



Charles N. Kahn III
President and CEO

November 4, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

Electronically Submitted via <http://regulations.gov>

**Re: *Program Integrity Enhancements to the Provider Enrollment Process;*
CMS-6058-FC; 84 Fed. Reg. 47,794 (Sept. 10, 2019)**

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. Our members are hospitals enrolled in the Medicare program, state Medicaid programs, and the Children's Health Insurance Program (CHIP). We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our views in response to the September 10, 2019 final rule with comment period regarding the *Program Integrity Enhancements to the Provider Enrollment Process* (Final Rule).

Despite stakeholders' comments concerning the infeasibility of the rule as initially proposed and the unnecessarily and impracticably broad proposed definitions of "affiliation" and "disclosable event," the Final Rule largely implements without amendment the affiliation data collection requirements that CMS proposed in 2016. *See Program Integrity Enhancements to the Provider Enrollment Process; CMS-6058-P; 81 Fed. Reg. 10, 720 (March 1, 2016) (Proposed Rule)*. Under the Final Rule, initially enrolling and revalidating providers will only be required to disclose reportable affiliation information when CMS, after determining that the provider or supplier may have at least one reportable affiliation, requests the disclosure. The Final Rule,

however, indicates that these disclosure obligations will be extended to all initially enrolling and revalidating providers and requests comments concerning potential approaches for obtaining affiliation information from this group in terms of timing, mechanism, and priority.

This phased-in approach, however, does not materially lessen the burden on providers under the Final Rule because the actual disclosure of information to CMS is only a secondary burden of the regulation. The primary compliance burden under the Final Rule involves collecting and tracking the affiliation information, and providers will need to begin collection efforts as the disclosure obligations are being phased-in and without the benefit of regulatory definitions of critical terms like “should reasonably have known” and “uncollected.” Moreover, a phased-in approach simply fails to respond to commenters’ grave concerns about the burden of researching, obtaining, tracking, and disclosing information that is not readily available to providers. The notion that reporting will not occur for most providers “for several years” and that CMS may, by that time “consider additional rulemaking,” 84 Fed. Reg. at 47804, does not address the significant concerns with the Final Rule’s infeasibility and compliance burdens, as identified by commenters.

The FAH highlighted the significant operational burdens – sometimes reaching the level of impossibilities – that complying with CMS’s new regulations would impose in its April 25, 2016 comments submitted in response to the Proposed Rule. *See* Attachment A, incorporated herein by reference. In the preamble to the Final Rule, CMS’s responses to the comments are largely perfunctory, simply referencing CMS’s disagreement with the comments or mistakenly asserting that a “phased-in” approach addresses the grave concerns raised, rather than providing any meaningful engagement on the issues or a rationale as to why the rule should stand. This does not satisfy CMS’s obligation under the Administrative Procedure Act or the Social Security Act. Considering the overwhelming burden that its now-final regulations will have on providers and suppliers, the FAH respectfully requests that CMS revisit these issues set forth in Attachment A (including a recommendation for an alternative, significantly less burdensome approach). The following list briefly summarizes feasibility and operational concerns with key definitions and policies adopted in the Final Rule, and these concerns are discussed in more detail in Attachment A:

- ***The Definition of “Affiliation” is Impermissibly Broad.*** The FAH maintains that CMS’s definition of “affiliation” is too broad and imposes undue burdens on providers with concomitant risk mitigation for government payers.
 - *Five Percent Threshold.* First, the five percent threshold should be increased significantly, preferably to a “majority ownership interest.”
 - *Indirect Ownership.* Second, the definition of “affiliation” should not include indirect ownership or should be amended to impose some practical limitation or cut-off at which attenuated indirect ownership interests in other providers and suppliers are excluded from the definition of affiliation (*e.g.*, indirect ownership interests that are less than a “majority interest.”) *See* 84 Fed. Reg. 47,800. At a minimum, individuals or entities that have an ownership interest in another provider or supplier through a publicly-traded company, mutual fund, or other large investment vehicle should be carved out of this definition. It will be virtually impossible for providers and suppliers to collect affiliation data from

these types of investors about other providers and suppliers in which they may have passively invested over the last five years.

- *Indirect Operational or Managerial Control Interest.* It is not reasonable to expect providers and suppliers to collect affiliation data about *other* providers and suppliers in which the disclosed officers, directors, or managing employees may have an indirect operational or managerial control interest. *See* 84 Fed. Reg. 47,800–01.
 - *Reassignment Relationships.* The Final Rule defines “affiliation” to include any reassignment relationship despite numerous comments opposing this definition due to the relatively low level of risk of exclusively reassignment relationships and the extraordinary burden hospital systems and other providers will have tracking and reporting on physicians and other practitioners with reassignment relationships and disclosable events.
- ***Disclosable Events***
 - *Uncollected Debt.* The Final Rule’s definition of “uncollected debt” is so broad that it leaves providers and suppliers with no reasonable method for identifying and disclosing these events. There is no public resource or ascertainable method by which a provider can determine whether affiliated providers or suppliers have any uncollected debt to government payers, but this data is known to government payers.
 - *Denials, Revocations, and Terminations.* Under the Final Rule, all denials, terminations, and revocations are disclosable, even if these events are “without fault” or “without cause,” significantly broadening the scope of disclosable events to circumstances that pose minimal to no risk to government payers.
 - *Appeal Rights.* Under the Final Rule, uncollected debt or a denial, revocation, or termination is disclosable even if the debt is being timely repaid or the provider is appealing the debt, denial, revocation, or termination. Requiring the disclosure of these non-final determinations is inconsistent with CMS’s general policy against taking action against a provider or supplier until the applicable appeal rights are exhausted.
 - ***Affiliation Look-Back Period.*** Prior affiliations, particularly those that ended more than one year prior to the date of the enrollment or revalidation application, pose minimal (if any) risks to government payers in most instances. Therefore, a significantly shorter look-back period, for example one year, is more realistic for balancing CMS’s goals with the feasibility and burden of meeting the requirement. Alternatively, at a minimum, the FAH urges CMS to delay the implementation of the look-back requirements for at least the length of time of the look-back period.
 - ***Time Limitations for Disclosable Events.*** The Final Rule does not establish a look-back period for disclosable events; rather, disclosable events that precede the start of the affiliation or post-date the end of the affiliation are reportable. The absence of any temporal boundaries is not just burdensome but is also infeasible. Neither the Proposed nor the Final Rule identifies any reasonable process by which a provider could gather the necessary data concerning a former affiliate’s disclosable events. The Final Rule

