From-HOGAN & HARTSON 18 May-29-02 12:55

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IMPORTANT NOTICE

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TO:	John Morrall OIRA. OMB		DATE:	5/28/2002
FROM:	Darrel J. Grinstead		TIME:	7:16 PM
TOTAL NO. OF PAGES, INCLUDING COVER:		7		
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MESSAGE:

Regulatory Reform Nominations of the American Ambulance Association (ALSO SENT BY E-MAIL)

FOR INTERNAL PURPOSES ONLY

TELECOPY/FAX NUMBER: 202-395-6974

> 67908-0004 CLIENT NUMBER:

ATTORNEY BILLING NUMBER: 0198

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May 28,2002

Via E-Mail and Facsimile

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 Seventeenth Street NW
Washington, D. C. 20503

Re: Nominations for Regulatory Reform—Regulations Affecting Ambulance Services Provided to Medicare Beneficiaries

This letter, submitted by the American Ambulance Association, responds to the Office of Management and Budget invitation for nominations of potential regulatory reforms that would advance the Administration's objective of reducing or eliminating unnecessary and burdensome regulations.

The American Ambulance Association represents for-profit, not-for-profit and public ambulance services that provide emergency and non-emergency medical transportation services to over 95% of the U.S. urban population. Many of our members provide critical 9-1-1 and emergency services, and as such, are an important part of our nation's health care safety net. The AAA was formed in 1979 to respond to the need for improvements in ambulance and emergency medical services. Today, the Association serves as a primary voice and clearinghouse for ambulance suppliers nationwide.

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Approximately 50 percent of our members' ambulance transports axe of Medicare beneficiaries. Thus, Medicare payment and regulatory policies significantly affect the cost and efficiency of our member's operations. Some of those regulatory policies are extraordinarily burdensome and do not warrant the costs that they upon Medicare ambulance suppliers, many of whom are small businesses or voluntary organizations. For that reason, we welcome your invitation to share our concerns about federal regulations and we urge that the following items be included within your review.

Suggested Regulatory Reform Improvements

1. Regulation: Physician Certification Statement for Non-Emergency Ambulance Services.

Regulatory Agency: Department of Health and Human Services, Center for Medicare and Medicaid Services ("CMS").

Citation: 42 C.F.R.410.40(d)(3)

Authority: There is no specific statutory authority or requirement for this regulation. See 42 U.S.C. 1395x(s))7

Description of the Problem:

CMS revised the ambulance regulations in 1999 to require ambulance suppliers to obtain a physician certification statement for most non-emergency trips. The regulations made obtaining this documentation within **48 hours** of the transport a pre-condition to the coverage of the service, even though **CMS** does not accept the certification as a determinant of medical necessity. Ambulance suppliers have found the expense and **delays** in payment that result from this requirement to be overly burdensome.

CMS recognized that it is impossible in many cases for suppliers to obtain the certificate **prior** to or within 48 hours of the transport (or even to obtain it at all). To deal **with** that fact, CMS developed an elaborate set of requirements for suppliers to be able to demonstrate that they had made a good faith attempt to obtain the certificate within the required time frame. Those requirements, which are laid out in detail in the now-final rule, involve such things as a hierarchy of practitioners authorized to **sign** the document, waivers of **the 48-hour requirement**, and resort to certified-returned receipt US. **mail** or **similar** delivery systems to document attempts to obtain **the** document. With all **this**, the regulation goes **on** to state that it will not accept the document as proof of the medical necessity of **any** transport.

CMS' paperwork burden analysis in the proposed and final regulation enormously understated the time and costs that would be required to comply with this regulation. Rather than CMS' estimate of only 5000 certifications being required on an annual basis, the regulation in fact requires the certification for almost all nonemergency transports, of which there are approximately 4,500,000 per year (according to CMS' own figures). Given that the document is not accepted by the agency itself as establishing medical necessity, we see no benefit that would justify Medicare requiring suppliers to obtain the certification.

Proposed Solution.

Given the enormous administrative burden and expense that this requirement imposes on ambulance suppliers and the limited relevance of the document as an indication of medical necessity, it is clear that the physician certification statement is an unnecessary paperwork requirement. For that reason, a physician certification statement should not be required for non-emergency Medicare ambulance services. Therefore, we believe 42 CFR 410.40(d)(3) should be removed from the Medicare regulations. (At this time we are not suggesting the removal of the requirement in 42 CFR 410.40(d)(2) for advance physician certification of the medical necessity of repetitive, scheduled ambulance trips.)

