Medicare, Medicaid or CHIP overpayments for which CMS or the state has sent notice of the debt to the affiliated provider or supplier;
2. Civil money penalties (as defined in § 424.57(a)); and
3. Assessments (as defined in § 424.57(a)).

In proposed 42 C.F.R. § 424.502, CMS proposes to define “affiliation” as:

1. A 5 percent or greater direct or indirect ownership that an individual or entity has in another organization.
2. A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
3. An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization (including, for purposes of § 424.519 only, sole proprietorships), either under contact or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
4. An interest in which an individual is acting as an officer or director of a corporation.
5. Any reassignment relationship under 42 C.F.R. § 424.80.

In proposed 42 C.F.R. § 424.519(f), CMS also proposes factors to consider when determining whether a particular affiliation creates an “undue risk” of fraud, abuse and waste:

Upon receiving the information described in paragraphs (b) and (c) of this section, CMS determines whether any of the disclosed affiliations poses an undue risk of fraud, waste or abuse by considering the following factors:

(1) The duration of the affiliation.

(2) Whether the affiliation still exists and, if not, how long ago it ended.

(3) The degree and extent of the affiliation.

(4) If applicable, the reason for the termination of the affiliation.

(5) Regarding the affiliated provider’s or supplier’s action under paragraph (b) of this section:

(i) The type of action.

(ii) When the action occurred or was imposed.

(iii) Whether the affiliation existed when the action occurred or was imposed.

(iv) If the action is an uncollected debt:

(A) The amount of the debt.

(B) Whether the affiliated provider or supplier is repaying the debt.

(C) To whom the debt is owed.

(v) If a denial, revocation, termination, exclusion or payment suspension is involved, the reason for the action.

(6) Any other evidence that CMS deems relevant to its determination.

 Under proposed 42 C.F.R. § 424.519(g), upon a finding of “undue risk” of fraud, abuse and waste, a provider’s or supplier’s initial enrollment application could be denied, or a provider’s or supplier’s enrollment could be revoked. In addition, the failure of a provider or supplier to fully and completely disclose the required affiliation-related information could result in denial or revocation when “the provider or supplier knew or should reasonably have known this information” may result in denial or revocation.

 Finally, CMS proposes a “look-back” period of 5 years for previous affiliations. In other words, an affiliation must have occurred within the 5-year period preceding the date on which the application is submitted in order to be reported to CMS. However, CMS also proposes no specified “look-back” period for “disclosable events”, which means that the event triggering the disclosure (for example, a revocation) could have occurred or been imposed more than 5 years previously, and would still require disclosure. Under CMS’ proposal, “disclosable events” could have occurred or been imposed either before an affiliation began or after it ended.

## **AHCA’s Recommendations**

## In the preamble to the Proposed Rule, CMS seeks comments regarding its proposed definition of “uncollected debt” found at 42 C.F.R. § 424.519(b). AHCA strongly believes that, as currently proposed, the definition of “uncollected debt” is far too broad. For example, why would CMS require disclosure of debt when: (1) debt is currently being repaid (for example, as part of a repayment plan); or (2) debt is currently being appealed? It is particularly worrisome that CMS would require disclosure of “uncollected debt” that is currently being appealed because the Department of Health and Human Services has a record of not processing appeals in a timely manner. In addition, if the debt is being repaid by a provider or supplier, and such provider or supplier has consistently and diligently made payments under a repayment plan, why would such debt have to be reported as “uncollected debt”? The required reporting of debt that is being repaid seems punitive and contrary to the demonstrated good faith of the provider or supplier who is actively striving to repay debt. Furthermore, AHCA believes that debt being appealed or repaid lacks any indicia of risk with respect to fraud, abuse or waste, which CMS indicates is the driving force behind the Proposed Rule. Stated otherwise, the provider is following the established process to repay or appeal the debt. AHCA urges CMS to exclude debt currently being repaid as well as debt currently being appealed from the definition of “uncollected debt”. We also recommend that CMS establish a threshold for the level of debt that would need to be reported. Our recommended threshold would be $100,000.

##  In the preamble to the Proposed Rule, the agency states that it is interested in comments on proposed § 424.519(b) and (c), particularly: (1) whether the types of disclosable affiliations should include additional ownership or managerial interests or other relationships; (2) whether 5 years is an appropriate look-back period for affiliations; (3) whether exclusions, denials and revocations that are being appealed should be exempt from disclosure; (4) whether the agency should establish a “reasonableness” test, whereby CMS explains what constitutes a sufficient effort to obtain information in the context of the “should reasonably have known” standard; and (5) whether there should be a look-back period for disclosable events and, if so, how long (for example, 15 years, 10 years, 7 years).

