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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 2011;
Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424

[CMS-1503-P]

RIN 0938-AP79

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

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

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses proposed 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 addresses, implements or discusses certain provisions of both the Affordable Care Act and the Medicare Improvements for Patients and Providers Act of 2008. In addition, this proposed rule discusses payments under the Ambulance Fee Schedule, Clinical Laboratory Fee Schedule, payments to ESRD facilities, and payments for Part B drugs. Finally, the proposed rule includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for Durable Medical Equipment and Provider and Supplier Enrollment Issues associated with Air Ambulances. (See the Table of Contents for a listing of the specific issues addressed in this proposed rule.)

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 24, 2010.

ADDRESSES: In commenting, please refer to file code CMS-1503-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions for "submitting a comment."

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-1503-P, 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-1503-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 before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

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

FOR FURTHER INFORMATION CONTACT:

Rebecca Cole, (410) 786-4497, for issues related to physician payment and for all other issues not identified below.

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

Rochel Kujawa, (410) 786-9111, for issues related to ambulance services.

Glenn McGuirk, (410) 786-5723, for clinical laboratory issues.

Randall Ricktor, (410) 786-4632, for Federally Qualified Health Center Issues.

Pauline Lapin, (410) 786-6883, for issues related to the chiropractic services demonstration BN issue.

Troy Barsky, (410)786-8873, or Kristin Bohl, (410)786-8680, for issues related to physician self-referral.

Troy Barsky, (410)786-8873, or Fred Grabau (410)786-0206, for issues related to timely filing rules.

Henry Richter, (410)786-4562, or Lisa Hubbard, (410)786-5472, for issues related to renal dialysis provisions and payments for end-stage renal disease facilities.

Diane Stern, (410)786-1133, for issues related to the physician quality reporting initiative and incentives for e-prescribing.

Sheila Roman, 410-786-6004, or Pamela Cheetham, 410-786-2259, for issues related to the Physician Resource Use Feedback Program and value-based purchasing.

Joel Kaiser, (410)786-4499, for issues related to the DME provisions.

Jim Bossenmeyer, (410)786-9317, for issues related to provider and supplier enrollment issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the *Code of Federal Regulations* (CFR). Information on the regulation's impact appears throughout the preamble, and therefore, is not discussed exclusively in section V. of this proposed rule.

I. Background

A. Development of the Relative Value System

provisions of the ACA related to the GPCIs are discussed in detail in section II.D. of this proposed rule.

D. Section 3103: Extension of Exceptions Process for Medicare Therapy Caps

Section 1833(g)(5) of the Act (as amended by section 3103 of the ACA) extends the exceptions process for therapy caps through December 31, 2010. Therapy caps are discussed in detail in section III.A. of this proposed rule.

E. Section 3104: Extension of Payment for Technical Component of Certain Physician Pathology Services

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), as amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), section 104 of division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), and section 136 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) is amended by section 3104 of the ACA to continue payment to independent laboratories for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital through CY 2010. The technical component (TC) of physician pathology services refers to the preparation of the slide involving tissue or cells that a pathologist interprets. The professional component (PC) of physician pathology services refers to the pathologist's interpretation of the slide.

When the hospital pathologist furnishes the PC service for a hospital patient, the PC service is separately billable by the pathologist. When an independent laboratory's pathologist furnishes the PC service, the PC service is usually billed with the TC service as a combined service.

Historically, any independent laboratory could bill the Medicare contractor under the PFS for the TC of physician pathology services for hospital patients even though the payment for the costs of furnishing the pathology service (but not its interpretation) was already included in the bundled inpatient stay payment to the hospital. In the CY 2000 PFS final rule with comment period (64 FR 59408 through 59409), we stated that this policy has contributed to the Medicare

program paying twice for the TC service: (1) To the hospital, through the inpatient prospective payment rate, when the patient is an inpatient; and (2) to the independent laboratory that bills the Medicare contractor, instead of the hospital, for the TC service. While the policy also permits the independent laboratory to bill for the TC of physician pathology services for hospital outpatients, in this case, there generally would not be duplicate payment because we would expect the hospital to not also bill for the pathology service, which would be paid separately to the hospital only if the hospital were to specifically bill for it. We further indicated that we would implement a policy to pay only the hospital for the TC of physician pathology services furnished to its inpatients.

