



# Federal Register

---

**Wednesday,  
November 19, 2008**

**Book 2 of 2 Books  
Pages 69725–70238**

---

## **Part II**

### **Department of Health and Human Services**

---

**Centers for Medicare & Medicaid Services**

---

**42 CFR Parts 405, 409, et al.  
Medicare Program; Payment Policies  
Under the Physician Fee Schedule and  
Other Revisions to Part B for CY 2009;  
E-Prescribing Exemption for Computer-  
Generated Facsimile Transmissions; and  
Payment for Certain Durable Medical  
Equipment, Prosthetics, Orthotics, and  
Supplies (DMEPOS); Final Rule**

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

**42 CFR Parts 405, 409, 410, 411, 413, 414, 415, 423, 424, 485, 486, and 489**

**[CMS-1403-FC] [CMS-1270-F2]**

**RINs 0938-AP18, 0938-AN14**

**Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**

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

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule with comment period implements changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It also finalizes the calendar year (CY) 2008 interim relative value units (RVUs) and issues interim RVUs for new and revised codes for CY 2009. In addition, as required by the statute, it announces that the physician fee schedule update is 1.1 percent for CY 2009, the preliminary estimate for the sustainable growth rate for CY 2009 is 7.4 percent, and the conversion factor (CF) for CY 2009 is \$36.0666. This final rule with comment period also implements or discusses certain provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). (See the Table of Contents for a listing of the specific issues addressed in this rule.)

**DATES:** *Effective Date:* This final rule with comment period is effective on January 1, 2009 except for amendments to § 410.62 and § 411.351 which are effective July 1, 2009.

*Comment Date:* Comments will be considered if we receive them at one of the addresses provided below, no later than 5 p.m. e.s.t. on December 29, 2008.

**ADDRESSES:** In commenting, please refer to file code CMS-1403-FC. 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 this regulation

to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1403-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1403-FC, 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 either of the following addresses:  
7500 Security Boulevard, Baltimore, MD 21244-1850; or

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

(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.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:**

Pam West, (410) 786-2302, for issues related to practice expense.

Rick Ensor, (410) 786-5617, for issues related to practice expense methodology.

Stephanie Monroe, (410) 786-6864, for issues related to malpractice RVUs.

Esther Markowitz, (410) 786-4595, for issues related to telehealth services.

Craig Dobyski, (410) 786-4584, for issues related to geographic practice cost indices.

Ken Marsalek, (410) 786-4502, for issues related to the multiple procedure payment reduction for diagnostic imaging.

Catherine Jansto, (410) 786-7762, or Cheryl Gilbreath, (410) 786-5919, for issues related to payment for covered outpatient drugs and biologicals.

Edmund Kasaitis, (410) 786-0477, or Bonny Dahm, (410) 786-4006, for issues related to the Competitive Acquisition Program (CAP) for Part B drugs.

Corinne Axelrod, (410) 786-5620, for issues related to Health Professional Shortage Area Bonus Payments.

Henry Richter, (410) 786-4562, for issues related to payments for end-stage renal disease facilities.

Lisa Grabert, (410) 786-6827, for issues related to hospital-acquired conditions and the Physician Resource Use Feedback Program.

August Nemec, (410) 786-0612, for issues related to independent diagnostic testing facilities; enrollment issues; and the revision to the "Appeals of CMS or CMS contractor Determinations When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing Privileges" final rule.

Lisa Ohrin, (410) 786-4565, Kristin Bohl, (410) 786-8680, or Don Romano, (410) 786-1401, for issues related to anti-markup provisions and physician self-referral (incentive payment and shared savings programs).

Diane Stern, (410) 786-1133, for issues related to the quality reporting system for physician payment for CY 2009.

Andrew Morgan, (410) 786-2543, for issues related to the e-prescribing exemption for computer-generated fax transmissions.

Terri Harris, (410) 786-6830, for issues related to payment for comprehensive outpatient rehabilitation facilities (CORFs).

Lauren Oviatt, (410) 786-4683, for issues related to CORF conditions of coverage.

Trisha Brooks, (410) 786-4561, for issues related to personnel standards for portable x-ray suppliers.

David Walczak, (410) 786-4475, for issues related to beneficiary signature for nonemergency ambulance transport services.

Jean Stiller, (410) 786-0708, for issues related to the prohibition concerning providers of sleep tests

Mark Horney, (410) 786-4554, for issues related to the solicitation for comments and data pertaining to physician organ retrieval services.

Regina Walker-Wren, (410) 786-9160, for information concerning educational

the under- or uninsured simply because the nonprofit entity cannot use an affiliated DME supplier to furnish a CPAP device prescribed after the HST. We note that health care entities can continue to provide CPAP when prescribed as a result of an attended facility-based PSG.