indicates respectful disagreement with comments concerning the burden of identifying disclosable events that post-date the affiliation by presenting the example of a situation where the disclosable event was itself related to the affiliation. Such a hypothetical situation could simply be addressed by limiting disclosure obligations for events post-dating the termination of the affiliation to those that arose from or were related to the affiliation. There is no reason to believe that disclosable events that are (1) unrelated to the affiliation and (2) postdate the termination of the affiliation would pose any cognizable risk to government payers.

- **“Reasonableness” Standard.** 42 C.F.R. § 424.519(e) and § 455.107(e) provide for denial or revocation for the failure to fully and completely disclose the required affiliation information if the provider “knew or should have known of this information.” The Proposed Rule suggested that each situation would be reviewed “on a case-by-case basis” to determine whether the disclosing entity should have known of the information. 81 Fed. Reg. at 10727. Despite extensive comments on the necessity of a reasonableness standard, the Final Rule does not provide further guidance, but indicates that CMS “intend[s] to issue subregulatory guidance that will clarify [its] expectations regarding the level of effort that is required in securing the relevant affiliation information.” 84 Fed. Reg. at 47811. The FAH strongly urges CMS to propose and adopt a reasonableness standard through notice-and-comment rulemaking, as required under the Social Security Act, 42 U.S.C. § 1395hh.

The FAH appreciates the opportunity to provide additional comments on the changes to the enrollment process. Given the magnitude of the burden that the rule will impose on providers, we respectfully request that you re-engage in the evaluation process of these regulations and consider including reasonable limitations to the affiliation disclosure requirements. If you have any questions about these comments or need further information, please contact me or Katie Tenoever of my staff at 202-624-1500.

Sincerely,





ATTACHMENT A

Charles N. Kahn III
President & CEO

April 25, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201
Attention: CMS-6058-P

Electronically Submitted via <http://www.regulations.gov>

Re: *Program Integrity Enhancements to the Provider Enrollment Process*; CMS-6058-P;
81 *Fed. Reg.* 10,720 (March 1, 2016)

Dear Acting Administrator Slavitt:

The Federation of American Hospitals (“FAH”) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural parts of the United States, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. Our members are hospitals enrolled in the Medicare program, state Medicaid programs as well as the Children’s Health Insurance Program (“CHIP”). We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (“CMS”) with our views in response to the March 1, 2016 proposed rule regarding the *Program Integrity Enhancements to the Provider Enrollment Process* (“Proposed Rule”).

Section 1866(j)(5) of the Social Security Act, as amended by Section 6401(a)(3) of ACA, requires that a provider or supplier that submits a Medicare, Medicaid or CHIP enrollment or revalidation application must disclose any current or previous affiliation, whether direct or indirect, with a provider or supplier that has had one of the following specifically enumerated adverse events: (i) has uncollected debt to Medicare, Medicaid or CHIP; (ii) has been or is subject to a payment suspension under a federal health care program; (iii) has been excluded

from participation in Medicare, Medicaid or CHIP; or (iv) has had its billing privileges denied or revoked. This provision further provides the Secretary of the Department of Health and Human Services with the authority to deny enrollment and revalidation applications based on affiliations that the Secretary determines pose an “undue risk of fraud, waste or abuse.” Section 6401(b) and 6401(c) extend these requirements to the Medicaid and CHIP programs, respectively.

While the FAH recognizes Congress’ concerns in statutorily mandating these requirements, as well as CMS’ efforts at addressing various program integrity objectives, we believe many provisions in the Proposed Rule are much too broad, and are unworkable and unduly burdensome. We also question whether these proposed provisions will achieve the desired result of reducing fraud, waste or abuse in the federal health care programs.

CMS discusses in the Proposed Rule that the purpose of the provider enrollment process is to ensure that providers and suppliers meet applicable Medicare requirements. The FAH is concerned that, as proposed, the rule will fundamentally shift this paradigm, essentially converting the enrollment process to an enforcement tool. The focus of the enrollment process will shift from validating that Medicare enrollment and participation requirements are met, to the termination, revocation and suspension of Medicare privileges for large categories of providers and suppliers who may have only been tangentially or indirectly related to other providers or suppliers who have had certain disclosable events.

The Proposed Rule represents an unprecedented shift in program integrity enforcement responsibility, essentially shifting the burden to providers and suppliers to police each other. As set forth below, this extraordinary shift of burden is complicated by the dearth of resources and means available to providers and suppliers to monitor the wide range of “disclosable events” by a broad group of “affiliates,” as defined in the Proposed Rule. **The FAH urges CMS to reconsider the approach taken in this Proposed Rule and narrow considerably many key provisions, as discussed further below.**

I. Definition of Affiliation

Under the Proposed Rule, providers and suppliers, either during the initial enrollment process, the revalidation process or upon changes of information, must disclose to CMS certain information regarding their “affiliations” with another provider or supplier that has had certain specific disclosable events (discussed further below).

The Proposed Rule would define “affiliation” as: (i) a five percent or greater direct or indirect ownership interest in another provider or supplier; (ii) a general or limited partnership interest in another provider or supplier; (iii) an interest in which the individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another provider or supplier; (iv) an interest in which an individual is acting as an officer or director of another provider or supplier; or (v) any reassignment relationship with another provider or supplier.