##  With respect to (1) above, AHCA believe that no further ownership or managerial interests or other relationships should be disclosed, in part because providers and suppliers currently provide a significant amount of information. With respect to (2) above, AHCA urges CMS to adopt a look-back period shorter than five years, and instead urges CMS to adopt a two-year look-back period. A two-year look-back period would allow CMS and its contractors to root out providers and suppliers with affiliations that could lead to fraud, waste and abuse in the federal health care programs without resulting in an unnecessarily onerous investigation and reporting on behalf of the submitting provider or supplier and without penalizing providers and suppliers for having affiliations with entities who have effectively moved past disclosable events.

##  AHCA strongly recommends that CMS exempt, from disclosure, exclusions, denials and revocations that are being appealed. Obviously if the affiliate of the provider or supplier is not successful in the appeal, the provider or supplier would be required to report such exclusion, denial or revocation at that point, and therefore, the federal health care programs would still receive the same protection intended by this proposal. Instead of instituting a “reasonableness” test, we urge CMS to implement an “actual knowledge” standard. This provides a much clearer standard to determine whether the provider or supplier should report the prior act. To the extent CMS is unwilling to adopt an “actual knowledge” standard, at minimum, we implore CMS to provide, in the final regulation or in the preamble to its final rule, strong and helpful examples about what the agency considers “should reasonably have known” to be. With respect to (5) above, we urge CMS to adopt a look-back period tied to disclosable events. In particular, we would recommend a three-year look-back period with respect to disclosable events. Indeed, imposing no look-back period with respect to disclosable events seems unduly, and unfairly, punitive and would result in a great administrative burden to providers and suppliers as well.

## In addition, AHCA urges CMS to remove “indirect ownership” from definition of “affiliation”. This could require extensive reporting obligations, and also could place the onus on the applicable providers to obtain information regarding disclosable events from a wide variety of individuals and entities over which they have no control. Just by way of example, under the Proposed Rule, certain providers and suppliers with complex ownership structures would potentially be required to maintain information on hundreds of affiliations due to minimal and attenuated ownership interests. Obtaining the required information from such affiliations would be extraordinarily burdensome for complex and chain provider organizations. In fact, certain of the entities remotely affiliated with providers—who, for all practical purposes have absolutely no role in or influence on the day-to-day operations of the health care provider or supplier—may be unwilling to provide such information due to confidentiality concerns or confidentiality agreements. Furthermore, as CMS is well aware, provider organizational structures have become increasingly complex and complex structures are becoming more common as providers affiliate with one another to serve patients across a continuum of care. In other words, including “indirect ownership” in the definition of “affiliation” will likely lead to increasing burdens on providers and suppliers as the health care industry, as a whole, continues to evolve.

##  Further, AHCA believes that there is no clear nexus between these expanded disclosure requirements and the agency’s (and statute’s) stated objective: stemming fraud, waste and abuse. In particular, the real “bad actors” may not comply with these disclosure requirements or share disclosable events with affiliated providers and suppliers. However, providers and suppliers striving to comply with the disclosure requirements will face increased administrative burdens and costly processes as they attempt to comply with the disclosure requirements, which may, in practice, be impossible to comply with.

 Finally, CMS solicited comments regarding the “undue risk” factors it proposed, including: (1)the duration of the disclosing party’s relationship with the affiliated provider or supplier; (2) whether the affiliation still exists and, if not, how long ago it ended; and (3) the degree and extent of the affiliation (for example, percentage of ownership), among other proposed factors. We believe that CMS should include additional factors, such as whether the disclosing provider or supplier was involved with the disclosable event and whether the affiliated individual or organization plays a tangible role in the day-to-day management and operations of the disclosing provider or supplier. AHCA urges CMS to furnish providers with a written explanation of why the agency believes “undue risk” exists, showing credible evidence of its belief before taking action based on the disclosable event. Further, AHCA recommends that CMS furnish examples, in the preamble discussion of the final provider enrollment rule, of how the agency plans to apply the “undue risk” factors.