*Comment:* One commenter points to guidance issued in mid 2002, where CMS recognized a separation between a hospital system and its ownership of a DME business (otherwise referred to as a Hospital-based supplier). By enacting this provision, the commenter concludes that CMS would no longer recognize this separation. The commenter concludes that this provision, if enacted, would result in other prohibitions for follow-up care following a diagnostic test.

*Response:* We disagree with the commenter's conclusion, and we note that the final rule's exemption of attended facility-based PSG would likely apply to many hospital affiliated sleep programs.

*Comment:* Several commenters stated that there is a clear conflict of interest for the provider of the test to also profit from the provision of the CPAP therapy.

*Response:* We appreciate the supportive comments.

*Comment:* Several commenters wrote that physicians who work for hospitals are under increasing pressure to generate revenue by conducting more tests and prescribing CPAP through a hospital owned DME supplier. Other commenters claim that bonus payments are made to physician's who prescribe CPAP through a hospital owned DME supplier. These commenters favor the payment prohibition.

*Response:* We appreciate the overall concerns expressed by the commenters about pressure on physicians, but we wish to minimize the disruption to programs that were in place prior to the March 2008 NCD expansion of coverage. We believe that an exemption for attended facility-based PSG is a reasonable balance between beneficiary access and protection at this time.

*Comment:* Several commenters support a payment prohibition where the diagnostic test facilities are not permitted to provide the CPAP and related supplies. According to the commenters, the DMEPOS suppliers claim to possess a higher degree of sophistication surrounding CPAP technologies and related supplies by focusing exclusively on the technologies rather than on the sleep diagnostics.

*Response:* We appreciate the supportive comment on the proposed regulation. However we have been persuaded for reasons described above

to except attended facility-based PSG from the payment prohibition for CPAP.

*Comment:* Several commenters stated that hospital-owned DME qualifies as a monopoly, and results in an unfair competitive advantage for hospitals and large sleep centers. The commenters favor the payment prohibition and state that such a prohibition is good for small businesses.

*Response:* Business monopoly is beyond the scope of this regulation and we will not discuss it here.

*Comment:* Several commenters stated that the term "affiliate" is ambiguous, and that the proposed rule is vague and overly broad in its use of the terms "affiliate" and "directly or indirectly". The commenters requested that CMS provide a clear definition of "affiliate". The commenters stated that without clear definitions from CMS it is impossible to discern what types of affiliations CMS intends to preclude under the rule or how the proposed rule would apply to any given set of circumstances. One commenter recommended that a definition of affiliate be common ownership of greater than 50 percent of the supplier of the CPAP device.

*Response:* We define "affiliate" as a person or organization that is related to another person or organization through a compensation arrangement or some type of ownership.

We have defined a provider of sleep test as an individual or entity that directly or indirectly administers and/or interprets the test and/or furnishes the sleep test device. By indirect we mean that one or more intermediary actors are used to accomplish the sleep test to its end. For example, if a DME supplier contracted with a sleep test provider to furnish HST, that supplier would indirectly provide the HST. Directly providing the test means there are no intermediary actors—no intervening persons or entities between them.

*Comment:* One commenter requested that sleep labs be permitted to develop criteria to gauge the competency of the DME. Further, the commenter requested that sleep labs be permitted to use such criteria to discriminate against DME companies who fail to perform at an acceptable level of competency.

*Response:* We believe that this concern can be addressed through the development and implementation of accreditation standards. Ideally, we would like to require that all entities furnishing sleep tests in any settings in addition to supplying CPAP be accredited. Once we are made aware of appropriate accrediting models, we will readdress the issue in future rulemaking.

Based on section 1871(a)(1) of the Act, which provides the Secretary with the authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title," and section 1834(j)(1)(B)(ii)(IV), which requires suppliers of equipment and supplies to "meet such other requirements as the Secretary may specify," and due to our concerns with respect to the potential for unnecessary utilization of sleep tests, we shall prohibit payment to the supplier of the CPAP device when such supplier or its affiliate is directly or indirectly the provider of the HST that is used to diagnose a Medicare beneficiary with OSA.

We considered several options. We considered whether a narrower prohibition could reasonably accomplish the purposes of this regulation at this time. Exceptions for providers that offer integrated sleep management programs were considered. We also considered allowing an exception for nationally accredited disease management programs but we are unaware of any current model that would encompass accreditation for both OSA diagnosis and CPAP supply under a single accreditation certificate.

After reviewing the public comments, we are finalizing the prohibition in § 424.57 as proposed but with an exception for attended facility-based PSG. Excepting facility-based PSG from the prohibition on providing CPAP would not except HST performed by the same entity, that is, the exception is at the test level not the facility level. We plan to solicit public input on accreditation models that might support future exceptions to this prohibition. We add additional definitions for "affiliate", "attended facility-based polysomnogram," and clarify the definitions of "Continuous positive airway pressure (CPAP)" and "Sleep test".