The FAH believes this definition is much too broad. Notably, “affiliation” would include five percent or greater direct or indirect ownership interest in another provider or supplier.

The FAH urges CMS to increase this five percent threshold significantly, and preferably to a “majority ownership interest.” Although we recognize that this five percent threshold currently is used in the enrollment process for reporting ownership interests, use of this same threshold for determining “affiliations” would create a disclosure process that is unreasonable and unworkable, if not virtually impossible. Below, we discuss specific examples that demonstrate the breadth and impracticable nature of various aspects of the definition of “affiliation.”

A. Indirect Ownership

The FAH believes the definition of “affiliation” should be substantially narrowed. For example, under the proposed definition, an applicant provider or supplier would be required to identify and investigate the indirect ownership relationships of each of its indirect owners. Through the CMS 855 enrollment process and the corresponding Medicaid and CHIP processes, providers and suppliers would disclose all five percent or greater direct or indirect owners in the enrolled entity along with their basic demographic information and adverse actions. If the proposal stands, in addition to reporting this information about its indirect owners, applicant providers and suppliers internally will need to identify all affiliation relationships held by the applicant’s indirect owners and then determine whether any of these “affiliations” is with a provider or supplier that has had a disclosable event. As ownership in health care providers and suppliers has become more complex and indirect, and increasingly non-healthcare entities are investing in health care solely as passive investment vehicles, compliance with this requirement will be extremely challenging, if not impossible.

For example, consider a privately-owned hospital system with a number of five percent or greater indirect owners that are passive investors. Some of these investors may be large mutual or pension funds or retirement vehicles, such as a state public employee retirement system that has extremely large and diverse investment holdings. If the Proposed Rule stands, then these types of entities, as indirect owners of an applicant provider or supplier, will need to identify all current and some previous indirect ownership interests they have had in other health care providers and suppliers, and further ascertain whether any of these “affiliated” providers and suppliers has or has had a disclosable event. Passive investors may have no way of knowing specifically what other providers and suppliers in which they have an indirect ownership interest, nor have any mechanism to determine whether they have or have had any disclosable events. This would make it difficult if not impossible for providers and suppliers with indirect owners to comply with the proposed disclosure requirements.

In addition, as the ownership in provider and supplier organizations has become more complex, it is not unusual for provider and supplier organizations to have three, four, five or more levels of indirect owners above the entity that are enrolled in the Medicare program. If the definition of affiliation includes a five percent or greater indirect ownership interest, each of these owners up the chain will separately need to track and monitor all of their indirect ownership interests in other providers and suppliers for possible disclosable events. This would be incredibly burdensome, and likely result in duplicative reporting of disclosable events so far removed from the applicant provider or supplier that it would be almost impossible to argue that any such “affiliation” leads to a risk of fraud, abuse or waste.

As such, the burden and feasibility of complying with disclosure requirements of indirect ownership interests far outweighs the incremental benefit the government may receive from such disclosures.

Notwithstanding these concerns, if CMS continues to include indirect ownership in the definition of an affiliation, the FAH urges the Agency to impose some practical limitation or cut-off at which indirect ownership interests in other providers and suppliers are excluded from the definition (such as indirect ownership interests that are less than a “majority interest.”) At a minimum, individuals or entities that have an ownership interest in another provider or supplier through a publicly-traded company, mutual fund or other large investment vehicle should be carved out of this definition. Such investors may have no idea if they have a passive ownership interest in other providers or suppliers. This could be similar to the exception to the referral prohibition for physician-owned hospitals contained in 42 C.F.R. § 411.356.

Similarly, publicly-traded companies should not be required to report any direct or indirect ownership interests held by mutual funds or other large investment or stock-holding vehicles on CMS Form 855. Since the ownership percentage of mutual funds or other large investment vehicles in publicly-traded companies may fluctuate daily, thereby rising above or below the five percent reporting threshold, it is unreasonable and burdensome for publicly-traded providers or suppliers to track and report such changes. In addition, the ability of publicly-traded providers or suppliers to gather necessary information to report these mutual fund or other large investment vehicles is oftentimes unreasonably difficult, if not impossible.

B. Officer, Directors and Indirect Operational or Managerial Control

Currently, providers and suppliers enrolled in the Medicare program are required to identify, as applicable, their officers, directors, partners, and managing employees, including basic demographic information and adverse actions history of those individuals on the CMS 855 initial, revalidation and/or change of information applications. **However, the FAH does not believe the disclosed officers’, directors’, or managing employees’ indirect operational or managerial control interests in other providers should be included within the definition of “affiliations.”** As outlined above, this would be extremely burdensome and impractical, result in duplicative reporting, and ultimately is unlikely to result in any finding of a real risk of fraud, waste or abuse.

The FAH also urges CMS to confirm that it does not intend to include officer, director or operational or managing control positions of another provider’s indirect owners and parent companies within the definition of “affiliation.” These are not individuals who fit within the current definition of a control interest in a provider or supplier, and as such are not individuals (absent some additional relationship with the provider or supplier) who are currently identified in CMS 855 applications. Further, these individuals generally are not involved in the day-to-day operations of the providers or suppliers, as they are often only associated with the enrolled providers and suppliers in indirect ways.

C. Any Reassignment Relationship

The FAH is concerned with inclusion of “any” reassignment relationship within the definition of an “affiliation,” and we urge CMS to remove these relationships from this definition. CMS discusses in the Proposed Rule that it believes there is a “sufficiently close relationship between the reassignor . . . and the reassignee” to support including such reassignments within the definition of an “affiliation.” While a reassignment relationship inherently involves some relationship between the reassignor and the reassignee, we do not believe this would constitute an “affiliation” pursuant to which each party should be required to monitor and report disclosable events.

