The **MAHON** Consulting Group LLC | *Health Care Fraud and Abuse Solutions and Services*

April 27, 2007

Centers for Medicare & Medicaid Services,
U.S. Department of Health & Human Services
Attention: CMS-6003-P2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

MAY - 2 2007

To Whom It May Concern:

On behalf of The Mahon Consulting Group LLC, I am very pleased to express our strong support of CMS's Proposed Rule, CMS-6003-P2—and specifically its proposed revisions to 42 CFR Section 424.535 under which CMS will (1) allow its Medicare fee-for-service contractors to revoke a provider's or supplier's billing privileges when that person or entity has billed Medicare for services or supplies that, on the face of it, could not have been provided as claimed, and (2) prohibit a party whose billing privileges have been revoked on that basis from re-enrolling in the Medicare program for three years.

Those proposed revisions:

- Are appropriately and effectively focused on some of the most egregious fraudulent- billing activity aimed at the program;
- Are eminently reasonable and entirely justifiable given the nature of such billing activity;
- Are clearly needed in an era when the Medicare program is subjected to fraudulent billings not simply by dishonest individual providers, but in many cases by sophisticated professional criminals;
- Are consistent with the intensified and more effective anti-fraud initiatives that CMS has undertaken in recent years;
- Will streamline an enforcement mechanism whose often lengthy and complex adjudication processes themselves contribute to the Medicare system's vulnerability and, to a certain degree, will establish a more level playing field on which to deal with some of the system's most flagrant offenders; and
- Perhaps most important from a practical standpoint—and while not constituting formal determinations of fraud—will enable CMS and its contractors to "stop the bleeding" of potential continued payments and/or costly claim-by-claim scrutiny while any formal legal action against those flagrant offenders is conducted.

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My 16-year career in the field of health care fraud, from 1991 through the present, spans the entire "modern era" of attention to and public- and private-sector efforts to address the crime more effectively. For 13 of those years, I served at the heart of those efforts, as chief staff executive of the National Health Care Anti-Fraud Association.

Throughout those 16 years, and despite our ever-increasing statutory and operational efforts to address fraud, as the sheer dollar volume of the nation's health care and health insurance systems (i.e., the motive and opportunity) has continued to grow, so have the degree and types of frauds aimed at those systems.

Throughout that time and still today, the Medicare system has been perceived—for the most part quite correctly—as being unusually vulnerable to fraud, due not only to its size and complexity, but to the related inability of its regulatory, operational and enforcement infrastructures to respond swiftly and nimbly to ever-increasing and evolving frauds, including the most blatant.

That systemic rigidity further enhances the inherent advantage that fraud perpetrators always enjoy—i.e., they know precisely what they are doing and how they are doing it, while claim payers and administrative, regulatory and law enforcement agencies face the often-difficult challenge of detecting, investigating and proving that fraudulent activity.

There are few if any shortcuts to due process in the investigation and prosecution of potential fraud, and rightly so. However, in the types of cases at which CMS's proposed revisions are aimed, it becomes clearly evident upon initial investigation that the services for which the program was billed quite simply could not possibly have been rendered.

Assuming a degree of investigation that reasonably rules out simple error—e.g., as the cause of a given provider's single such claim—the *prima facie* aspects of such cases clearly warrant both the revocation of privileges and at least the three-year re-enrollment prohibition that CMS proposes. In cases where the subject of those actions is subsequently prosecuted and convicted of fraud, then one assumes that any resulting Medicare exclusion would supersede, and perhaps exceed in duration, the re-enrollment prohibition.

From the very broadest perspective, and however unfairly, the Medicare system has been perceived by many—including dishonest health care providers and professional criminals—as being one of its own worst enemies for not mounting stronger, more effective defenses against fraud.

Especially in the last several years, however, CMS has matched its policy-level commitment to address fraud more effectively with Program Integrity resources and actions that are producing unprecedented field-level results in its detection and investigation of fraud in specific regions where it is most widespread.

CMS's proposed rule revisions will make those efforts even more fruitful by enabling it to curtail some of the worst offenders' ability to continue to exploit the system—i.e., rob the taxpayers—even when on the face of it, their actions are blatantly fraudulent.

In specific cases, the revocation of privileges will serve a very beneficial practical purpose of halting a scheme pending its formal adjudication. From a broader perspective, the authority of CMS and its contractors to take swift and decisive action against such activity in all likelihood will have some deterrent effect—difficult to gauge, but useful and welcome in any degree.