### 3. Beneficiary Signature for Nonemergency Ambulance Transport Services

In the CY 2008 PFS final rule with comment period (72 FR 66406), we created an additional exception to the beneficiary signature requirements, applicable for emergency ambulance transports, in § 424.36(b)(6). The exception allows ambulance providers and suppliers to sign on behalf of the beneficiary, at the time of transport (that is, the time during which the beneficiary is picked up and dropped off at the receiving facility), provided that certain documentation requirements are met. To take advantage of the exception at § 424.36(b)(6), an

ambulance provider or supplier must maintain in its files: (1) A contemporaneous statement, signed by an ambulance employee who is present during the trip, that the beneficiary was mentally or physically incapable of signing (and that no other authorized person was available and or willing to sign); (2) documentation as to the date, time and place of transport; and (3) either a signed contemporaneous statement from the receiving facility that documents the name of the beneficiary and the date and time the beneficiary was received by that facility, or a secondary form of verification from the facility that is received at a later date.

In the CY 2008 PFS final rule with comment period (72 FR 66324), we clarified that, apart from the new exception in § 424.36(b)(6), 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 (b)(5). We further clarified that only providers of services, and not ambulance suppliers, can take advantage of § 424.36(b)(5), which states that a representative of the provider or of the nonparticipating hospital may sign on behalf of the beneficiary if the provider or nonparticipating hospital was unable to have a claim signed in accordance with § 424.36(b)(1) through (b)(4) (72 FR 66322).

Subsequent to publication of the CY 2008 PFS final rule with comment period, ambulance provider and supplier stakeholders requested that we extend the exception in § 424.36(b)(6) to nonemergency ambulance transports in instances where the beneficiary is physically or mentally incapable of signing. These stakeholders stated that there are many nonemergency transports for which a beneficiary is physically or mentally incapable of signing a claim form. For example, stakeholders asserted that beneficiaries residing in long term care facilities often need to be transported for nonemergency medical treatment, yet may be incapable of signing the claim due to physical or mental ailments, such as Alzheimer's disease or other forms of dementia. In these instances, there may be no other individual who is immediately available and authorized to sign the claim as specified in § 424.36(b).

Because we do not anticipate an increased risk of fraud or program abuse if the exception in § 424.36(b)(6) is

extended to include nonemergency transports, we proposed to revise § 424.36(b)(6) to refer specifically to nonemergency transports. We also proposed to add language to § 424.36(a) to clarify that, apart from the use of the exception in § 424.36(b)(6), providers and suppliers must make reasonable efforts to obtain the beneficiary's signature before relying on one of the exceptions in § 424.36(b). We note that § 424.36(b)(5) specifies that a provider may not invoke the exception to sign a claim on behalf of a beneficiary unless it is unable to have one of the persons specified in § 424.36(b)(1) through (b)(4) sign the claim. Finally, given that most claims are submitted electronically, we proposed to amend § 424.36(a) to define "claim" for purposes of the beneficiary signature requirements as the claim form itself or a form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

We received comments that urged us to eliminate entirely the beneficiary signature requirement where a beneficiary is mentally or physically incapable of signing a claim and no other person authorized to sign a claim on behalf of the beneficiary is available or willing to sign at the time of transport. In addition, the commenters stated that the proposed documentation requirements would be costly and burdensome to ambulance providers and suppliers. Several commenters objected to our proposal to amend § 424.36(a) to clarify that, apart from the use of the exception in § 424.36(b)(6), providers and suppliers must make reasonable efforts to obtain the beneficiary's signature before relying upon one of the exceptions in 424.36(b).

We are adopting our proposals, with modification. Specifically, we are amending the exception in § 424.36(b)(6) to include nonemergency ambulance transports. We are also amending § 424.36(a) to define "claim" for purposes of the beneficiary signature requirements, as the claim form itself, or a form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary. We are revising § 424.36(b)(6)(ii)(C)(2) to include secondary forms of verification from either a hospital or a facility.

The following is a summary of the comments we received and our responses.

*Comment:* The majority of commenters stated that it is a burden on ambulance providers and suppliers to obtain a signature for nonemergency ambulance transports when a beneficiary is mentally incapable of signing the "waiver." The commenters contended that asking for additional documentation to verify that a patient was transported creates a financial burden on the ambulance provider. One commenter stated that its billing office has to do more mailings, follow-up calls and faxes to get a "waiver" completed, and that spouses are reluctant to sign the form for fear that they will be responsible for the ambulance transport bill. The commenter also stated that the forms are confusing to its ambulance crew and that hospital and rehabilitation representatives are reluctant to sign forms. One commenter suggested that checking hospital and rehabilitation bills would be an easier way to document a patient transport, whereas another commenter suggested that we should abolish the signature requirement entirely.