Estimate of Economic Impacts:

CMS' paperwork burden analysis of this requirement vastly understated the actual costs that **this** requirement would impose on suppliers. There are approximately **4.5** million non-emergency transports per year. It is reasonable to assume that approximately one hour in staff time will be required to obtain the certification (or document the inability to obtain it). This estimate includes the time to locate and contact the responsible physician or other professional, to mail the request for completion of the form, follow up where necessary and record the form when received. Assuming an hourly rate of \$12.00 for the clerical staff involved and assuming SO percent of nonemergency trips will require a PCS, this requirement would impose an annual cost of almost \$43 million on ambulance suppliers. Regular postage charges would add another \$1.2 million. Assuming the alternate certified mail option is required in 10 percent of the cases, this will cost another \$1.2 million (\$3.40 x 360,000 cases). (Thisanalysis does not include the burden imposed on physicians and other professionals who must be tracked down to provide this statement.) The \$45.4 million annual paperwork cost imposed on ambulance suppliers by this regulation exceeds any benefit the program would derive from the requirements. Given the administrative burden and expense that this requirement imposes on ambulance suppliers, and the limited use of the document as an indication of medical necessity, the physician certification statement is a prime example of an unnecessary and unwise federal paperwork requirement.

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2. Regulation: Waiver of Deductibles and Copayments for Ambulance Services Provided by Public Entities.

Regulating Agency: Department of Health and Human Services, CMS.

Citation: Medicare Carrier Manual section 2309.4 and Medicare Intermediary Manual section 3153.3A)

Authority: None

Description of **Problem**: Creating an Even **Playing** Field Between Public and Private Ambulance Operations

The HHS Office of Inspector General has issued a series of advisory opinions, based on a CMS manual provision, which conclude that while public ambulance suppliers may waive beneficiary deductible and co-payment amounts, private suppliers are required to collect those amounts from beneficiaries. See, OIG Advisory Opinions 01-10. 01-11, and 01-12. The result is that, where private ambulance companies must compete with public suppliers (such as fire services), the public services have a distinct competitive advantage because they are able to advertise and provide services at no cost to beneficiaries, while private operations must collect the 20 percent co-payment or risk prosecution for offering illegal kickbacks to beneficiaries.

Proposed Solution:

We believe the anti-kickback provisions of the law should be applied equally to public and private suppliers. This can easily be accomplished by deleting a provision in both the Medicare Carrier and Intermediary Manuals (CMS Carrier Manual section 2309.4 and CMS Intermediary Manual section 3153.3A) which permit waivers of co-payments only by public suppliers, or by revising those provisions to permit waivers by any suppliers. Otherwise, private ambulance services will be unable to compete fairly in areas where such waivers are offered by public entities.

Estimate of Economic Impact:

No overall monetary impact, but the change would permit public and private ambulance services to compete equally on the basis of price and quality of services.

3. Regulation: Medicare Signature on File Requirement for Ambulance Services.

Regulating Agency: Department of Health and Human Services, CMS

Citation: Medicare Carrier Manual Section 3057(A)(3)

Authority: None

Description of Problem:

Medicare currently requires that the signature of the beneficiary be obtained in order to authorize the release of the ambulance company's medical records to Medicare and other third party payers. Frequently, because of the very nature of our business, we are unable to obtain the signature at the time the service is rendered. If the signature cannot be obtained, due to the patient being physically or mentally unable to sign, Section 3057(A)(3) of the Carrier Manual permits the supplier to obtain the signature from the legal representative, relative, friend or representative of an institution giving care. If no one else can sign on the beneficiary's behalf, the ambulance supplier can sign the document and must then indicate the reason why the beneficiary or one of these other representatives was unable to sign. Often, the patient cannot sign due to the emergency situation which results in the ambulance service itself'. Even in non-emergent situations, patients are often not physically or mentally capable to sign the required form.

To complicate this issue further, suppliers find themselves in a difficult situation when answering the required question related to signature on file when submitting an electronic form. The question they must answer either "yes" ox "no" on every submitted claim simply asks if the patient's signature is on file. Although the other options of authorized signature sources listed above satisfy the current signature requirement, if the provider answers truthfully when someone other than the patient signs their form, they must answer "no" to the question as it is currently phrased. Once they answer "no" to this question, the claim is removed from the automated adjudication process to require additional development before it can be paid or denied. This creates an unnecessary delay and associated increased costs on both the carrier/intermediary and supplier/provider to continue the processing of their submitted claim.

Proposed Solution:

We recommend either of the following two resolutions to this issue:

A. Allow suppliers to submit electronic claims stating that the signature on file requirement has been met when a signature has been obtained from

the patient OR any of the allowed patient representatives, including when the ambulance personnel documents the reason why the patient was unable to sign. This would allow claims to be processed correctly during their initial submission without having unnecessary appeal work involved during adjudication.

B. When a patient applies for Medicare benefits, they should be asked to sign a form that authorizes the release of their medical records to CMS for any services provided to that beneficiary by any physician, supplier or provider. This would resolve many of the current concerns about the upcoming HIPAA regulation for the entire healthcare industry as well; not just the ambulance industry's current problems related to the issue as described above.

Estimate of Economic Impacts:

We expect significant administrative savings for ambulance suppliers and Medicare carriers/intermediaries who **must** currently provide unnecessary additional documentation and process manual information in connection with ambulance claims.

Thank you for allowing us to submit our concerns to you for your consideration. We would be happy to provide you with whatever additional information you may require regarding any of the issues discussed above, or any other questions that may arise about ambulance industry concerns. Please contact us if we can be of any assistance,

Sincerely,

Darrel J. Grinstead
Counsel To the American Ambulance Association

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