We appreciate this opportunity to comment on these well-balanced and properly focused proposed revisions, which represent a common-sense approach to addressing the more blatant aspects of what remains a widespread and damaging nationwide crime problem.

Sincerely yours,

William J. Mahon
President

Submitter : Mr. Tristan North **Date:** 04/25/2007

Organization : American Ambulance Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6003-P-9-Attach-1.DOC

AMERICAN AMBULANCE ASSOCIATION

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April 25, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–6003-P2
P.O. Box 8017
Baltimore, MD 21244-1850

RE: Billing Privileges
File Code CMS-6003-P2

Dear Sir or Madam:

The American Ambulance Association (AAA) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule dated March 2, concerning billing privileges (72 FR 9479). AAA is the primary trade association representing ambulance service providers that participate in serving communities with emergency and non-emergency ambulance services. The AAA is composed of more than 600 ambulance operations and members include private, public and fire and hospital-based providers covering urban, suburban and rural areas. The AAA was formed in 1979 in response to the need for improvements in medical transportation and emergency medical services. The Association serves as a voice and clearinghouse for ambulance service providers who view pre-hospital care not only as a public service but also as an essential part of the total public heath care system.

The comments submitted herein are on behalf of our members and focus on our three primary concerns.

1. Revocation of Billing Privileges

The proposed regulation at 42 CFR 424.535(a)(8) would permit the billing privileges of a provider or supplier to be revoked for submitting claims that could not have been furnished on the date of service. One of the specified examples is "where the beneficiary is deceased". We are very concerned with this provision since ambulance providers and suppliers can, legitimately, bill for services that intermediaries and carriers often deny with a denial code CO-13, i.e. date of death precedes date of service. This may seem unusual but actually happens in two circumstances:

- A patient is transported to the hospital where they later die on the same day. Most often this will happen in emergency situations, but can happen following non-emergency transports, as well.
- An ambulance provider or supplier responds to the scene of an unconscious patient who has not been declared dead. At the scene or subsequently, the coroner back-dates the date of death, based on their determination of when death occurred.

The first situation noted above occurs very often. The second situation occurs on a much less frequent basis. In both cases, the ambulance provider or supplier has done nothing wrong by billing for the response to the scene or for the transport (if the patient was not legally pronounced dead). If you check your records you will see many CO-13 denials. This is not abusive billing. On the contrary, billing for the response or transport follows Medicare guidelines in these situations. Our concern is that a contractor looking at statistics will see a pattern of denials and incorrectly jump to the conclusion that the provider or supplier has billed "abusively". Currently, these are handled by appealing denials, which are then reversed when the contractor compares the ambulance trip report to the death certificate or the admission or discharge record of the facility.

The more common situation noted above would be avoided if CMS implemented an edit for date of death plus one day so that claims would not be denied for responses to the scene and for transports where the patient dies on the same day as the date of transportation. Unfortunately, the second problem will not be resolved unless CMS is able to implement a policy that declares the date of death to be the date when the patient is pronounced dead, rather than the effective date of that pronouncement.

In any event, ambulance providers and suppliers are not billing incorrectly in these situations and should not be punished by having their billing privileges revoked. Please note, if this tragic event occurs, 424.535(c) does not allow the provider or supplier to reapply for three years from the date of revocation. A provider or supplier should be allowed to explain the "dead after dispatch" situation so as to avoid the proposed revocation of billing privileges.

2. Definition of Supplier

Section 498.2 defines "Supplier" as "...ambulance service provider". Perhaps this was intended to include facility based ambulance providers and independent ambulance suppliers. However, as it reads, it appears to only include the facility based ambulance providers when, in fact, the vast majority of those providing ambulance services are "suppliers" who bill Part B. We recommend the definition be amended to read "ambulance service provider or supplier".

3. Appeal Rights

Section 405.874(c)(2) indicates that the reconsideration of a redetermination would be handled by a carrier hearing officer. For ambulance providers and suppliers, the appeal of adverse decisions is now to the carrier or intermediary for the redetermination and then

the appeal is to the QIC for the reconsideration. There no longer are carrier hearing officers for ambulance issues. Thus, we are confused by the wording in this section and recommend that it be clarified.