*Response:* We note that whereas several commenters referred to a "waiver" of the signature requirement of § 424.36, in fact § 424.36 sets forth a signature requirement and alternative means of satisfying the signature requirement. That is, § 424.36 generally requires that the beneficiary sign the claim, unless the beneficiary is deceased or unavailable to sign the claim, in which case other individuals or entity representatives (as enumerated in § 424.36(b), (c) and (d)) may sign the claim. We are adopting our proposal to amend § 424.36(a) to clarify that "the claim" includes the actual claim form or such other form that contains adequate notice to the beneficiary or other authorized individual signing on behalf of the beneficiary that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary. The purpose of the beneficiary signature is to verify that the services were in fact rendered and were rendered as billed.

Our proposal does not impose any new burdens on ambulance providers or suppliers, but rather offers an optional, alternative method, for satisfying the beneficiary signature requirement. We do not agree with the commenters that it is a significant burden on ambulance providers and suppliers to comply with the proposed signature and documentation requirements in order to meet the proposed exception for nonemergency ambulance transports when a beneficiary is incapable of signing a claim form; however, those

ambulance providers and suppliers that believe that the signature and documentation requirements of the new exception at § 424.36(b)(6) are burdensome may avail themselves of the other means specified in § 424.36 for satisfying the beneficiary signature requirement.

In response to the assertion that the forms are confusing, we reiterate that we did not create any new forms for ambulance personnel or facility staff to sign. Ambulance providers or suppliers may use whatever forms they wish (such as the patient care trip report, etc.) for capturing the signature and documentation requirements specified in § 424.36(b)(6). In response to the assertion that spouses are reluctant to sign a form for fear that they will be responsible for the ambulance transport bill, signing of the claim form (or such other form used as a proxy for the claim form) does not make a person financially liable to pay the provider or supplier. However, if a beneficiary or the beneficiary's authorized representative refuses to sign the claim form, the ambulance company may bill the beneficiary directly for the transport service. In addition, if the transport service is deemed not medically necessary, and thus is not covered by Medicare, the beneficiary may be held responsible for payment (subject to the limitation of liability provisions of section 1879 of the Act and our regulations at §§ 411.404).

We are not persuaded to adopt the suggestion that we eliminate entirely the beneficiary signature requirement for ambulance transports. We are concerned that there may be an increased risk of fraud or program abuse if we were to remove the signature requirement. Moreover, we did not propose to eliminate the signature requirement and therefore may lack the authority to abolish the requirement through this final rule even if we were otherwise inclined to do so. With respect to the suggestion that we should check hospital and rehabilitation bills to document a patient transport (which is tantamount to suggesting that we eliminate the signature requirement), we do not agree that it should be the program's responsibility, at the time of processing the claim, to guess whether the beneficiary would have authorized the claim if asked, or to have to secure documentation from providers and suppliers (which, to the extent that they have not furnished the transport, may not be required to supply us with such documentation and may even be precluded by privacy laws from supplying us with such documentation). Accordingly, we believe providers and

suppliers should go on record, at the time of submitting the claim, that the beneficiary (or someone authorized on his behalf) authorized the filing of the claim.

*Comment:* Several commenters noted that, in light of our proposal to expand the (b)(6) exception to include nonemergency ambulance transports as well as emergency ambulance transports, the signature requirements may apply when a beneficiary is being transported from or to skilled nursing facilities, hospitals and other permissible destinations. Therefore, the commenters requested that we revise § 424.36(b)(6)(ii)(C)(2), which makes reference to "the hospital registration/admission sheet", "the hospital log", or "other internal hospital records," and replace "hospital" with "facility."

*Response:* We agree with the commenter that there may be nonemergency transports where the beneficiary is being transported from or to skilled nursing facilities, hospitals and other permissible destinations. Thus, we are revising § 424.36(b)(6)(ii)(C)(2) to replace "hospital" with "hospital or other facility".

*Comment:* One commenter requested that we clarify whether secondary forms of verification must be signed by a representative of the receiving facility. In response to a similar request for clarification in the CY 2008 PFS final rule (72 FR 66323) we stated that secondary forms of verification did require a signature; however, this requirement was not included in the text of § 424.36(b)(6)(ii)(C)(2), as finalized in the CY 2008 PFS final rule. The commenter also stated that hospitals are moving toward electronic recordkeeping, and urged us to clarify that secondary forms of documentation used to verify transport do not need to be signed by a representative of the facility, provided that the form of documentation obtained is an official facility record that clearly indicates the name of the patient, and the date and time the patient was received by or transported from that facility.

*Response:* We acknowledge that, although the preamble language in the CY 2008 PFS final rule stated that all forms of secondary documentation used to verify transport need to be signed by a representative of the receiving facility, the regulation text at § 424.36(b)(6), as published in the 2008 CY PFS final rule, did not include this specific requirement. We are clarifying § 424.36(b)(6)(ii)(C)(2) to provide that secondary forms of documentation used to verify transport do not need to be signed by a representative of the

receiving facility if the form of documentation obtained is an official hospital or facility record, (such as the facility or hospital registration/admissions sheet, patient medical record, facility or hospital log, or other facility or hospital record), and it documents the beneficiary's name, date, and time the beneficiary was received by that facility.