A reassignment relationship is a billing or contractual arrangement pursuant to which one party bills for services rendered by another party. Under a valid reassignment, both the reassignor and the reassignee are jointly responsible for the reassigned claims submitted and any corresponding overpayment. As such, if there are any billing problems resulting from a reassignment relationship, under existing law both parties are held directly accountable. If both parties are already jointly responsible for claims and associated overpayment risk associated with the reassignment relationship, it seems unnecessary to go the additional step of defining a reassignment relationship as an “affiliation.”

Further, hospital systems, large physician groups and other provider entities may have extensive networks of physicians who reassign benefits to them. While the reassignees have sufficient relationships with the reassignors to support the reassignment, as a practical matter, reassignees may have nominal relationships with the reassignor. For example, a radiation oncologist may partially reassign his or her right to bill Medicare to a hospital where he or she provides occasional consults. Beyond these occasional consults, the hospital has no insight into the specialist’s non-hospital practice or services rendered outside the hospital setting. To say that the hospital is affiliated with this specialist to such a degree that specific disclosures are required is a stretch. It also would be unduly burdensome to require the hospital to have an ongoing responsibility to monitor the practice of the specialist and all of its other reassigning physicians to ascertain whether or not these physicians have had any disclosable events.

In addition, if the definition of an “affiliation” continues to include parties to a reassignment, every hospital within a chain of hospitals arguably could be required to report every disclosable event associated with every reassigning physician to any hospital in the chain. Along the same lines, it would be equally burdensome, if not outright impossible, for a physician who reassigns benefits to a large medical group to monitor both the group itself and all of the other physicians also reassigning benefits to the group to determine whether any of these entities or physicians have had any disclosable events that would require reporting. Such a process would be unnecessarily onerous on both the reassignors and reassignees, and would result in a tremendous increase in the volume and duplication of Medicare, Medicaid and CHIP disclosure filings that would need to be submitted and processed. Absent extremely unusual circumstances, it is highly unlikely that these indirect reassignment relationships could give rise to an undue risk of fraud, waste or abuse if the underlying events were not additionally reported by the parties to the reassignment relationships.

D. Alternative Approach to Disclosure Process and Determining “Affiliations”

As discussed above, the FAH believes the definition of “affiliation” is much too broad and would result in an unworkable disclosure process, including one that ultimately could put some providers and suppliers in an untenable legal position (as discussed below). **We urge CMS to consider alternative, less invasive approaches to meeting the disclosure requirements for affiliated providers and suppliers.**

We believe the statute permits CMS to consider such alternative approaches. Specifically, the ACA provides the Secretary with the authority to determine the form, manner and timing of the provider or supplier disclosure regarding disclosable events of other providers and suppliers with which they are affiliated.

In accord with this authority, CMS could, for example, restructure the disclosure requirements such that providers and suppliers (and all applicable owners, partners, officers, directors and managing employees) disclose whether they have had any disclosable events. This disclosure would not need to extend to other suppliers and providers at the time an initial or revalidation application is submitted. Rather, upon receipt of these disclosures, CMS, CHIP and the state Medicaid programs (and their respective contractors) could review the information disclosed, confirm its accuracy, and determine whether it raises an undue risk of fraud, waste or abuse either for the disclosing provider or supplier or any other provider or supplier with which they may be affiliated. If federal payors validate that a disclosable event has occurred and that it creates a risk of fraud, waste or abuse for affiliated providers or suppliers, at that time, they could query the disclosing provider or supplier for additional information about their affiliation relationships. This would meet the ACA requirements, while averting the need for providers and suppliers to monitor continuously their affiliations and the affiliations of all of their owners, officers, directors, partners and managing employees for potential disclosable events. Government payors are in a much better position to identify the proposed disclosable events, as well as determine the level of risk posed by a disclosable event, and whether further information is warranted.

This alternative is a much more practicable and workable approach. CMS, CHIP, the state Medicaid programs and their contractors have full access to information about which providers and suppliers have had their enrollments denied, revoked or terminated. It also places providers and suppliers in the position of disclosing their own disclosable events, and not those of other providers and suppliers.

II. **Disclosable Events**

Under the proposed rule, when a provider or supplier or any of its owners, officers or directors, partners or managing employees has, or within the previous five years, has had an affiliation with another provider or supplier, this affiliation must be disclosed if the affiliated individual or organization has or has had any of the following disclosable events:

- Has an uncollected debt to Medicare, Medicaid or CHIP, including overpayments, CMPs and assessments, regardless of the amount of the debt; whether the debt is currently being repaid or appealed;

- Has been or is subject to a payment suspension under a federal health care program, regardless of when the payment suspension occurred or was imposed;
- Has been or is excluded from participation in Medicare, Medicaid or CHIP; or
- Has had its Medicare, Medicaid or CHIP enrollment denied, revoked, or terminated, regardless of: the reason; whether the denial, revocation or termination is being appealed; or when the denial, revocation or termination was imposed or occurred. Termination includes situations where the affiliated provider voluntarily terminated its Medicare, Medicaid or CHIP enrollment to avoid a potential revocation or termination.

The FAH believes these requirements are much too broad-based and should be refined and scaled back significantly, as outlined in greater detail below.

