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August 13, 2008

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1403-P Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009

OTHER ISSUES-BENEFICIARY SIGNATURE

Ladies and Gentlemen:

We are submitting comments regarding CMS's Proposed Rule regarding changes to the beneficiary signature requirements at 42 CFR §424.36.

We applaud CMS's proposal to expand the "ambulance exception" at 424.36(b)(6) to include non-emergencies. However, the proposed amendment to 424.36(a) that would add an undefined "reasonable efforts" provision is extremely problematic and should not be adopted. Further, though this proposal was embedded in a proposed Physician Fee Schedule rule and presented under a heading that implied it dealt only with non-emergency ambulance services, the proposed "reasonable efforts" provision would affect all health care providers that bill Medicare. Surely, hospitals, physicians, and other healthcare providers were not afforded any sort of fair and reasonable notice that this change would potentially impact them when it was "buried" in this fashion in the Proposed Rule. The proposed regulatory changes also lack clarifying language to direct providers and suppliers on how to fulfill their signature obligations. Moreover, CMS has still not addressed lingering confusion from the previous regulation change.

In our role as advisors to the ambulance service industry, we know firsthand that ambulance providers and suppliers alike are having great difficulty in complying with the existing regulations, and would have even greater difficulty complying with CMS's proposed modifications. In addition, the preamble and commentary on these issues is unclear and inaccurate, and will cause even greater uncertainty among all healthcare providers and suppliers. Also, while CMS has previously stated that its intent was to provide more options and flexibility for ambulance providers and suppliers, that intent has been overshadowed by the selection of very confusing and undefined terms, and has actually compounded the problems that CMS intended to address, and added new and unforeseen burdens that could undermine the delivery of these vital services.

Notably, CMS seems to overlook the fact that ambulance providers and suppliers do not have registration clerks and other support staff who handle these paperwork issues at the time of service, unlike virtually every other type of healthcare provider. In the EMS profession, these burdens fall not to paperwork specialists, but to EMTs, paramedics and other emergency care providers in the field who, frankly and justifiably, find these rules to be impenetrably confusing, inconsistent and wholly burdensome. Most significantly, these burdens interfere with the patient care responsibilities of these EMTs and paramedics who only have a limited period of time with the beneficiary, often under difficult circumstances.

Brief Overview of Our Firm

Page, Wolfberg & Wirth, LLC is a law firm with a practice limited to the representation of ambulance services and emergency medical services (EMS) agencies. We represent nearly 1,000 ambulance services across the United States in the private, nonprofit and public sectors. We also represent many EMS billing companies and other organizations which serve the nation's ambulance industry. Medicare and Medicaid compliance and reimbursement issues constitute the predominant part of our practice. In addition, we conduct the industry's leading ambulance reimbursement and compliance conference, ABC3, the Ambulance Billing, Coding and Compliance Clinic, which is attended by over 1,000 ambulance billing professionals annually. Our founding partners have also been active EMTs, paramedics and ambulance service administrators over the years.

Comments on the Proposed Rule

- 1. The proposed "reasonable efforts" provision should not be added to 42 §CFR 424.36(a) because it is unnecessary.**

The proposed amendment to 42 CFR §424.36(a) states that "[i]n order to utilize one of the provisions of paragraph (b)(1) through (b)(5), the provider [or supplier], must make reasonable efforts to obtain the signature of the beneficiary." The amendment is unnecessary because the regulation already requires that certain conditions must exist before a provider or supplier may utilize one of the exceptions in (b)(1) – (b)(5). Specifically, the rule already clearly articulates that a provider or supplier may only utilize the signature of an authorized signor in paragraph (b) "if the beneficiary is physically or mentally incapable of signing the claim."

Therefore, a provider or supplier is already required to attempt to obtain the signature from the beneficiary in the first instance, and may proceed to obtaining the signature of an authorized representative only when a determination is made that the beneficiary is physically or mentally incapable of signing. The proposed language of §424.36(a) is therefore superfluous.