*Comment:* Several commenters objected to our proposal to clarify § 424.36(a) to state that a provider or supplier must make "reasonable efforts to locate and obtain the beneficiary's signature" before a provider or supplier could rely upon one of the exceptions set forth in § 424.36(b)(1) through (5).

*Response:* We are not adopting our proposal because, having reexamined the issue, we believe that the current language in § 424.36(b)(5) provides adequate protection for the beneficiary and the Medicare program. Prior to, and during the course of, the CY 2008 PFS rulemaking, we were alerted to the fact that some ambulance providers and suppliers were signing the claim on behalf of the beneficiary simply because the beneficiary was not able to sign the claim at the time of transport. We clarified in the preamble to the CY 2008 PFS final rule with comment period that signing the claim on behalf of the beneficiary simply because the beneficiary was not able to sign the claim at the time of transport was not proper and, further, that only providers (and not suppliers) are eligible to use the exception at § 424.36(b)(5). Our decision to make an exception to the requirement that reasonable efforts must be made to obtain the signature of the beneficiary, by creating a new exception at § 424.36(b)(6) in the CY 2008 PFS final rule with comment period for emergency ambulance transports, and in this final rule for nonemergency ambulance transports, and to allow the provider or supplier to sign the claim on behalf of the beneficiary at the time of the service, provided certain safeguards are met, was a deliberate departure from the general rule. However, because we amended § 424.36(b)(5) in the CY 2008 PFS final rule with comment period to state that, before relying on that exception, providers must "mak[e] reasonable efforts to locate and obtain the signature of one of the individuals specified in paragraph (b)(1), (2), (3) or (4) of this section," rather than to state that the provider must first make reasonable efforts to locate and obtain the signature of the beneficiary, we are concerned that we might create confusion or add an unneeded degree of complexity if we were to finalize our proposal to amend § 424.36(a) to state

that a provider or supplier must make reasonable efforts to locate and obtain the *beneficiary's* signature before a provider or supplier could rely upon one of the exceptions set forth in § 424.36(b)(1) through (5). By requiring providers and suppliers to not sign claims on behalf of the beneficiary under § 424.36(b)(5) without having first made reasonable efforts to procure the signature of the beneficiary or an authorized individual, we address our core concerns. It is true that, as clarified, our regulations allow providers and suppliers to procure the signature of an authorized individual in a situation where the beneficiary may be only temporarily unable to sign the claim, but, on balance, we believe it is preferable, for the sake of convenience, to give providers and suppliers some flexibility as to whether they obtain the signature of the beneficiary or that of an authorized individual. With respect to *ambulance* providers and suppliers, the matter of making reasonable efforts to locate and obtain the signature of the beneficiary or another authorized individual should largely be moot. Ambulance providers and suppliers should be able to rely on the exception at § 424.36(b)(6) to sign the claim in the case of both emergency and non-emergency transports, provided they meet the documentation requirements therein. To the extent that ambulance providers and suppliers do not wish to, or are unable to, comply with the documentation requirements of § 424.36(b)(6), they may obtain the signature of an authorized individual specified at § 424.36(b)(1) through (b)(4) (including in the situation where one of the authorized individuals is available and willing to sign at the time of transport). Moreover, an ambulance provider (but not a supplier), may rely on the exception at § 424.36(b)(5) to, itself, sign the claim, after having made reasonable efforts (including over a reasonable period of time) to locate and obtain the signature of either the beneficiary or an authorized individual.

*Comment:* Several commenters requested that we make the new exception in § 424.36(b)(6) for non-emergency transports retroactive to January 1, 2008. Commenters also asked us to clarify in this final rule and/or in guidance on the CMS Web site that we will not take any adverse action against an ambulance provider or supplier that made good faith (but unsuccessful) attempts to comply with the beneficiary signature requirement rules prior to January 1, 2009. The commenters stated that, despite multiple attempts to obtain the required signatures from the

beneficiary or the beneficiary's authorized representative, many ambulance providers and suppliers have been unsuccessful, and thus, they are holding claims for non-emergency transports. The commenters also asserted that ambulance providers and suppliers have experienced difficulty in obtaining signatures from facility representatives because of concerns that their signature would render the facility financially liable for the transport.