A. Uncollected Debt

While the FAH recognizes that the statute requires the reporting of uncollected debt of affiliated relationships, CMS’s proposed definition of “uncollected debt” is so broad that we believe that there is no reasonable method for providers and suppliers to ascertain whether an affiliated provider or supplier has “uncollected debt.” At the very least, providers and suppliers would need to devote substantial time and financial resources to assess whether it or any of its officers, directors, managing employees or direct or indirect owners has any affiliation relationships with other providers and suppliers who have such debt. Further, to our knowledge, there is no database or other publicly available resource to determine whether providers or suppliers have an uncollected debt to Medicare, Medicaid or CHIP. **Therefore, the FAH is concerned that there is no reasonable method for providers and suppliers to obtain this information, and as a result, failures to disclose could result in non-compliance by many well-intentioned, compliance-minded providers and suppliers unable to obtain the required information.**

We believe scaling back the definition of “uncollected debt” would not create material risk that CMS is not notified of uncollected debt of Medicare providers and suppliers. In fact, CMS and other governmental payors already have full knowledge of which individuals and entities have unpaid debts. Through the enrollment process, the governmental payors also know the individuals and entities who have an ownership or control interest in any other provider or supplier with an unpaid or uncollected debt. If CMS has a concern about an individual or entity circumventing the rules to avoid a debt and re-enrolling through a separate organization or entity, it can flag these individuals and entities and track them through the existing enrollment process. It should not place the duplicative burden on providers and suppliers to identify and re-disclose the unpaid debts of other entities on such a broad-scale basis.

Finally, there is a separate statutory and regulatory process in place, with separate requirements, timelines and consequences for the failure to comply, for provider and supplier overpayments. Overpayments should be handled through this already well-defined and finalized process and not brought within the scope of this rule.

As a result of these existing statutory and regulatory processes, CMS should narrow the definition of “uncollected debt” by establishing a minimum threshold for disclosing such unpaid debt. Further, debt should not be considered “uncollected” if it is being appealed or repaid pursuant to a repayment plan because it does not meet Congress’ standard of posing an undue risk of fraud, waste or abuse. If a debt is in the process of being appealed or paid, the FAH does not believe it is properly characterized as “uncollected.”

B. Enrollment Denials, Revocations and Terminations

In new Section 424.519(b), CMS proposes that a provider or supplier must disclose when it has an affiliation relationship with another provider or supplier that has had its Medicare, Medicaid or CHIP enrollment denied, revoked, or terminated, regardless of the reason, including whether the denial, revocation or termination is being appealed or when it was imposed or occurred. The proposal further contemplates that even voluntary terminations are disclosable events when the voluntary termination was to avoid a potential revocation or termination by the Medicare, Medicaid or CHIP programs.

The ACA requires a disclosing provider or supplier to disclose when, among other things, it has an affiliation with another provider or supplier that has had its billing privileges denied or revoked. Importantly, the statute does not require the disclosure of terminations. Thus, at a minimum, CMS must limit the regulatory definition of disclosable events to the specific disclosable events included in the statute under 42 U.S.C. §1395cc(j)(5)(A).

Further, the FAH is concerned about other significant issues in the Proposed Rule with regard to disclosures of denials, revocations and terminations. First, providers and suppliers routinely have enrollment applications denied, billing privileges revoked or enrollments terminated through no fault of their own. For example, a provider or supplier may have an enrollment application denied for failure to respond timely to a request by the Medicare contractor for supplemental information in support of an application. This can be the case even when the supporting documentation is not yet available (for example, a bill of sale for a transaction that has not closed yet) and the basis for the delay has been communicated to the contractor.

Additionally, a provider may have an enrollment application denied because a Medicare contractor issued a deficiency letter that the provider did not receive and the application was denied in light of the provider’s failure to timely respond to the deficiency letter. Moreover, providers or suppliers who have not billed the applicable payor for an extended period of time may have their billing privileges revoked or enrollments terminated. These providers or suppliers may not learn of these revocations or terminations until years later when they attempt to submit claims. This is not information that would necessarily be known to the provider or supplier or by extension any affiliated providers or suppliers. **The FAH urges CMS to carve out of the disclosure requirements these “without fault” or “without cause” denials, terminations or revocations, including at a minimum, those relating to the failure to timely provide requested additional information to the Medicare contractor (or their Medicaid or**

CHIP equivalents), failure to bill the respective payor for an extended period of time, or other denials, terminations or revocations not based on fraud, integrity or quality concerns.

The FAH also has concerns about the proposed requirement that enrollment denials, revocations or terminations of affiliated providers and suppliers must be reported even if an appeal is pending. Unfortunately, enrollment applications are routinely denied or current enrollment and billing privileges revoked or terminated in error. When this is done, sometimes providers and suppliers are able to have the errors corrected in the ordinary course. In other instances, providers and suppliers must initiate appeals and go through the time and expense of an appeal process in order to have the errors resolved.

If denials, revocations and terminations must be reported while appeals are pending, then errors could be compounded by putting the provider and supplier enrollments of affiliates in jeopardy. This could set about a chain of events that would be catastrophic. **Providers and suppliers and their affiliates should be permitted to exhaust their appeal rights with only final denials, revocations or terminations considered disclosable events.** In initial proposed ACA regulations, the Secretary specifically recognized and stated circumstances when CMS will not take action against a provider or supplier until the applicable appeal rights are exhausted (including, for example, revoking a provider's Medicare enrollment as a result of a Medicaid termination). **The FAH believes this same standard should apply under the Proposed Rule with regard to disclosure of denials, revocations and terminations.**

III. Timing Challenges

A. Affiliation Look-Back Period

CMS is proposing a five-year "look-back" period for identifying affiliations. This means that for purposes of assessing whether a particular individual or entity has an affiliation with a provider or supplier, the disclosing individual or entity will need to consider all current affiliations as well as all prior affiliations within the five years prior to the submission.

While CMS has indicated that the proposed five-year look-back limit for affiliations was intended, at least in part, to reduce the burden on providers and suppliers, a five-year look-back period is still incredibly onerous, and compliance with this requirement would be very difficult to achieve. A significantly shorter look-back period, for example one year, is more realistic for balancing CMS's goals with the feasibility and burden of meeting the requirement. If an affiliation relationship has ended more than one year prior to the disclosing provider or supplier submitting an enrollment application, this prior affiliation would not, in most instances, pose any real risk to government payors. Further, the burden of monitoring former affiliation relationships to determine if there have been any disclosable events more than one year after the termination of such affiliation substantially outweighs the incremental benefit the government may obtain from any corresponding disclosures. **The FAH also urges CMS to delay the implementation of the look-back requirements for at least the length of time of the look-back period.** This will allow providers and suppliers to identify all affiliations in effect as of the effective date of this rule and monitor them prospectively for disclosable events.