2. CMS's commentary regarding the meaning of "reasonable efforts" in the proposed rule misinterprets the plain language of the regulation and is inconsistent with its own previous interpretations.

The only place where CMS currently uses the phrase "reasonable efforts" is in subsection (b)(5) of the existing regulation (42 CFR §424.36(b)(5)). This section only applies to situations where a representative of a provider may sign and only in the situation where the patient is unable to sign and none of the other authorized signers are able to sign "after making reasonable efforts to locate and obtain the signature" of one of the other authorized signers. The "reasonable efforts to locate and obtain" requirement in (b)(5) makes some sense here, since this is the only situation where the provider of service for which payment is being made may sign the claim (other than the new (b)(6) exception for emergency ambulance transports) so this added safeguard would be properly placed here.

But in the preamble to this proposed rule, CMS (improperly) appears to interpret this requirement to make "reasonable efforts to locate and obtain" as an affirmative obligation to follow-up with the beneficiary or an authorized signor before even submitting the claim when any of the authorized representatives sign on behalf of the patient. But the regulation itself does not indicate that a provider or supplier has any affirmative obligation to "follow-up" with the patient before submitting a claim as, in the opinion of some industry commentators, the preamble comments vaguely suggest.

More specifically, in describing the history of the Rule in the preamble to this proposed regulation, CMS incorrectly states that "where a beneficiary is unable to sign a claim at the time the service is rendered, ambulance providers and suppliers are required to use reasonable efforts to follow-up with the beneficiary and obtain his or her signature before submitting the claim with a signature from one of the individuals or entities specified in §424.36(b)(1) through (5)." CMS cites to 72 FR 66324 (the November 2007 Final Rule). However, the citation does not, at all, state what CMS alleges it states. There is no reference to "following up" with a beneficiary after a proper alternative signature is obtained when the beneficiary is unable to sign. Instead, that citation (from the November Final Rule) simply discusses an obligation to make reasonable efforts to attempt to obtain a patient signature before a provider signs on behalf of the patient --- and that requirement is contained in §424.36(b)(5) only. The language in the preamble to the November 2007 Final Rule makes no mention of any obligation to follow-up with the beneficiary before utilizing the signature of a representative obtained at the time of service.

Rather the regulation only provides (in §424.36(b)(5)) that a provider may sign on behalf of a patient after it makes reasonable efforts to locate and obtain a signature from an authorized representative - not the signature of the beneficiary. The regulation clearly states that the beneficiary's own signature is required unless the beneficiary has died or the provisions of

paragraph (b), (c), or (d) apply. (42 CFR §424.36(a)). In other words, the beneficiary's own signature is not required if an exception applies; such as the exception allowing for an authorized representative to sign when the beneficiary is incapable of signing. The regulation clearly allows a claim to be submitted where the beneficiary was mentally or physically incapable of signing, and a representative under §424.36(b)(1) through (4) has signed on behalf of the beneficiary.

It would make little sense to enumerate different categories of individuals in §424.36(b)(1)-(5) who are permitted to sign on behalf of the beneficiary --- and then also require the provider or supplier to make some undefined "reasonable effort" to obtain the signature of a beneficiary already determined to be incapable of signing.

Furthermore, CMS's interpretation of the proposed language is wholly inconsistent with its position regarding obligations of ambulance providers and suppliers. As you know, for Medicare coverage purposes, ambulance coverage is always based on the patient's condition at the time of transport and CMS acknowledged this in the (b)(6) exception. "The exception allows ambulance providers and suppliers to sign on behalf of the beneficiary, at the time of transport, provided that certain documentation requirements are met." (73 FR 38580). CMS has also stated that an ambulance provider or supplier may submit the claim *without* making reasonable efforts to have the beneficiary or an authorized signor sign the claim when it relies on the (b)(6) exception. It makes little sense to say that when the ambulance service is unable to obtain the signature of the beneficiary or an authorized signor at the time of transport and signs on behalf of the patient under the (b)(6) exception that it is under no obligation to make reasonable efforts to follow up with the patient, BUT, when an ambulance service does in fact properly obtain the signature of an authorized signor, it must later make "reasonable efforts" to follow up with the patient.