Your consideration of these comments is greatly appreciated. If you need additional information, please contact AAA Senior Vice President of Government Affairs Tristan North at (202) 486-4888 or AAA Medicare Consultant David Werfel at (631) 582-3283.

Sincerely,

Jim McPartlon
President

Federation of American Hospitals®

FEDERATION OF AMERICAN HOSPITALS 40 Years of PROVEN LEADERSHIP 1966 - 2006

Charles N. Kahn III
President

May 1, 2007

VIA HAND DELIVERY

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: *Comments to the Medicare Program; Appeals of CMS or Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges; Proposed Rule (File Code CMS-6003-P2)*

Dear Ms. Norwalk:

The Federation of American Hospitals ("FAH") is the national representative of 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 areas, as well as rehabilitation, long term acute care, cancer, and psychiatric hospitals. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Proposed Rule that would establish an appeals process for Medicare providers and suppliers whose applications for enrollment or renewal of enrollment are denied, which was published in the *Federal Register* on March 2, 2007 (the "Proposed Rule"). (*See* 72 *Fed. Reg.* 9,479.)

I. General Comments Regarding Appeals of Medicare Enrollment

FAH supports the establishment of appeals procedures for providers and suppliers whose applications for initial Medicare enrollment or enrollment renewal are denied. However, as explained further below, we have concerns with some aspects of the appeals process as set forth

in the Proposed Rule. We also strongly believe that CMS has improperly exercised its authority with respect to the impact of a revocation of enrollment billing privileges.

The remainder of this letter provides specific comments on provisions of the Proposed Rule.

II. Applicability of 42 C.F.R. § 405.874 to Providers

The Proposed Rule would make several changes to the regulation at 42 C.F.R. § 405.874, which governs supplier appeals of carrier determinations. Section 405.874 is part of the Part B appeals procedures set forth in Part 405, Subpart H and appears to apply solely to supplier appeals. However, many of the proposed changes (discussed below) reference both suppliers and providers.

We request that CMS clarify whether section 405.874 applies solely to suppliers or to both suppliers and providers. If the changes are intended to apply to providers, we question whether it would be more appropriate to make conforming changes to other subparts of Part 405, such as Subpart G or Subpart I. In our view, it would be confusing to have Subpart H apply to providers when it otherwise does not for other types of determinations that may be appealed.

III. Definitions – 42 C.F.R. §§ 498.2

With regard to 42 C.F.R. § 498.2, the Proposed Rule would add additional types of suppliers to the existing definition of "supplier," and separate out the definition of "prospective supplier." Currently, however, this regulation does not separately define "prospective provider," as that term would still remain defined as part of the existing definition of "provider." To ensure a consistent regulatory structure, we recommend that CMS separately define "prospective provider" in § 489.2 and modify the definition of "provider" accordingly. If the provisions in Section 405.874 are intended also to be applicable to providers, we recommend that separate definitions of "provider" and "prospective provider" be included in Section 405.802 as well.

IV. Reinstatement of Billing Privileges Following Revocation – 42 C.F.R. § 405.874(d)(3)

The Proposed Rule states that where revocation of a provider's or supplier's billing privileges is reversed upon appeal, the provider's or supplier's billing privileges would be reinstated back to the date that the revocation became effective. FAH supports the proposed policy timeframe of reinstatement of billing privileges following revocation.

V. Reinstatement of Billing Privileges Following Denial – 42 C.F.R. § 405.874(d)(4)

Where the denial of a provider's or supplier's billing privileges is reversed upon appeal, the Proposed Rule provides that the date of the appeal decision would establish the effective date

of the provider's or supplier's billing privileges. FAH believes that this proposed effective date is inappropriate and would unfairly restrict a provider's ability to file claims for a time period it otherwise could have if it had been approved initially. We recommend that if a denial of a provider's or supplier's billing privileges is reversed upon appeal, then the effective date of the billing privileges should be the effective date listed in the enrollment application. Our recommendation is consistent with current enrollment practices, which provide that an enrollment application is generally approved with the effective date listed by the provider in the application as the date services began.

As a practical matter, using the appeal decision date as the effective date opposed to the enrollment application effective date would likely render the appeals process for enrollment denials largely meaningless. This is because, in our view, few providers would avail themselves of the process if their ability to submit claims is restricted to after the date of the appeal decision. Instead, they would simply reapply for billing privileges. Therefore, the proposed policy effectively creates a disincentive for providers to file appeals when billing privileges are denied, which we think is an inappropriate public policy outcome.