B. No Time Limitation for Disclosable Events or Former Affiliates

The broad definition of affiliation, along with the extended look-back period, is especially challenging. Once a relationship between a provider or supplier or its current owners, officers, directors, partners, or managing employees and another provider or supplier is found to be an affiliation (including, under the proposal, a former affiliation from five years ago), the proposed rule goes on to require, any disclosable events that have ever occurred either before or after the affiliation, or before or after the affiliated provider or supplier was enrolled in Medicare, Medicaid or CHIP must be reported. In other words, CMS is proposing that once an affiliation is identified, there is no limitation on when the disclosable event by the affiliated provider or supplier occurred, even if it occurred before the affiliation was initiated or after there was no longer an affiliation.

Disclosures related to individuals and entities who are no longer affiliated with the disclosing provider or supplier seem especially troubling. Once a provider or supplier's affiliation with another provider or supplier ends, it seems unreasonable to nonetheless require the disclosing provider and supplier to continue to monitor the individuals and entities with which it previously had an affiliation. Thus, we urge CMS to significantly limit the proposed five-year look-back period.

C. The "Reasonableness" Standard

In some cases, as with competitors, it may be difficult for disclosing providers and suppliers to obtain information about other providers and suppliers with which they previously had affiliation relationships. For example, if a hospital CEO leaves the organization to become the CEO of a large ambulance company, the CEO now owes a fiduciary duty to the ambulance company, and this may limit or restrict the CEO's ability to share information about the ambulance company's disclosable events with the hospital. The CEO may be advised that disclosing the event to the former hospital employer jeopardizes the privilege held by the ambulance company or will simply place it at a competitive disadvantage. For these reasons, the CEO may have strong disincentives – or even legal prohibitions – against sharing information about the disclosable event to the former hospital employer. **The FAH encourages CMS to avoid imposing requirements that potentially would put current or former affiliates in such untenable positions or create conflicts of interest.**

CMS recognizes that disclosures regarding former affiliations may be difficult, and has built in a "reasonableness" standard in § 424.519(e), such that a disclosing provider or supplier would only be subject to denial or revocation for failure to disclose required information it "knew or reasonably should have known." The FAH believes that it would be difficult, or impossible, for disclosing providers and suppliers to ascertain and disclose whether other providers or suppliers with which they have affiliation relationships have disclosable events.

Further, CMS has not provided any guidelines of how it will interpret whether a disclosing provider or supplier "reasonably should have known" of a disclosable event by an affiliated individual or entity. Instead, it has indicated it will review such incidences on a case-by-case basis. Without more guidance on how this reasonableness standard will be applied,

providers and suppliers have no way of knowing the effort they must expend to continue to track and monitor other affiliated providers and suppliers. Should providers and suppliers be making inquiries monthly, annually, or each time they need to submit new, revalidation or change of information applications? What efforts are required to maintain contact with individuals or entities with which they previously had affiliation relationships? What should providers and suppliers do if individuals or entities, with which they currently or previously had an affiliation relationship, refuse to respond to such inquiries or requests for information?

Further, the FAH is concerned that the undefined reasonableness standard would be applied as a presumption that a disclosure should have been made, and providers and suppliers will be forced to rebut this presumption through the appeals process after the Medicare, Medicaid or CHIP programs have taken action against the provider or supplier for failure to disclose.

For these reasons, the FAH is concerned that even a “reasonableness” standard is not reasonable. Instead, providers and suppliers should only be required to disclose those disclosable events of affiliated providers and suppliers of which they have actual knowledge. Further, if a Medicare contractor or CMS determines that a provider or supplier failed to disclose a reportable event of an affiliation, it should be required to provide notice of the disclosable event to the provider or supplier and give it the opportunity to explain the basis for the failure to disclose before taking any action.

IV. Factors in Assessing Fraud, Abuse and Neglect Implications of Affiliate Disclosures

Upon receiving information from a provider or supplier regarding disclosable events of affiliated providers and suppliers, CMS has proposed a number of factors that it will consider when it evaluates whether the affiliation relationship poses an undue risk of fraud, waste or abuse. Specifically, CMS would consider the duration of the disclosing party’s relationship with the affiliated provider or supplier, whether the affiliation still exists (and if not, how long ago it ended), the degree and extent of the affiliation, the reason for termination of the affiliation (if applicable), as well as specific information about the disclosable event, including the type of event, when it occurred, whether the affiliation existed at the time it occurred and “any other evidence that CMS deems relevant to the determination.”

The FAH urges CMS also to evaluate whether the disclosing provider or supplier had any involvement with or was otherwise implicated by the disclosable event. In addition, CMS should not take action against the disclosing provider or supplier without credible evidence or information showing that there will be undue risk of fraud, waste or abuse unless action is taken against the disclosing provider or supplier. The FAH is concerned that without such a limitation, large groups of providers and suppliers and chains of providers and suppliers will be at risk of having their Medicare enrollment revoked or terminated as a result of loose, indirect common affiliation relationships with other providers and suppliers that have had disclosable events that have nothing to do with the disclosing entities.

It is concerning that CMS has not provided any specific guidelines about what would constitute an undue risk. CMS has only discussed that affiliations vary widely and that the Agency must “retain the flexibility to deal with each situation on a case-by-case basis.”