CMS should therefore not adopt the proposed language requiring "reasonable efforts" under paragraph (a). In the alternative, CMS should apply the same position it has always taken with respect to ambulance services and state expressly that "reasonable efforts" under 42 C.F.R. §424.36(a) are "reasonable efforts at the time of transport." CMS should clearly state that there is no obligation to "follow-up" with the beneficiary to attempt to obtain his or her signature prior to submitting the claim for payment, when it has already been determined that the beneficiary is physically or mentally incapable of signing at the time of service, and the ambulance service has obtained the signature of an authorized representative under the existing, well-established signature exceptions of (b)(1) – (b)(4).

3. If CMS adds the "reasonable efforts" language to 424.36(a), it should define the precise meaning of the term in the actual regulation.

The proposed regulation would require a provider or supplier to make "reasonable efforts" to obtain the signature of the beneficiary in order to "utilize" one of the authorized signor provisions. However, CMS does not define the terms "reasonable efforts" or "utilize" in the proposed regulation. Instead, it is only in the preamble that CMS suggests some obligation to "follow" up with the beneficiary prior to submitting a claim after proper reliance on a representative signature. Simply, the terms used in the preamble and the regulation are wholly

inconsistent. CMS should define in the regulation itself – and not rely on the confusing statements it has made in its “commentary” – exactly what “reasonable efforts” entail. Would verification of the patient’s condition at the time of service be sufficient? Would a phone call suffice? A request by mail? By fax? An e-mail? How long must the ambulance service wait for a response before those efforts are deemed to be “reasonable?” If a beneficiary is comatose, or otherwise permanently “unable” to sign for him or herself, what good would a follow-up with that patient serve, other than to add delay and expense to the ability to submit a claim - the precise thing that was trying to be avoided when the revisions to the signature rule first came about.

To now require ambulance service providers and suppliers to chase the patient’s signature for some “reasonable period” after the transport will dramatically increase the administrative costs associated with billing for Medicare patients, at a time when Medicare already pays most ambulance services less than their costs, according to a recent GAO report. Therefore, to the extent that some unnecessary requirement to “follow-up” with a beneficiary must remain as part of the regulation, we ask that CMS define “reasonable efforts” in the regulation, and that it does so in a manner that imposes the least burdensome obligations on the ambulance industry.

Likewise, the reasonable efforts that must be made before one of the authorized signor provisions is “utilized” is unclear. Does the term “utilize” mean to “rely” upon a representative signature for claim submission purposes, or does it mean to simply “utilize” the exception? That is, must the provider or supplier first “assure” that the beneficiary is physically or mentally incapable of signing before availing itself to the exceptions of §424.36(b)(1) through (4)? Or, is CMS stating that even if a representative signature is obtained under §424.36(b)(1) – (b)(4) that efforts must be made to nonetheless “follow-up” and also obtain (or attempt to obtain) the beneficiary’s signature? If the latter, this completely nullifies the “representative” exception, duplicates efforts, and instead of facilitating claim submission (the initial intent of the revisions to the signature rule) it in fact complicates and will delay the process. It would thus make it completely meaningless for ambulance personnel to attempt to obtain qualifying signatures at the time of service, which runs counter to common practice in healthcare.

4. This proposed rule does not provide notice to all Medicare providers and suppliers and should therefore be rescinded and republished in a manner that affords proper notice of all who are affected.

The commentary on the proposed amendment to §424.36(a) appears under the heading “*Beneficiary Signature for Nonemergency Ambulance Transport Services.*” (73 FR 38580). The heading directly implies that the section only applies not only to ambulance services, but only those that provide non-emergency ambulance transport services. Additionally, the commentary fails to mention the potential impact upon all Medicare providers and suppliers and confines the discussion solely to the ambulance industry.