# **Conditions of Payment for Claims for Ordered, Certified, Referred, or Prescribed Covered Part A or B Services, Items or Drugs**

## **Proposed Rule’s Proposals**

 The Proposed Rule, at 42 C.F.R. § 424.507(a)(iii)(C), would require that to order, certify, refer or prescribe any Part A or B service, item or drug, a physician or, when permitted under state law, an eligible professional must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program. In addition, pursuant to 42 C.F.R. § 424.516(f) of the Proposed Rule, the provider or supplier furnishing the Part A or B service, item or drug, as well as the physician or eligible professional who ordered, certified, referred or prescribed the service, item or drug, would have to maintain documentation relating to written orders, certifications, referrals, prescriptions or requests for payments for Part A or B services, items or drugs for seven years from the date of the service and furnish access to that documentation upon a CMS or Medicare contractor request.

## **AHCA’s Recommendation**

 First, AHCA objects to the proposed requirement that providers can only dispense and furnish services ordered by an enrolled physician (or one that has “validly” opted out). Since skilled nursing facilities (“SNFs”), pharmacies and other providers and suppliers receive orders and referrals from physicians and other eligible professionals who are not their employees or even acting as independent contractors, we question whether CMS or its contractors currently can provide a practical way for providers and suppliers receiving such referrals to ensure such physicians or eligible professionals are “enrolled in an approved status” or “validly opted out”. This requirement seemingly would necessitate providers and suppliers to confirm a physician’s status with every order or referral. Such confirmation, if required for every order or referral, would impose an onerous administrative burden on providers and suppliers and would likely require the dedication of significant staff time to conduct such confirmations. Moreover, such a requirement could unduly delay appropriate care and treatment. For example, assume that a hospital wishes to discharge a patient to a skilled nursing facility on a Friday at 6 p.m. The patient’s physician is a community physician with no other relationship to the skilled nursing facility. Under the Proposed Rule, the skilled nursing facility would have to delay the admission from the hospital until it could verify that the community physician is enrolled in an approved status with Medicare or validly opted out—information that may not be readily available to the facility. Likewise, assume a patient is newly admitted to a facility at 11 p.m. and has an order for pain medication. Again, the order is from a community physician. Under the Proposed Rule, the skilled nursing facility would have to delay providing pain-relieving treatment to the patient until the facility can track down the Medicare status of the physician.

 We understand that Medicare contractors have developed processes to be utilized in checking whether a physician is “enrolled in an approved status” or has “validly opted out”, but we also understand that this process is unwieldy and burdensome to providers. Therefore, CMS should either: (1) delay implementation of this proposal until it has an accurate, efficient and workable database or other mechanism for providers to check whether the ordering physician or eligible professional is enrolled or validly opted out; (2) remove this requirement entirely; or (3) indicate how providers may rely on an initial check of a physician’s or eligible professional’s Medicare enrollment—perhaps occurring through a provider’s credentialing process—with respect to all subsequent orders and referrals from the applicable physician or eligible professional. CMS should also consider an exception for emergency circumstances.

 Second, the proposed seven-year documentation requirement is quite onerous, and there is seemingly no basis for this lengthy of a documentation retention requirement. As a consequence, we recommend that the proposed documentation requirement be reduced to three years, recognizing, however, that providers and suppliers may choose or be required, under state law, to maintain such documentation for longer periods.

# **Increasing the Medicare Program Re-Enrollment Bar Period**

## **Proposed Rule’s Proposals**

## The Proposed Rule, at proposed 42 C.F.R. § 424.535(c), would increase the existing maximum re-enrollment bar from three years to 10 years. In addition, the Proposed Rule would allow CMS to add three more years to the provider’s or supplier’s re-enrollment bar if the provider attempts to re-enroll in Medicare under a different name, numerical identifier or business identity. Finally, the Proposed Rule would impose a maximum 20-year reenrollment bar if the provider or supplier is being revoked from Medicare for the second time.

## **AHCA’s Recommendations**

 AHCA believes that increasing the enrollment bars would be overly punitive. While perhaps a measured increase in the maximum re-enrollment bar would further protect the federal health care programs, increasing the current maximum bar from three to 10 years strikes us as draconian. The same is true of imposing a maximum 20-year re-enrollment bar. In addition, the proposed, extended maximum enrollment bars comes with no accompanying protections for providers. We recommend that CMS set the re-enrollment bar at five years, and consider a maximum re-enrollment ban of 10 years.

