

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services**

42 CFR Parts 409, 410, 411, 413, 414, 415, 418, 423, 424, 482, 484, 485, and 491

[CMS–1385–P]

RIN 0938–AO65

Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

DATES: To be assured consideration, except for comments on section II.M.10 of the preamble, comments must be received at one of the addresses provided below, no later than 5 p.m. on Friday, August 31, 2007.

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ADDRESSES: In commenting, please refer to file code CMS–1385–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link “Submit electronic comments on CMS regulations with an open comment period.” (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Attention: CMS–1385–P,
P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services,
Attention: CMS-1385-P, Mail Stop C4-26-05,
7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201;

or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.



N. Beneficiary Signature for Ambulance Transport Services

[If you choose to comment on issues in this section, please include the caption “BENEFICIARY SIGNATURE” at the beginning of your comments.]

Section 424.36 requires that a beneficiary’s signature must appear on all claims submitted for Medicare services, unless the beneficiary has died, or another exception applies. For example, if a beneficiary is physically or mentally incapable of signing the claim, the claim may be signed on the beneficiary’s behalf by another individual listed in § 424.36(b). Ambulance suppliers and providers have stated that, in emergency situations, it is impossible or impractical for ambulance providers or suppliers to obtain a beneficiary’s or other authorized person’s signature on a claim to properly bill Medicare for ambulance transport services because:

(1) Many beneficiaries are incapable of signing claims due to their medical condition at the time of transport; and

(2) another person authorized to sign the claim under § 424.36(b) is not available, or is unwilling to sign the claim at the time of transport; and

(3) if an individual listed in § 424.36(b) is not available or willing to sign a claim on behalf of the beneficiary at the time of transport, it is impractical later to locate the beneficiary (or the beneficiary's authorized representative) to obtain a signature on the claim form before submitting it to Medicare for payment.

We are sympathetic to the concerns of ambulance providers and suppliers insofar as emergency transport services are involved. Therefore, at § 424.36, we are proposing that, for emergency ambulance transport services, where the ambulance provider or supplier documents that the beneficiary was physically or mentally incapable of signing a claim form at the time the service was provided and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign a claim on behalf of the beneficiary, the ambulance provider or supplier may submit the claim without a beneficiary signature. Such claim submission would be permitted only if: (1) The beneficiary was physically or mentally incapable of signing the claim form at the time the service was provided; (2) none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; and (3) the ambulance provider or supplier maintains in its files for a period of at least 4 years from the date of service certain documentation. Required documentation would include:

(1) A signed contemporaneous statement, made by an ambulance employee present during the trip to the receiving facility, that the beneficiary was physically or mentally incapable of signing a claim form and that none of the individuals listed in § 424.36(b)(1) through (5) was available or willing to sign the claim form on behalf of the beneficiary at the time the service was provided; (2) the date and time the beneficiary was transported, and the name and location of the facility where the beneficiary was received; and (3) a signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the time and date that the beneficiary was received by that facility.

For non-emergency ambulance transport services, the ambulance provider or supplier would continue to be required to obtain a beneficiary's signature on a claim form (or the signature of someone who is authorized to sign on behalf of the beneficiary under § 424.36(b)(1) through (5) prior to submitting claims to Medicare.

III. Fee Schedule for Payment of Ambulance Services Update for CY 2007; Ambulance Inflation Factor Update for CY 2008; and Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

[If you choose to comment on issues in this section, please include the caption "AMBULANCE SERVICES" at the beginning of your comments.]

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated.

Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

For Ground—

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)
- Advanced Life Support, Level 2 (ALS2)
- Specialty Care Transport (SCT)
- Paramedic ALS Intercept (PI)

For Air—

- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW)

A. History of Medicare Ambulance Services

1. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to

specific conditions and limitations as specified in § 410.40. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

3. Transition to National Fee Schedule

The national fee schedule for ambulance services was phased in over a 5-year transitional period beginning April 1, 2002, as specified in § 414.615. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers is based on 100 percent of the national ambulance fee schedule. In accordance with section 414 of the MMA, we added § 414.617 which specifies that for ambulance services furnished during the period July 1, 2004, through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate through CY 2009. Thus, as of January 1, 2007, the total payment amount for ground ambulance providers and suppliers is based on either 100 percent of the national ambulance fee schedule amount, or a combination of 80 percent of the national ambulance fee schedule and 20 percent of the regional ambulance fee schedule.