The FAH agrees that affiliations vary widely, but is concerned that the flexibility CMS has retained will translate to different CMS contractors applying these factors and assessing similar disclosures differently, with adverse and inconsistent consequences for providers and suppliers who in good faith report required disclosable events. **At a minimum, CMS should provide examples of disclosable events and outline how it anticipates these factors will be applied, and what action CMS may take in response. These scenarios should be made available to the provider and supplier communities with an opportunity to comment before the rule is finalized.**

This is critical because if CMS finds that the disclosing provider's or supplier's ongoing enrollment (and perhaps all other enrollments of the provider or supplier organization) in the Medicare program creates an undue risk of fraud, waste or abuse because of a particular disclosure about an affiliate, CMS could revoke that provider or supplier's enrollment across the organization. The Proposed Rule asserts that there need not be any finding of actual fraud to support revoking a provider or supplier's enrollment (perhaps at every practice location) upon such a disclosure. This means, for example, that if a hospital discloses that it has an affiliation with a physician who had an enrollment application denied, then CMS could potentially revoke all of the enrollments of the entity that owns the hospital (including for other provider or supplier organizations the hospital entity owns that did not have the relationship with the physician) as well as for enrollments of other entities under common ownership.

The FAH is very concerned about the due process rights of its members and the larger provider and supplier communities who can lose their right to participate in the Medicare and Medicaid programs simply because of a determination that conduct by a loosely or indirectly affiliated provider or supplier results in the categorization of the disclosing provider or supplier as "risky." This is especially troubling given CMS' recent amendment to the appeals process (without notice and comment but instead through a manual revision) requiring providers and suppliers to perfect their appeals at the reconsideration level without the ability to add additional evidence beyond this stage. Through this change, providers and suppliers already have had their appeal rights curtailed without proper process. With implementation of this rule as proposed, and with CMS' seeming intent to use the enrollment disclosure process as an enforcement tool, providers and suppliers will face a significant increase in the risk of denials, terminations and revocations at all of their locations because of indirect or loose affiliations without sufficient due process or appeal rights.

V. **The Secretary's Authority to Deny Applications, Revoke Enrollments and Require the Submission of Change of Information Submissions and Related Considerations**

The affiliation disclosure requirements addressed in the Proposed Rule are established under Section 1866(j)(5)(A) of the Social Security Act, which requires providers and suppliers to disclose certain disclosable events flowing from affiliation relationships either during the initial enrollment process or at the time an existing enrollment is revalidated. Section 1866(j)(5)(B) further provides that "[i]f the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application [for enrollment or revalidation]." Pursuant to this language in the enabling statute, if a provider or supplier identifies an affiliation related disclosable event in either an initial enrollment application or an

application to revalidate enrollment, the Secretary may, but is not required to, deny that application.

Critically, the statute does not give the Secretary the authority to revoke a currently enrolled provider or supplier outside of the revalidation application context. Notwithstanding, CMS proposed to use this authority in the Proposed Rule, saying that having the authority to revoke the existing enrollment of providers and suppliers with affiliations that may pose an undue risk is “necessary to protect the integrity of the Medicare program.” Pursuant to its general rulemaking authority, CMS has proposed both to require providers and suppliers to submit CMS 855 change of information submissions to report any new or changed required disclosures for affiliates and to permit revocation of any corresponding enrollment if an undue risk is found in the provider’s or supplier’s change of information submission.

This goes far beyond the authority provided by ACA. CMS cannot, through the regulatory process, grant itself the authority to terminate or revoke current enrollments beyond the authority granted to it by Congress.

Furthermore, requiring already enrolled providers and suppliers to submit change of information applications every time it enters into an affiliation relationship with another provider or supplier that has had a disclosable event would be incredibly burdensome, both on the providers and suppliers completing the applications and on the Medicare, Medicaid and CHIP programs processing the applications. By way of example, imagine a large hospital system under common indirect ownership. A single physician who has a reassignment relationship with one hospital has his or her billing privileges revoked for failure to submit claims to the Medicare program for several years. Because the physician does not regularly bill Medicare, he or she does not know of the revocation or appeal it. The hospital learns of this event, and determines it is disclosable. Because every other hospital in the system is under common ownership, its indirect owners are also indirect owners of the reassignee hospital. As a result, pursuant to the proposed regulations, every hospital in the system would be required to submit change of information filings to report this incident. This could mean hundreds of different change of information filings reporting the same single event.

If large providers and suppliers, systems and chains are required to submit change of information filings to Medicare and corresponding disclosures to the Medicaid and CHIP programs each time any provider or supplier with which they have an affiliation has a disclosable event, they may very well be submitting a constant, never ending stream of change of information filings. **Rather than requiring providers and suppliers to submit change of information filings each time there is a such a disclosable event, CMS should work within the statutory framework established by Congress and require that these events be disclosed only during the initial enrollment or revalidation process. Any corresponding right to deny applications also should be limited to these initial and revalidation submissions.**

Furthermore, consistent with this approach, CMS should adopt a look-back period for disclosable events. Providers and suppliers should not be required to report prior disclosable events of any other providers or suppliers it has or had an affiliation

relationship with beyond the last submitted revalidation application, or three years, whichever is shorter.

VI. Expanding the Re-Enrollment Bar

The Proposed Rule would increase the maximum re-enrollment bar, currently three years, to a maximum of 10 years. In addition, three additional years may be added (even if this takes the total bar beyond 10 years) if CMS determines that the provider or supplier is attempting to circumvent the existing bar by enrolling under a different name, numerical identification number or business identity. CMS also is proposing to impose a re-enrollment bar of up to 20 years if the provider or supplier is being revoked from the Medicare program for the second time. Lastly, CMS has indicated that the re-enrollment bar applies to a provider or supplier under any current, former or future business names, identifiers or business identities.

While the FAH recognizes that expanding the re-enrollment bar beyond three years may be appropriate under certain limited circumstances for program integrity reasons, expanding the bar to 10, 13 or 20 years in other circumstances could be unreasonably draconian and unduly punitive. We urge CMS to reconsider these expanded re-enrollment time frames. The FAH also is concerned about the breadth of CMS’ proposal to apply the re-enrollment bar to “any current, former or future business names, identifiers or business identities,” as this could result in applying the re-enrollment bar far too broadly to well-intentioned and compliant providers and suppliers.