Therefore, in the CY 2000 PFS final rule with comment period, we revised § 415.130(c) to state that for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC furnished to a hospital inpatient. Ordinarily, the provisions in the PFS final rule with comment period are implemented in the following year. However, the change to § 415.130 was delayed 1 year (until January 1, 2001), at the request of the industry, to allow independent laboratories and hospitals sufficient time to negotiate arrangements.

Full implementation of § 415.130 was further delayed by section 542 of the BIPA and section 732 of the MMA, which directed us to continue payment to independent laboratories for the TC of physician pathology services for hospital patients for a 2-year period beginning on January 1, 2001 and for CYs 2005 and 2006, respectively.

In the CY 2007 MPFS final rule with comment period (71 FR 69624 and 69788), we amended § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the TC of physician pathology services furnished to a hospital inpatient or outpatient. However, section 104 of the MIEA–TRHCA continued payment to independent laboratories for the TC of physician pathology services for hospital patients through CY 2007, and section 104 of the MMSEA further extended such payment through the first six months of CY 2008.

Section 136 of the MIPPA extended the payment through CY 2009. Most recently, section 3104 of the ACA amended the prior legislation to extend the payment through CY 2010.

Consistent with this legislative change, we are proposing to revise

§ 415.130(d) to: (1) Amend the effective date of our payment policy to reflect that for services furnished after December 31, 2010, an independent laboratory may not bill the Medicare contractor for the TC of physician pathology services furnished to a hospital inpatient or outpatient; and (2) reformat this subsection into subparagraphs.

F. Sections 3105 and 10311: Extension of Ambulance Add-Ons

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports which originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports which do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the ACA further amend section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. We are revising § 414.610(c)(1)(i) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of these payment add-ons, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. The statute specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, shall continue to be

treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009. Sections 3105(b) and 10311(b) of the ACA amend section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the “rural” indicator on the ZIP Code file for air ambulance services, effective January 1, 2010 through December 31, 2010. We are revising § 414.610(h) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this MIPPA provision, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the MMA added paragraph (12) to section 1834(l) of the Act, which specified that in the case of ground ambulance services furnished on

or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary’s estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a “qualified rural area”; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). Sections 3105(c) and 10311(c) of the ACA amend section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. Therefore, as directed by the ACA, we are

continuing to apply the rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2010 and before January 1, 2011 where transportation originates in a qualified rural area.

We are revising § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. The statute requires a one-year extension of the rural bonus (which was previously established by the Secretary), and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this rural bonus, please see Transmittal 706 (Change Request 6972) dated May 21, 2010.

G. Section 3107: Extension of Physician Fee Schedule Mental Health Add-On

Section 3107 of the ACA amends section 138(a)(1) of the MIPPA to continue the 5 percent increase in Medicare payment for specified mental health services through December 31, 2010. This payment increase was originally authorized under section 138 of the MIPPA from July 1, 2008 until December 31, 2009. Accordingly, payment for the 24 psychiatry CPT codes in Table 33, representing “specified services,” remains increased by 5 percent until December 31, 2010.

TABLE 33—SPECIFIED MENTAL HEALTH SERVICES SUBJECT TO THE FIVE PERCENT INCREASE IN MEDICARE PAYMENT THROUGH DECEMBER 31, 2010

**Office or Other Outpatient Facility
Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy**

- 90804 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient).
- 90805 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services).
- 90806 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient).
- 90807 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services).
- 90808 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient).
- 90809 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services).