The signature requirements under 42 CFR §424.36 apply to all Medicare providers and suppliers. Only subsection (b)(6) is specifically applicable to ambulance providers and suppliers. The requirement that reasonable efforts be made under 42 §CFR 424.36(a) certainly imposes an

additional obligation under the regulation for all Medicare providers and suppliers alike. Because neither the heading nor the subsequent commentary gives notice to all Medicare providers and suppliers other than ambulance services, it does not afford proper notice to all affected parties. Therefore, in order to afford all interested parties a fair opportunity to comment on the proposed rule, CMS should rescind and republish the proposed rule in a manner sufficient to afford proper notice to all affected providers, such that appropriate comments may be solicited.

5. CMS should eliminate the distinction between “emergency and non-emergency ambulance transport services” in §424.36(b)(6) to simply read “ambulance services.”

With respect to the proposed change to §424.36(b)(6), instead of adding the word “non-emergency” to §424.36(b)(6), CMS should simply eliminate the term “emergency” from the subsection. CMS’s intent is to allow (b)(6) to apply to all ambulance services, so it would be clearer to delete all qualifications and limitations. (We further note that the terms “emergency ambulance transport services” and “non-emergency ambulance transport services” are vague terms nowhere defined in regulations). Therefore, the language in 424.36(b)(6) would simply read “An ambulance provider or supplier if the following conditions and documentation requirements are met.” This change has the effect of including “non-emergency” transports to the existing exception that exists for “emergency” transports, but also includes certain transports that have neither the designation of “emergency” or “non-emergency” (e.g. SCT and ALS2).

6. CMS should amend §424.36(b)(6)(ii)(C)(2)(i)-(iv) to allow for additional forms of secondary verification to be utilized specific to the non-emergency context.

Because CMS proposes to extend the (b)(6) exception to all types of ambulance transports (by now including non-emergency transports), we ask that the list of forms of secondary verification be amended to reflect those forms of verification commonly utilized in the non-emergency context. Four out the five current forms of secondary verification contain the word “hospital.” However, in the non-emergency context, often the destination will not be to a hospital, but could be to similar “institutional” facilities, such as a skilled nursing facility. Instead of trying to list certain forms of “secondary verification” under §424.36(b)(6) that would be applicable and appropriate to various non-hospital destinations, we would simply request that CMS amend this subsection to replace the word “hospital” with “facility or other permissible destination” This phraseology would permit secondary forms of documentation from any approved destination since the §424.36(b)(6) will be expanded to apply to non-emergency situations as well. This minor adjustment would best enable secondary forms of verification from these “non-emergency” destinations to be available for use (if needed) under §424.36(b)(6), without having to try to develop an exhaustive list of specific secondary forms of verification that could be used to satisfy this exception.

Conclusion

We respectfully request that CMS review the original intent behind the changes initially made to §424.36 and compare it to the overreaching effect these latest proposed changes will have. CMS should not implement the “reasonable efforts” language proposed in the final rule under §424.36(a) for the above-stated reasons. If CMS does implement the proposed rule as written, CMS should at least clarify the phrase “reasonable efforts” in a manner that is both consistent with the plain language of the regulation and does not create an additional and undue burden on ambulance providers and suppliers, recognizing the unique environment in which ambulance services are provided and in which registration clerks are not present. Additionally, we trust that CMS wishes to provide fair notice of these proposed signature rule changes to *all* healthcare providers and suppliers, and will accordingly withdraw and republish a Proposed Rule that is not “buried” under a misleading heading in an exceedingly long Proposed Rule on the Physician Fee Schedule.

Thank you for considering our comments on the Proposed Rule.

Very truly yours,

Stephen R. Wirth

Douglas M. Wolfberg

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