B. Ambulance Inflation Factor (AIF) During the Transition Period

As we noted in the previous section, the national fee schedule for ambulance services was phased in over a 5-year transition period beginning April 1, 2002, as specified in § 414.615. During the transition period, the ambulance inflation factor (AIF) was applied separately to both the fee schedule portion of the blended payment amount (regardless of whether a national or regional fee schedule applied) and to the supplier's reasonable charge or provider's reasonable cost portion of the blended payment amount, respectively, for each ambulance provider or supplier. Then, the two amounts were added together to determine the total payment amount for each provider or supplier.

C. Ambulance Inflation Factor (AIF) for CY 2008

Section 1834(l)(3)(B) of the Act provides the basis for updating payment amounts for ambulance services. Section 414.610(f) specifies that certain components of the ambulance fee schedule are updated by the AIF annually, based on the consumer price index for all urban consumers (CPI-U) (U.S. city average) for the 12-month period ending with June of the previous year. At this time, the CPI-U for the 12-month period ending with June 2007 is not available. We will announce the AIF for CY 2008 in the final rule which will be published in the **Federal Register** later this year. In addition, as

set forth in Section III.D., we propose to announce the AIF for CY 2009 and subsequent years via CMS instruction and on the CMS Web site.

D. Proposed Revisions to the Publication of the Ambulance Fee Schedule (§ 414.620)

Currently, section 414.620 specifies that changes in payment rates resulting from incorporation of the AIF will be announced by notice in the **Federal Register** without opportunity for prior comment. We believe it is unnecessary to undertake notice and comment rulemaking to update the AIF because the statute and regulations specify the methods of computation of annual inflation updates, and we have no discretion in that matter. Thus, the annual AIF notice does not change or establish policy, but merely applies the update methods specified in the statute and regulations.

By mid-July of each year, we have the CPI-U for the 12-month period ending with June of such year. Therefore, we know what the AIF for the upcoming calendar year will be by mid-July of each year. However, the AIF is not published by CMS until November because § 414.620 currently states that the AIF will be announced in the **Federal Register**. Each document published in the **Federal Register** requires scheduling and a thorough review by CMS, HHS, and OMB prior to publication. Therefore, even though we know the AIF by mid-July of each year, the final rule announcing the AIF is not published until November. This publication timeframe does not allow Medicare contractors the optimal amount of time to update their systems so that they can effectuate the proper payment on Medicare ambulance claims timely. In addition, it does not provide an optimal amount of time for either the Medicare contractors or the ambulance industry to take advantage of testing practices to make sure that the update is working properly as implemented.

We believe that announcing the AIF via CMS instructions and on the CMS Web site would enable the AIF to be released earlier in the calendar year, allowing the Medicare contractors to test their data systems, and to timely effectuate and provide accurate payments on Medicare ambulance claims.

Therefore, we are proposing to revise § 414.620 to state that we will announce the AIF via CMS instruction and on the CMS Web site and to remove the language that states that we will announce the AIF by notice in the **Federal Register**.

IV. Collection of Information Requirements

Section 424.36 Signature Requirements

Section 424.36(a) requires the beneficiary's signature on a claim for payment of services unless the beneficiary has died or the provisions of § 424.36(b), (c), or (d) apply. Section 424.36(b) states that if the beneficiary is physically or mentally incapable of signing the claim, the claim may be signed by one of the persons specified in § 424.36(b)(1) through

(5). Proposed § 424.36(b)(6) states that, for emergency ambulance transport services, if certain conditions and documentation requirements are met, an ambulance provider or supplier would be permitted to sign the claim on behalf of the beneficiary. Specifically, § 424.36(b)(6)(ii)(A) through (C) lists the documentation that would be required, all of which would have to be maintained by the ambulance provider or supplier in its files for a period of at least 4 years from the date of service. An ambulance provider or supplier would be required to obtain a signed, contemporaneous statement from an ambulance employee present during transport of the patient that, at the time the service was provided, the beneficiary was physically or mentally incapable of signing the claim and that none of the other qualified persons listed in § 424.36(b)(1) through (5) were available or willing to sign the claim on behalf of the beneficiary.