# **Failure to Report Enrollment Updates**

## **Proposed Rule’s Proposals**

 Under the revocation authority currently existing in 42 C.F.R. § 424.535(a)(9), CMS may revoke the billing privileged of an individual or group of physicians or non-physician practitioners that fails to report a change in practice location or final adverse action. In the Proposed Rule’s preamble, CMS explains:

Any failure to report changed enrollment data, regardless of the provider or supplier type involved, is of concern to us. We must have complete and accurate data on each provider and supplier to help confirm that the provider or supplier still meets all Medicare requirements and that Medicare payments are made correctly. Inaccurate or outdated information puts the Medicare Trust Funds at risk. 81 Fed. Reg. 10,720, 107,33 (Mar. 1, 2016).

Because of the above, CMS proposes to extend its revocation authority to include the failure to timely report any change in enrollment data. However, CMS indicates, in the preamble to the Proposed Rule, that “our proposal is focused on egregious cases of non-reporting” and that it will examine a number of factors in determining whether a 42 C.F.R. § 424.535(a)(9) revocation is appropriate, including: whether the data in question was reported and the materiality of the data in question.

## **AHCA’s Recommendations**

##  AHCA is concerned that the expanded authority CMS proposes pursuant to proposed 42 C.F.R. § 424.535(a)(9) would provide CMS with a specific basis to revoke a provider or supplier if such provider or supplier is delayed in reporting changes to enrollment data or fails to report a change in enrollment data. This proposed authority could allow CMS to revoke providers and suppliers for inadvertent errors, even if no federal health care program reimbursement was involved with the enrollment change that the provider or supplier failed to report (*e.g.,* the closure of a practice location). Therefore, we recommend that CMS delete this proposal in its final provider enrollment rule.

# **Collection of Information Requirements/Regulatory Impact Analysis**

 In the Proposed Rule’s preamble, CMS estimates that it would take each provider or supplier an average of 10 hours to obtain the affiliation information for initial enrollments and revalidations. In addition, CMS estimates it would take 30 minutes for a provider or supplier to report and submit new or changed affiliation information. We believe this grossly underestimates the amount of time to obtain, maintain and update the required information.

CMS requests feedback regarding how frequently affiliation changes must be reported. However, the answer to this request would depend on the definition of “affiliation” and the complexity of the provider’s organization and ownership structure. For example, a single physician may not have any changes in 10 years of Medicare enrollment. By contrast, a large skilled nursing facility organization with a complex ownership structure could have changes on nearly a weekly basis. Even today many organizations have one full-time employee (if not more) who is dedicated to Medicare and Medicaid enrollment updates. With the proposed changes, the required time and effort would multiply exponentially.

# **The Proposed, Expanded Sanction Authority Lacks Parallel Expansions to Ensure Due Process and Provider and Supplier Protections**

 AHCA is concerned that through the Proposed Rule, CMS has created a de facto exclusion with no accompanying due process. In other words, there is no way for a provider or supplier who has been denied enrollment or has been revoked to obtain due process within the currently existing appeals process.

 The current appeals process, which is a two-step process, provides an extremely short time frame for a provider or supplier to submit evidence demonstrating its level of compliance with the rules. Within that process, the provider or supplier may be denied access to the documentation supporting the enrollment denial or revocation, such as the site verification visit report or the information identified during a Medicare or Medicaid contractor investigation, further limiting the ability to mount a defense. When a provider or supplier is retroactively revoked, the revocation is most often accompanied by overpayment demands for the services billed from the effective date of the revocation. The unpaid overpayment demands are often reported to a recovery contractor or even the U.S. Treasury Department, resulting in expenses not only to appeal the revocation but expenses to appeal the overpayment demands and dispute the debt referral. There is no right to an expedited appeal, so the lack of Medicare payments while awaiting an appeal date has resulted in providers and suppliers simply having to close or sell the business, even in situations when the appeal may have had a successful outcome. And, when the appeal is successful, there is no process to ensure that billing privileges are timely restored, that the enrollment record is updated to remove the notation that the provider or supplier had a revocation, that any associated overpayment demand is reversed, or that referred debts are recalled.

 We recommend that CMS consider the far-reaching implications of the Proposed Rule, and modify its existing appeals processes to ensure that providers and suppliers can effectively appeal denials and revocations. Furthermore, we recommend that in the case of an overpayment demand for the services billed from the effective date of the revocation, CMS provide that the overpayment obligation is held in abeyance when a provider or supplier is retroactively revoked to allow providers and suppliers to challenge such determination through the appeals process.

 On behalf of our members, AHCA thanks you for the opportunity to submit these comments. We thank you for consideration of our comments, and we would be pleased to answer any questions you may have.

Sincerely,



 Mike Cheek

AHCA, Sr. V.P., Finance Policy & Legal Affairs