*Response:* We are not making the new exception in § 424.36(b)(6) for non-emergency ambulance transports retroactive to January 1, 2008, and are not making an exception for good faith efforts to comply with the regulation as it existed prior to this final rule with comment period. There would be significant legal issues if we were to make the rule retroactive to January 1, 2008 or to waive the requirements as they existed prior to this final rule. Moreover, apart from the legal constraints, we are not persuaded that either course of action is warranted. The CY 2008 PFS final rule did not create any new burden for ambulance providers and suppliers (and, to the contrary, made it easier for ambulance providers and suppliers to comply with the beneficiary signature requirement for emergency transports). It did, however, clarify our longstanding policy that providers and suppliers must make reasonable efforts to obtain the beneficiary's signature before submitting the claim and that it was not sufficient for *providers* to submit the claim (utilizing the exception at § 424.36(b)(5)) simply because the beneficiary was able to sign the claim at the time of transport. We also clarified that only providers, and not suppliers, may utilize the exception at § 424.36(b)(5), consistent with the plain language of the exception. To the extent that, following the November 27, 2007 final rule, ambulance providers and suppliers have found it difficult to obtain the beneficiary's signature for non-emergency transports (because they had not previously been following our rules), we have addressed their concerns in two ways. First, on July 24, 2008, we placed guidance on the CMS Web site at [http://www.cms.hhs.gov/AmbulanceFeeSchedule/downloads/Guidance\\_On\\_Beneficiary\\_Signature\\_Requirements\\_for\\_Ambulance\\_Claims.pdf](http://www.cms.hhs.gov/AmbulanceFeeSchedule/downloads/Guidance_On_Beneficiary_Signature_Requirements_for_Ambulance_Claims.pdf) that reiterated our position that ambulance providers and suppliers may utilize the exception at § 424.36(b)(4), which allows facilities to sign on behalf of the beneficiary, and explained that such facilities do not assume liability for payment of the

services simply by signing on behalf of the beneficiary. Second, in this final rule we are finalizing our proposal to expand the exception in § 424.36(b)(6) to non-emergency transports. The new exception is effective for "claims" filed on or after January 1, 2009. Therefore, if claims have been held and are still within the timely filing limit, as specified in § 424.44, the claims may be submitted to Medicare for payment in accordance with the new exception.

*Comment:* A commenter recommended that the existing language in § 424.36(b)(6)(ii)(A) be modified to state that, in the case of an emergency transport, the general crew signature on an emergency ambulance incident report is sufficient to meet the requirements of § 424.36(b) and that a separate crew signature is not required. The commenter suggested, as an alternative, that if we determine that the signature of an ambulance employee present during the transport is necessary, it should be sufficient if the employee signature on the incident report is obtained "after the fact," rather than contemporaneous with the transport. The commenter stated that it is necessary that we allow signatures obtained after the transport because the ambulance crew's primary concern is taking care of the patient, not doing paperwork, such as a signed incident report.

*Response:* We are not persuaded to modify the requirement in § 424.36(b)(6)(ii)(A) to state that the general crew signature on an incident report is sufficient and that a separate crew signature is not required. We believe that the commenter's suggestion that any member of the general crew be permitted to sign the incident report as evidence that the service was rendered as billed would not satisfy our integrity concerns, because the general crew member would have no direct knowledge regarding the transport services. It is also our understanding that the ambulance crew completes a trip report that describes the condition of the beneficiary, treatment, origin/destination, etc. Therefore, we believe it would be a minimal burden upon the ambulance crew signing the incident or trip report to prepare a statement detailing why the beneficiary is unable to sign a claim form at the time of transport. We also emphasize that § 424.36(b)(6)(ii)(A) requires that a contemporaneous statement signed by an ambulance employee present during the trip be obtained. A contemporaneous statement, rather than one obtained after the fact, is necessary to meet our integrity concerns, that is,

to verify that the trip took place as claimed on the bill.

*Comment:* Several commenters suggested that we eliminate the terms “emergency and nonemergency ambulance transport services” in § 424.36(b)(6) and replace those words with “ambulance services.”

*Response:* We are not persuaded to revise § 424.36(b)(6) in the manner suggested by the commenters. Although readers familiar with the **Federal Register** publications of the CY 2008 PFS final rule and the CY 2009 PFS final rule would realize that “ambulance services” would refer to both emergency and nonemergency transports, we wish the regulation text that will appear in the CFR to be clear on its own, particularly to readers who may be accessing the regulation years from now. Therefore, we believe it is preferable to retain the proposed language “emergency and nonemergency ambulance transport services” so as to leave no doubt that both emergency and nonemergency transports are covered by the exception in § 424.36(b)(6).

#### 4. Solicitation of Comments and Data Pertaining to Physician Organ Retrieval Services

Since 1987, we have limited the amount an Organ Procurement Organization (OPO) may reimburse a physician for cadaveric kidney donor retrieval services. Chapter 27 of the Provider Reimbursement Manual (CMS-Pub. 15-1) limits the payment to a physician for cadaveric kidney retrieval to \$1,250 per donor (one or two kidneys). Although the payments made to physicians for organ retrieval services associated with other types of organ transplants have increased, kidney retrieval rates have remained at \$1,250. We have received several requests to change the amount we pay for kidney retrievals. To date, we do not have data upon which to base a change in payment.