The ambulance provider or supplier would also be required to maintain documentation of the date and time that the beneficiary was transported and the name and location of the facility that received the beneficiary. In addition, the ambulance provider or supplier would be required to obtain and maintain a signed contemporaneous statement from a representative of the facility that received the beneficiary. The statement would have to contain the name of the beneficiary and the date and time the beneficiary was received at the facility.

The burden associated with the recordkeeping requirements contained in § 424.36(b)(6) is the time and effort associated with drafting, obtaining, and maintaining written statements from both employees of the ambulance provider or supplier transporting the beneficiary and employees of the facility receiving the beneficiary. We estimate that approximately 9,000 ambulance providers or suppliers will comply with these requirements. We estimate that it will take no more than 5 minutes for each provider or supplier to comply with the recordkeeping requirements.

Based on the best available data at this time, we estimate the total annual burden associated with the requirements in § 424.36(b)(6) to be 541,667 hours nationwide. The annual total number of burden hours was arrived at by multiplying 5 minutes by the total estimated number of emergency ambulance transports of 6,500,000. We note that the total number of burden hours may be overstated, because not every beneficiary who receives emergency ambulance transport services is unable to sign the claim. However, we also note that the 6.5 million figure for emergency transports is the estimated number of ALS1-emergency and BLS-emergency ambulance claims processed by Part B carriers, incurred in 2006 and processed through April 2007, and thus, does not include the number of emergency ambulance transport services billed to fiscal intermediaries by ambulance providers (this number is not available to us). In any event, we believe our proposal will benefit ambulance providers and suppliers by allowing them an alternative procedure for submitting claims to Medicare. In the absence of the proposed procedure for signing claims on behalf of beneficiaries for emergency ambulance transport services, ambulance suppliers and providers would be required to track down beneficiaries after the emergency transport services have been rendered, in an attempt to have the beneficiary sign the claim. Moreover, such attempts may prove fruitless, thereby preventing the ambulance suppliers and providers from submitting the claim to Medicare.

Subpart H—Fee Schedule for Ambulance Services

§ 414.620 [Amended]

32. In § 414.620, the phrase “notice in the **Federal Register** without opportunity for prior comment” is removed and the phrase “CMS by instruction and on the CMS Web site” is added in its place.

Subpart C—Claims for Payment

50. Section 424.36 is amended by adding paragraph (b)(6) to read as follows:

§ 424.36 Signature requirements.

* * * * *

(b) * * *

(6) An ambulance provider or supplier with respect to emergency ambulance transport services, if the following conditions and documentation requirements are met.

(i) None of the individuals listed in paragraphs (b)(1) through (b)(5) of this section was available or willing to sign the claim on behalf of the beneficiary at the time the service was provided;

(ii) The ambulance provider or supplier maintains in its files the following information and documentation for a period of at least 4 years from the date of service:

(A) A contemporaneous statement, signed by an ambulance employee present during the trip to the receiving facility, that at the time the service was provided the beneficiary was physically or mentally incapable of signing the claim and that none of the individuals listed in paragraphs (b)(1) through (5) of this section were available or willing to sign the claim on behalf of the beneficiary.

(B) Documentation with the date and time the beneficiary was transported, and the name and location of the facility that received the beneficiary.

(C) A signed contemporaneous statement from a representative of the facility that received the beneficiary, which documents the name of the beneficiary and the date and time the beneficiary was received by that facility.

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§ 424.37 [Amended]

51. Section 424.37(a) is amended by removing the reference to “§ 424.36(b)” and adding in its place the reference “§ 424.36(b)(1) through (5).”