VI. Submission of Claims after Revocation or Denial – 42 C.F.R. § 405.874(g)

The Proposed Rule provides that a provider or supplier who succeeds in having its enrollment application denial or billing number revocation reversed or in having its billing number reinstated may submit claims to the carrier for services furnished during periods of Medicare qualification subject to the timely filing limitations in 42 C.F.R. § 424.44. If claims were filed timely but were rejected, they would be considered filed timely upon resubmission. Previously denied claims for items or services rendered during a period of denial or revocation may be resubmitted within one year after the date of reinstatement or reversal.

As a threshold matter, this provision would appear to apply only to a billing number revocation or reinstatement of a billing number, because a provider whose application has been denied has not yet been issued a billing number and therefore is not "qualified" to submit claims. We believe the scope of this provision should be clarified accordingly.

Also, we recommend that with respect to reversal of revocation decisions and reinstatement of billing privileges, a provider or supplier be permitted to submit claims for a period of one year from the date that a provider's or supplier's billing number is reinstated or in accordance with the timely filing limitations in 42 C.F.R. § 424.44, whichever is later. It appears that the new policy is intended to compliment, and not supersede, existing rules, so we think this modification would be appropriate. With respect to applications that have been denied, as discussed in Section V above, we recommend that a provider or supplier be permitted to submit claims from the effective date listed in the enrollment application.

VII. Appeal of Both Termination of Provider Agreement and Revocation of Billing Privileges – 42 C.F.R. § 424.545(a)(1)

The Proposed Rule would clarify if a provider appeals both the termination of its provider agreement and the revocation of billing privileges, then both matters will be resolved using a single appeals process as set forth in 42 C.F.R. Part 498. The Proposed Rule indicates that the appropriate process for the consolidated appeal would be to follow the appeals procedures established for billing privilege revocations. FAH generally supports using a consolidated appeals process for provider agreement termination and billing privileges revocation actions. However, we have concerns with applying certain procedures from Part 498 that are specific to provider and supplier enrollment appeals to provider agreement termination actions. As discussed in this comment letter, CMS intends to adopt certain procedures specific to enrollment appeals that are more limiting than the current appeal procedures contained in Part 498. To the extent that CMS adopts a consolidated appeals process based on the revocation procedures, we do not believe that these limitations should also apply to provider agreement termination procedures.

As specified in proposed Section 498.5(f)(1), CMS or a contractor is entitled to request reconsideration of an enrollment determination and also request review before an administrative law judge ("ALJ") and the Departmental Appeals Board ("DAB"). However, currently, neither CMS nor a contractor is considered a party under the existing Part 498 appeals procedures. Therefore, making CMS and the contractor a party in enrollment appeals represents a substantive departure from the current Part 498 procedures. The FAH believes that the appeal procedures for termination of provider agreements should not be revised to include CMS or the contractor as a party to these proceedings and, to ensure consistency within the existing Part 498 processes, we believe CMS or a contractor should not be entitled to request administrative appeals of adverse decisions for the provider which are overturned.

As discussed in Section XIII below, the Proposed Rule would limit the submission of new provider enrollment issues or evidence at the higher levels of the appeal process, specifically the ALJ and DAB levels. Notably, the current Part 498 procedures do not contain this limitation. The FAH opposes this limitation altogether, and thinks the existing evidentiary rules should be applied to these new types of determinations. At the very least, we think this limitation should not be applied to provider agreement termination proceedings.

VIII. Adjudication Timelines – 42 C.F.R. § 405.874(h)

The Proposed Rule would establish deadlines for adjudication of provider enrollment actions. Specifically, contractors would be required to adjudicate initial determinations and revalidations within 180 days of receipt, and carriers would be required to adjudicate change-of-information and reassignment of payment requests within 90 days of receipt.

In our view, the proposed timeframes are excessive and inconsistent with the current contractor processes. Currently, as set forth in the Program Integrity Manual, contractors are

required to process 80% of enrollment applications within 60 calendar days of receipt, 90% of applications within 120 calendar days of receipt, and 99% of applications within 180 calendar days of receipt. (Program Integrity Manual (CMS Pub. 100-08), Ch. 10, § 2.) We also understand that the 60-day period is a mandatory requirement in the contractors' agreements with CMS. With respect to change of information applications, contractors are required to process 80% within 45 calendar days of receipt, 90% of such applications within 60 calendar days of receipt, and 99% of such applications within 90 calendar days of receipt. (Program Integrity Manual (CMS Pub. 100-08), Ch. 10, § 2.2.)