In the event that any re-enrollment bar is applied, CMS should ensure this occurs only when there is sufficient evidence that serves a program integrity goal, and only upon robust due process and appeal rights for any providers or suppliers that may be subject to the re-enrollment bar. CMS also should apply any re-enrollment bar as narrowly as possible to meet program integrity needs, and should not subject the bar across multiple providers or suppliers that may be affiliated with a provider or supplier, but who had no knowledge of the behavior leading to the bar on re-enrollment.

Finally, CMS should allow flexibility in extenuating circumstances that appropriately balances program integrity risk with community need. For example, such flexibility could apply if an entity is seeking re-enrollment and could demonstrate that it would provide certain services or providers where a community is experiencing a shortage.

VII. Conditions of Payment for Claims for Part A or Part B Services, Items or Drugs Ordered, Certified, Referred, or Prescribed by Physicians and Other Eligible Professionals

The Proposed Rule would require that physicians (or when permitted under state law, other eligible professionals) be enrolled in Medicare in an approved status (which would include limited 8550 “ordering” type enrollments) or have validly opted-out of the Medicare program in order to order, certify, refer or prescribe any Part A or Part B services, items or drugs. This is an expansion of the current rule that is limited to a smaller universe of services (including, for example, DMEPOS items or home health services).

This proposal presents a significant practical problem for providers and suppliers who submit claims for Part A or Part B services, but who do not employ or contract with the physicians or independent practitioners who order, certify, refer or prescribe the underlying item, service or drug. To the knowledge of the FAH, there is no system or process whereby a provider or supplier can check a CMS or other publicly available data source to determine if an ordering, certifying, referring or prescribing practitioner is enrolled or has properly opted-out of Medicare. **The FAH believes that CMS should delay implementation of this requirement until such a system is available to providers and suppliers.**

VIII. Other Considerations

A. Consistency in Applying the Standards

For Medicare purposes, disclosures of affiliation relationships and associated disclosable events will be handled through the 855 submission process and will be processed by the Medicare Administrative Contractors (“MACs”). Medicaid and CHIP disclosures will be handled through separate processes. The FAH is concerned that different MACs and Medicaid programs and CHIP representatives will review and assess disclosures and the reasonableness of failures to disclose otherwise disclosable information differently, which will result in different standards and consequences being applied to different providers and suppliers. **We urge CMS to ensure this does not occur and provide further guidance to its contractors and other payor representatives, as well as the provider and supplier communities, about how the affiliated disclosure factors should be applied and assessed to determine if there is an undue risk of fraud, waste or abuse.**

B. Burden on Medicare, Medicaid and CHIP

Without narrowing the look-back period on affiliations, placing a time limitation on disclosable events or altering the nature of the reporting obligations (*i.e.*, revalidations *v.* changes of information filings), the provisions in the Proposed Rule, if adopted, would result in a tremendous increase in the volume of 855 submissions by providers and suppliers. The FAH believes this will have an adverse negative impact on the current workload and demands of the Medicare contractors and other payor representatives. These contractors and payor representatives already struggle with keeping up with their current workload and accurately and timely processing CMS 855 submissions. **Exponentially expanding the disclosure and submission requirements will undoubtedly lead to processing errors and delays that will impact the ability of providers and suppliers to make enrollment changes and get paid in a timely manner.**

C. Proposal Too Burdensome for the Benefit

CMS has estimated that the annual cost to providers and suppliers of complying with the Proposed Rule would be \$290 million in each of the first three years. The FAH believes this number likely is significantly underestimated. CMS estimates that it would take providers and suppliers approximately 10 hours to prepare and submit the affiliation related disclosure information during the initial and revalidation Medicare enrollment applications, and approximately 30 minutes to prepare similar disclosures in routine change of information

submissions. CMS also estimates that this work would be done by provider and supplier administrative staff at an average rate of \$34/hour.

The FAH does not believe these estimates are at all close to the amount of time it would take providers and suppliers to comply with the new requirements as proposed. Working with these affiliated providers and suppliers to obtain any required disclosure information would be extremely time-consuming, and likely would require a significant amount of follow-up. Providers and suppliers likely would need to invest time and resources in monitoring this information to learn of disclosable events. In fact, virtually all providers and suppliers would need to develop systems to track and monitor all identified affiliation relationships. Further, to gather the information necessary to comply with the Proposed Rule, providers and suppliers likely would need to rely on higher paid, more sophisticated employees or an outside consultant or attorney, at a rate substantially higher than \$34/hour. **Therefore, we urge CMS to reconsider its estimates of the cost compliance with the Proposed Rule.**

The FAH also questions whether the increased disclosure requirements would be effective in addressing CMS's program integrity concerns. We have no doubt that well-intentioned, compliance-minded providers and suppliers will do their best to comply with final disclosure requirements. However, it is difficult to imagine that the providers and suppliers about which CMS is most concerned will voluntarily disclose these affiliated disclosable events in their 855 submissions. It seems further unlikely that providers and suppliers who do not report these disclosable events to CMS would disclose them to other providers or suppliers, especially to competitors. As a result, these increased disclosure requirements likely would result in tremendous additional work on the part of compliance-minded providers and suppliers in monitoring their current and past affiliation relationships for any disclosable events with the providers and suppliers who are less compliance-minded, more aggressive or who know they have troubled histories and elect not to self-report or share information about disclosable events.

The FAH appreciates this opportunity to provide comments on these changes to the enrollment process. We stand ready to work with CMS to reach a suitable resolution to the numerous and significant issues raised under the Proposed Rule. If you have any questions about our comments or need further information, please contact me or Katie Tenover of my staff at 202-624-1500.

Sincerely,