Interactive Psychotherapy

- 90810 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient).
- 90811 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services).
- 90812 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient).
- 90813 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services).
- 90814 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient).

update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor). Section 3401(k) of the ACA amends section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that “any annual update under [the ASC payment] system for the year * * * shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)” (which we refer to as the MFP adjustment) effective with the calendar year beginning January 1, 2011. Section 3401(k) of the ACA states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the “percentage increase” in the CPI-U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we propose to hold the CPI-U update factor for the ASC payment system to zero. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the ACA, then requires that the Secretary reduce the CPI-U update factor (which would be held to zero if the CPI-U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the CPI-U percentage increase would result in a MFP-adjusted CPI-U update factor that is less than zero, then the annual update to the ASC payment rates would be negative and payments would decrease relative to the prior year.

Table 35 provides illustrative examples of how the MFP would be applied to the ASC payment system.

These examples show the implication of a positive CPI-U update factor with a smaller MFP, a positive CPI-U update factor with a large MFP, and a CPI-U update factor of 0. We discuss the application of the MFP to the CPI-U update factor for the ASC payment system under the OPPTS/ASC CY 2001 proposed rule (1504-P), which will be published around the same time as this proposed rule. Comments on the specific mathematical calculation of the MFP should be made to this PFS proposed rule. Comments on the application of the MFP to the CPI-U update factor under the ASC payment system should be made to the OPPTS/ASC CY 2011 proposed rule (1504-P).

TABLE 35—MULTIFACTOR PRODUCTIVITY ADJUSTED PAYMENT UPDATE: ILLUSTRATIVE EXAMPLE

CPI-U (percent)	MFP (percent)	MFP-Adjusted CPI-U update factor (percent)
4.0	1.3	2.7
4.0	4.7	-0.7
0.0	0.2	-0.2

b. Ambulance Fee Schedule (AFS)

In accordance with section 1834(l)(3)(B) of the Act, the AFS is required to be increased each year by the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. We refer to this update as the Ambulance Inflation Factor (AIF). Section 3401(j) of the ACA amends section 1834(l)(3) of the Act to add a new subparagraph (C) which states that, for CY 2011 and each subsequent year, after determining the percentage increase under section 1834(l)(3)(B) (that is, the CPI-U percentage increase, or AIF), the Secretary shall reduce such percentage increase by the MFP adjustment described in section

1886(b)(3)(B)(xi)(II) (as discussed above). Section 3401(j) further amends section 1834(l)(3) to state that the application of subparagraph (C) (that is, the reduction of the CPI-U percentage increase by the MFP adjustment) may result in that percentage increase being less than zero for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

In accordance with section 1834(l)(3) of the Act as amended by section 3401(j) of the ACA, before applying the MFP adjustment, the Secretary first determines the “percentage increase” in the CPI-U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we propose to hold the AIF to zero. The statute then requires that the Secretary reduce the CPI-U percentage increase (which would be held to zero if the CPI-U percentage change is negative) by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage increase below zero. If the application of the MFP adjustment to the CPI-U percentage increase would result in an MFP-adjusted AIF that is less than zero, then the annual update to the AFS would be negative and payments would decrease relative to the prior year.

Table 36 provides illustrative examples of how the MFP would be applied to the AFS. Finally, we propose to revise § 414.610(f) to require that the AIF be reduced by the MFP adjustment as required by the statute in determining the annual update under the ambulance fee schedule for CY 2011 and each subsequent year, and to revise § 414.620 to state that changes in payment rates resulting from the incorporation of the AIF and the MFP adjustment will be announced by CMS by instruction and on the CMS Web site, as we discussed above.

TABLE 36—EXAMPLES OF THE APPLICATION OF THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT TO THE AMBULANCE FEE SCHEDULE

A CPI-UA	B AIF	C MFP	D Final update rounded
2.0%	2.0%	1.3%	0.7%
0.0%	0.0%	1.3%	-1.3%
-2.0%	0.0%	1.3%	-1.3%
1.0%	1.0%	1.3%	-0.3%

c. Clinical Laboratory Fee Schedule

Section 1833(h)(2)(A)(i) of the Act, as amended by section 3401(l) of the ACA, requires the Secretary to annually adjust

the CLFS “by a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers

(United States city average minus, for each of the years 2009 through 2010, 0.5 percentage points.” Therefore, the

B. Ambulance Fee Schedule Issue: Policy for Reporting Units When Billing for Ambulance Fractional Mileage

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated and all other applicable medical necessity requirements are met. 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) (emergency and nonemergency).
 - ++ Advanced Life Support, Level 1 (ALS1) (emergency and nonemergency).
 - ++ 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).