In order to determine fair and reasonable payment for cadaveric organ retrieval services, we solicited public comments and data that are reflective of organ retrieval service costs. We did not limit our solicitation to costs associated with kidney retrieval services, but rather stated that we are interested in receiving comments and data pertaining to retrieval services for all types of organs. We indicated that we may use this information to determine the extent to which a recalculation of the payment for cadaveric organ retrieval services furnished by a physician is warranted and to inform any future rulemaking on this subject. Any future rulemaking

would provide for notice and public comment.

We received four timely public comments in response to our request for information and data for use in updating the organ retrieval physician payment amount included in organ acquisition costs. The following is a summary of the comments we received and our responses.

*Comment:* The commenters believed that the kidney retrieval rate of \$1,250 per donor is insufficient and three of the commenters recommended that we increase that limit by either the Consumer Price Index for all urban consumers (CPI-U) or the Medicare Economic Index. Two commenters stated that little or no data on actual organ retrieval services exists, and that any rulemaking without such data would be inappropriate. The commenters stated that due to the extreme variability associated with these services, they had serious concerns as to the feasibility of establishing an accurate cost or payment for organ retrieval using an approach like that employed by the AMA’s Relative Value Scale Update Committee (RUC). According to the commenters, there are specific factors impacting the cost of organ retrieval including donor evaluation, travel and wait time, dry runs and other risks and costs. These factors contribute to the great variability in measuring the time and expense associated with organ retrieval services. These commenters offered to assist us in establishing a process to collect data for the purpose of updating the organ retrieval rates. One commenter stated that the retrieval rate should be paid per kidney and not per donor.

*Response:* We thank the commenters who responded to our solicitation of comments and appreciate the offer that some made to be involved in future efforts to design a revised payment method. We are not inclined to propose that the base organ retrieval rate for kidneys and other organs simply be increased by an indexed amount (such as the CPI-U) because we believe the base payment amounts for retrieval of the various organs may need to be updated. Therefore, we are again soliciting information from the transplant community. Specifically we would like to obtain information on the physician effort and resources required to procure an organ. These resources include surgical time, dry runs (number and percentage of retrievals in which an organ is not recovered), travel and wait times, as well as the incremental time required for extended criteria donors and donors after cardiac death. Additionally, because currently we limit

kidney retrieval physician reimbursement to \$1,250 per donor, we would need resource information to determine the difference in procuring one kidney or a pair of kidneys from a single donor in order to determine a payment on a per kidney basis as suggested by a commenter.

#### 5. Revision to the “Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails To Meet the Requirements for Medicare Billing Privileges” Final Rule

In the June 27, 2008 **Federal Register**, we published the “Appeals of CMS or CMS contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges” final rule. In § 405.874(b)(2), we stated, “The revocation of a provider’s or supplier’s billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier. A revocation based on Federal exclusion or debarment is effective with the date of the exclusion or debarment.”

During the 30 days after CMS or our contractor mails a revocation notice to a provider or supplier, the provider or supplier is afforded the opportunity to submit a corrective action plan. A corrective action plan gives a provider or supplier an opportunity to provide evidence that demonstrates that the provider or supplier is in compliance with Medicare requirements. Moreover, a provider or supplier can use a corrective action plan to correct the deficiency without filing an appeal under 42 CFR part 498, and remain in the Medicare program when the provider demonstrates that the provider or supplier is in compliance with Medicare requirements and the Medicare contractor accepts the corrective action plan. In those situations where a provider or supplier submits an acceptable corrective action plan, the provider or supplier maintains their billing privileges and the revocation determination is not implemented.

We maintain that providers or suppliers are able to provide sufficient evidence through a corrective action plan that demonstrates that they are in compliance with Medicare requirements when CMS or our contractor imposes a revocation based on certain types of adverse actions such as a Federal exclusion or debarment. Accordingly, consistent with revoking billing privileges with the date of exclusion or debarment, we believe that similarly situated revocations such as felony convictions and license suspension or revocation do not lend themselves to a

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) \* \* \*

(2) Calculation of the average sales price. (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) \* \* \*

(3) Widely available market price and average manufacturer price. If the

Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in CYs 2005, 2006, 2007, 2008 and 2009, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) \* \* \*

(1) \* \* \*

(i) Treatment of Certain Drugs.

Beginning with April 1, 2008, the payment amount for—

(A) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(1) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(2) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(B) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(1) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(2) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

\* \* \* \* \*

**PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS**

■ 32. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart C—Part B Carrier Payments for Physician Services to Beneficiaries in Providers**

**§ 415.130 [Amended]**

■ 33. In § 415.130(d), the phrase "December 31, 2007" is removed and the phrase "December 31, 2009" is added in its place.

**PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

■ 34. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 35. Section 423.160 is amended by revising paragraph (a)(3)(i) to read as follows:

**§ 423.160 Standards for electronic prescribing.**

(a) \* \* \*

(3) \* \* \*

(i) Until January 1, 2012, entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. After January 1, 2012, entities transmitting prescriptions or prescription-related information must utilize the NCPSP SCRIPT standard in all instances other than temporary/transient network transmission failures.