Under the Proposed Rule, contractors would be given up to six months to adjudicate initial determinations and revalidations and up to three months to adjudicate change-of-information and reassignment of payment requests. It would seem that the proposed time periods for these actions are more than is necessary to complete the work and therefore unreasonable, especially when considering the inferences regarding overall performance from the Program Integrity Manual. The Proposed Rule does not provide a sufficient explanation as to why these extended timeframes are necessary. Our members have reported that, in fact, most contractors are timely processing enrollment applications and they do not see any reason why the contractors would need a longer period of time when most of them are meeting the timeframes contained in the Program Integrity Manual.

The proposed 180-day timeframe also seems entirely unworkable for providers undergoing a change of ownership ("CHOW"). For example, a hospital which is undergoing a CHOW must submit both an 855 enrollment application and a licensing application to the appropriate State health agency. The State health agency generally will not make the final approval decision on the licensing application until it receives the fiscal intermediary's recommendation approving the enrollment application. Thus, the fiscal intermediary approval letter is a precondition for moving forward the entire licensing and certification process for new providers. Therefore, if the fiscal intermediary is given six months to process an application, it will cause significant licensing problems for CHOW providers. In our members' experience, it is logistically impossible for providers to plan for this kind of delay by submitting an enrollment application earlier due to the fact that the information needed to complete an enrollment application for a CHOW provider cannot generally be received from the seller until the purchase agreement is signed. Therefore, it would be impossible for a buyer to complete and submit an application six months prior to the acquisition closing. We are also aware of contractors that regularly deny applications that are submitted more than 30 days prior to the closing date of an acquisition.

We also note that, as discussed below, CMS proposes to shorten the time period providers have to submit information in support of an enrollment application. In our view, this creates an inequitable balance of public policy as contractors would be given significant latitude in processing enrollment applications and revalidations but providers would be afforded considerably less time to meet their obligations. In contrast, we believe that consistent with the 30-day timeframe that CMS proposes to impose on providers for submission of supporting information, that contractors be required to adjudicate initial determinations and revalidations

and change-of-information and reassignment of payment requests within 30 days of receipt. We believe that a 30-day timeframe will ensure that enrollment actions are accomplished as quickly as possible for the benefit of all providers and suppliers.

Lastly, CMS needs to clarify whether the 90-day timeframe applies to change-of-information and reassignment of payment requests submitted to fiscal intermediaries and not just carriers. We would assume that it applies to both but, as discussed in Section I above, it is not clear whether Section 405.874 is limited to suppliers or extends to both providers and suppliers.

IX. Time Limit for Submitting Supporting Information – 42 C.F.R. § 424.525(a)(1)

The Proposed Rule would reduce from 60 days to 30 days the time limit for submission of supporting information requested by a contractor. If a provider or supplier submits an incomplete application or fails to include all required supporting documentation within 30 days of receipt, the application would be rejected.

As discussed above, we believe the proposed 30-day time limit is reasonable only if CMS's contractors are required to follow this same timeframe for processing enrollment applications. However, it would be unreasonable to impose this more limited timeframe on providers and suppliers but afford the contractors up to six months to adjudicate an enrollment application or revalidation. Thus, we recommend that CMS adopt a policy addressing both timeframes that is appropriate and equitable for all concerned.

X. Expansion of Revocation Authority - 42 C.F.R. § 424.535(a)(8)

The Proposed Rule would expand the revocation authority by allowing contractors to revoke billing privileges when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary. As explained in the Preamble, CMS believes this is both "appropriate and necessary" because it has found numerous situations where a physician or other practitioner billed for services furnished to beneficiaries that are undeliverable (*e.g.*, the beneficiary was deceased, the beneficiary did not reside in the State or country when the services were furnished, or the beneficiary was in another setting when the services were administered). The Preamble also states that this determination would not constitute a determination of fraud and that providers and suppliers who "expressly flag claims that they believe might be perceived by us as being in this category would not face prosecution under the False Claims Act." (72 *Fed. Reg.* at 9485.) We have several comments on this proposed change.

At the outset, FAH does not believe that this proposed basis for revocation is comparatively consistent with the substantively significant grounds for revocation contained in Section 424.535. This section sets forth bases for revocation which parallel the grounds upon which a provider or supplier is subject to exclusion from the Medicare program as set forth in 42 U.S.C. § 1320a-7, including Medicare or Medicaid exclusion, conviction of specified felonies and submission of false or misleading information. The new revocation standard "for services

that could not have been furnished to a beneficiary" is not comparable to the existing standards for revocation from a severity standpoint and, therefore, we believe it should be eliminated.

If CMS retains this new basis for revocation, it should be better defined because, as proposed, it is too open-ended. For example, it is not clear whether one incident of furnishing services that "could not have been furnished to a beneficiary" would result in revocation or whether there must be a pattern or practice of non-compliance to trigger revocation. There may also be instances where a provider or supplier could not have known that they furnished a service or item to an unqualified beneficiary. For example, pharmacies that service skilled nursing facilities regularly provide medications (and bill for those medications) for residents on a monthly basis. The orders for these monthly fills come from physician notes in the patient records which are reviewed monthly. These medications are generally ordered to continue until the order changes. Therefore, if a patient dies, is discharged or moves to another facility, the pharmacy may not be made aware of this until the following month when the patient's chart is reviewed again. At that point, the pharmacy can reverse the claims for the prior month, but may have already run afoul of the proposed policy and be in line for revocation. Therefore, we recommend that, if CMS adopts this revocation standard, it specify that revocation should only occur for a provider or supplier who shows a pattern of submitting claims for services that could not be rendered and those claims are not subsequently corrected when additional information is received that shows the original billing was incorrect.

If CMS goes forward with this policy, the agency should provide clarity on how a provider or supplier would "flag" a claim that may fall into this revocation category. For example, should a specific billing code or modifier be used? What other ways can the "flagging" occur?

Finally, the discussion regarding liability under the False Claims Act is out of place and misleading. Clearly, CMS does not have legal authority to opine whether a provider or supplier would face prosecution under the False Claims Act for violating this revocation standard. Rather, the enforcement authority rests with the Department of Justice. Therefore, we strongly recommend that CMS remove this discussion from any final rule as not to mislead the provider and supplier community about what enforcement posture the Department of Justice may or may not take.

XI. Reapplication Timeframe – 42 C.F.R. § 424.535(c)

The Proposed Rule would require those providers and suppliers whose billing numbers are revoked to wait three years before they can reapply for billing privileges. This means that a provider or supplier would be prohibited from enrolling in Medicare for three years after revocation of billing privileges. In proposing this timeframe, CMS believes that "revocations are serious matters and must be treated as such to maintain the integrity of the program" and invites public comment on the proposed three-year timeframe. (72 *Fed. Reg.* at 9485.)

The FAH strongly opposes a three-year waiting period before one can reapply for billing privileges. In our view, a three-year waiting period following revocation of a provider's or supplier's billing privileges is punitive and tantamount to a three-year exclusion from Medicare participation. As such, this punitive action is not within CMS's legal authority. As set forth in 42 U.S.C. § 1302a-7, only the Office of Inspector General has been granted legal authority to exclude individuals and entities from Medicare participation. While we appreciate the fraud and abuse concerns associated with unscrupulous providers and suppliers who serially enroll in Medicare, we question CMS's legal authority to impose a three-year ban on the ability to re-enroll following a revocation. The statutory bases for this regulation identified by CMS address normal parameters for program administration, but do not authorize the punitive action that CMS proposes here. We therefore strongly believe that CMS should eliminate the three-year waiting period post revocation of billing privileges.

Notably, section 424.535(c) already establishes procedures for re-enrollment after revocation. Under the existing procedures, a provider or supplier can re-enroll in Medicare following revocation through completion and submission of a new enrollment application and undergoing a resurvey and recertification as a new provider. We believe these procedures, which require a revoked provider or supplier to begin the entire enrollment process anew, are sufficient and should not be modified. Moreover, the Proposed Rule does not provide any reason, let alone a compelling one, for why the agency now believes it is necessary to modify the existing standard that was promulgated just last year as part of the Medicare enrollment final rule. (*See* 71 *Fed. Reg.* 20754 (April 21, 2006)(codified at 42 C.F.R. Part 424, Subpart P.)