\* \* \* \* \*

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

■ 36. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart C—Claims for Payment**

■ 37. Section 424.36 is amended by revising paragraphs (a), (b)(6) introductory text, and (b)(6)(ii)(C)(2) to read as follows:

**§ 424.36 Signature requirements.**

(a) General rule. The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraphs (b), (c), or (d) of this section apply. For purposes of this section, "the claim" includes the actual claim form or such other form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

(b) \* \* \*

(6) An ambulance provider or supplier with respect to emergency or nonemergency ambulance transport



services, if the following conditions and documentation requirements are met.

- \* \* \* \* \*
- (ii) \* \* \*
- (C) \* \* \*

(2) The requested information from a representative of the hospital or facility using a secondary form of verification obtained at a later date, but prior to submitting the claim to Medicare for payment. Secondary forms of verification include a copy of any of the following:

- (i) The signed patient care/trip report;
- (ii) The facility or hospital registration/admission sheet;
- (iii) The patient medical record;
- (iv) The facility or hospital log; or
- (v) Other internal facility or hospital records.

\* \* \* \* \*

■ 38. Section 424.44 is amended by—

- A. Revising the introductory text of paragraph (a).
- B. Adding paragraph (e).

The revision and addition read as follows:

**§ 424.44 Time limits for filing claims.**

(a) *Basic Limits.* Except as provided in paragraph (b) and (e) of this section, the claim must be delivered to the intermediary or carrier as appropriate:

\* \* \* \* \*

(e) *Exceptions.* Any claims filed by the following suppliers with Medicare billing privileges whose time limits for filing claims are linked to their enrollment status and are governed under § 424.516, § 424.520, and § 424.521 of this subpart:

- (1) Physician or nonphysician organizations.
- (2) Physicians.
- (3) Nonphysician practitioners.
- (4) Independent diagnostic testing facilities.

**Subpart D—To Whom Payment Is Ordinarily Made**

■ 39. Section 424.57 is amended by—

- A. Amending paragraph (a) by adding the definitions of “Affiliate”, “Attended facility-based polysomnogram”, “Continuous positive airway pressure (CPAP)” device, and “Sleep test” in alphabetical order.

- B. Adding new paragraph (f).  
The additions read as follows:

**§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.**

(a) \* \* \*

*Affiliate* means a person or organization that is related to another person or organization through a

compensation arrangement or ownership.

*Attended facility-based polysomnogram* means a comprehensive diagnostic sleep test including at least electroencephalography, electro-oculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.

\* \* \* \* \*

*Continuous positive airway pressure (CPAP) device* means a machine that introduces air into the breathing passages at pressures high enough to overcome obstructions in the airway in order to improve airflow. The airway pressure delivered into the upper airway is continuous during both inspiration and expiration.

\* \* \* \* \*

*Sleep test* means an attended or unattended diagnostic test for a sleep disorder whether performed in or out of a sleep laboratory. The ‘provider of the sleep test’ is the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test.

\* \* \* \* \*

(f) *Payment prohibition.* No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.

**Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges**

■ 40. Section 424.502 is amended by adding the definitions “Final adverse action” and “Physician or nonphysician practitioner organization” in alphabetical order to read as follows:

**§ 424.502 Definitions.**

\* \* \* \* \*

*Final adverse action* means one or more of the following actions:

- (1) A Medicare-imposed revocation of any Medicare billing privileges;
- (2) Suspension or revocation of a license to provide health care by any State licensing authority;
- (3) Revocation or suspension by an accreditation organization;
- (4) A conviction of a Federal or State felony offense (as defined in

§ 424.535(a)(3)(i) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or

(5) An exclusion or debarment from participation in a Federal or State health care program.

\* \* \* \* \*

*Physician or nonphysician practitioner organization* means any physician or nonphysician practitioner entity that enrolls in the Medicare program as a sole proprietorship or organizational entity.

\* \* \* \* \*

■ 41. Section 424.516 is added to read as follows:

**§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.**

(a) *Certifying compliance.* CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, all of the following requirements:

(1) Compliance with title XVIII of the Act and applicable Medicare regulations.

(2) Compliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

(3) Not employing or contracting with individuals or entities that meet either of the following conditions:

(i) Excluded from participation in any Federal health care programs, for the provision of items and services covered under the programs, in violation of section 1128A(a)(6) of the Act.

(ii) Debarred by the General Services Administration (GSA) from any other Executive Branch procurement or nonprocurement programs or activities, in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76.

(b) *Reporting requirements Independent Diagnostic Testing Facilities (IDTFs).* IDTF reporting requirements are specified in § 410.33(g)(2) of this chapter.

(c) *Reporting requirements DMEPOS suppliers.* DMEPOS reporting requirements are specified in § 424.57(c)(2).

(d) *Reporting requirements for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* Physicians, nonphysician practitioners, and