XII. Timeframe for Processing Applications - 42 C.F.R. §§ 498.1 and 498.5

The Proposed Rule would make certain changes to 42 C.F.R. §§ 498.1 and 498.5 regarding appeal rights for provider enrollment. In proposing these changes, the Proposed Rule states that "while we are establishing an outside limit for processing these applications, the vast majority of these decisions are made within 120 days." (72 *Fed. Reg.* at 9486.) Comments are requested on this proposed standard.

It is not clear from this statement what the "outside time limit" of 120 days refers to. Any such rule or standard is not included in the proposed regulatory text and so this area needs clarification. For example, it is not clear how CMS will know that the contractors will process the "vast majority" of decisions within 120 days or how it will communicate this standard to the contractors. Also, the Preamble text references an outside time limit for processing "applications" but then refers to "decisions." It is not clear whether application in this context refer to enrollment appeal decisions or submission of enrollment applications. CMS should provide further clarifications regarding this issue.

XIII. Submission of Evidence – 42 C.F.R. §§ 498.56(a)(2), (e) and 498.86(a)

The Proposed Rule would prohibit providers and suppliers from submitting new provider enrollment issues or evidence at higher levels of the appeal process, specifically the ALJ and

DAB levels, except where there is "good cause." The pertinent regulations otherwise allow the ALJ or DAB to consider new issues even if they were not included in the prior proceedings or arose after the hearing request was filed.

We believe that the existing standards in Part 498 should apply equally to provider and supplier enrollment appeals. As explained in the Preamble, it is "presumed" that the contractors made a reasonable determination of an enrollment denial or revocation based on the information it had at the time of the decision. (72 *Fed. Reg.* at 9486.) However, the Proposed Rule does not provide any support for this presumption. In our view, it is dangerous to automatically presume contractors made a reasonable enrollment decision based on the available information. Indeed, the very purpose of appeal procedures is to allow providers and suppliers to demonstrate that the contractor decision was erroneous, whether due to bad faith, neglect, or substantive disagreement. To accomplish this, submission of additional evidence that the contractor did not have available at the time the enrollment decision was made may be appropriate. In our view, the Proposed Rule should follow the existing ALJ and DAB procedures to allow for consideration and for submission of additional evidence related to a provider or supplier enrollment appeal.

Although the Proposed Rule indicates that Section 498.86 is revised to create a good cause exception for submission of new evidence at both the ALJ and DAB appeal levels, the proposed regulatory text at Section 498.86(a) does not reference a good cause exception for DAB appeals. Rather, the text states that the DAB may admit evidence into the record that it considers to be "relevant and material." We recommend that Section 498.86(a) adopt and follow the good cause exception set forth in proposed Section 498.56(e) for ALJ proceedings.

XIV. Request for Remand - 42 C.F.R. § 498.78(a)

The Proposed Rule would allow remand of an ALJ proceeding upon request by CMS. However, the Proposed Rule does not specify the bases upon which CMS could make this request. We believe it would be unreasonable for CMS to have unfettered authority to request remand of an ALJ proceeding and recommend that CMS specify the bases for remand of an ALJ proceeding.

Also, it is not clear whether CMS can request a remand when it is concurrently a party to an ALJ proceeding as permitted in proposed Section 498.5(f)(1). We believe it would be inappropriate for CMS to have the ability to request a remand when it is also a party to an ALJ proceeding. We, therefore, recommend (notwithstanding our earlier comment opposing CMS being a party to the proceeding) that Section 498.78(a) specify that CMS does not have authority to request a remand when it is also a party to an ALJ proceeding.

XV. ALJ and DAB Adjudication Timeframes - 42 C.F.R. §§ 498.79 and 498.88(g)

The Proposed Rule would establish a 180-day timeframe for adjudication of ALJ and DAB decisions, respectively. Consistent with our earlier comments regarding the proposed

timeframes for adjudication of initial enrollment decisions, we believe that 180 days for adjudication of an ALJ or DAB decision is excessive and unnecessary. The Proposed Rule does not provide any justification why an ALJ or DAB proceeding would take up to six months to adjudicate and is not consistent with current practices. We would recommend that CMS adopt a 45-day time period for adjudication of ALJ and DAB decisions. We believe that this timeframe is adequate and reasonable and will ensure that provider and supplier appeals are adjudicated in a timely manner.

* * * * * *

We appreciate the opportunity to comment on the Proposed Rule. If appropriate, we would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions about our comments or need further information, please contact Jeffrey Micklos of my staff at (202) 624-1500.

Sincerely,