1. History of Medicare Ambulance Services

a. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplementary Medical Insurance) 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.

b. 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 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Mileage Reporting

a. Background and Current Process for Reporting Ambulance Mileage

Historically, the Medicare fee-for-service (FFS) claims processing system lacked the capability to accept and process fractional unit amounts reported in any claim format. Therefore, the standard for reporting units for ambulance mileage was to bill in whole number increments. Thus, if the total units of service for ambulance mileage included a fractional amount, providers and suppliers of ambulance services (hereafter referred to collectively as "providers and suppliers") were instructed to round the fraction up to the next whole number. Claims billed with fractional units of service were, at that time, returned as unprocessable as CMS' claims processing systems could not accept nor adjudicate fractional unit amounts properly.

Consequently, in Change Request (CR) 1281 (Transmittal AB-00-88, issued on September 18, 2000), we instituted an operational procedure requiring whole-unit reporting of mileage on ambulance claims. Specifically, we instructed providers and suppliers that "If mileage is billed, the miles must be whole numbers. If a trip has a fraction of a mile, round up to the nearest whole number." Our instructions also stated that "1" should be reported for trips totaling less than a single mile. This was an operational instruction based on Medicare's FFS system limitations and capabilities at the time, as our claims processing systems were not capable of accepting and processing claims submitted with fractional units of service. Since then, our claims processing system functionality has evolved to the point where this rounding process is no longer necessary for most ambulance transports, as it is now possible for our FFS systems to capture and accurately process fractional units on both paper and electronic forms.

Under our current instructions, providers and suppliers continue to report loaded mileage as whole-number units on both paper and electronic claims. Providers and suppliers utilize the appropriate Healthcare Common Procedure Coding System (HCPCS) code for ambulance mileage to report the number of miles traveled during a Medicare-covered trip rounded up to the nearest whole mile at a minimum of 1 unit for the purpose of determining payment for mileage. Transmittal AB-00-88 established a list of HCPCS codes accepted by Medicare for the purpose of billing mileage. Providers and suppliers were instructed to use these specific HCPCS codes and enter the total number of covered miles in the "units" field of the claim form. For example, if a covered trip from the point of pickup (POP) to the Medicare-approved destination (see § 414.40 for a list of approved destinations) totaled 9.1 miles, the provider would enter the appropriate HCPCS code for covered mileage and a "10" in the units field. Providers and suppliers billing for trips totaling, for example, 0.5 covered miles, would enter "1" in the units field along with the appropriate HCPCS code for mileage.

b. Concerns Regarding the Potential for Inaccuracies in Reporting Units and Associated Considerations

Often an ambulance provider will transport a distance that is either not an exact whole number of miles or less than one whole mile during a covered trip. Currently, providers and suppliers billing for ambulance services must round up the total billable mileage to the nearest whole mile for trips that include a fraction of a mile or less than one whole mile. Under our current instructions, a provider or supplier is required to bill as much as .9 of a mile more than what was actually traveled.

We have been contacted by suppliers on several occasions with concerns regarding our current instructions for reporting ambulance mileage. Certain suppliers believe that our instructions require them to bill inaccurately. One company in particular stated that they routinely need to bill for trips totaling less than 1 mile. The beneficiaries that are being transported by this company live in the immediate vicinity of the facility to which they are being transported, and therefore, the number of loaded miles for each trip totals approximately one half of a mile. The company was concerned that since Medicare requires that they enter a "1" in the units field of their claims for mileage, they are being overpaid by

Medicare for mileage based on the service they actually provided.

However, the company's main concern revolved around the risk of creating an appearance of impropriety. Although our instructions clearly state that providers and suppliers should, as a matter of procedure, round up fractional mileage amounts to the nearest whole mile, some providers and suppliers indicated that they wanted to bill as accurately as possible and that they only wanted to be paid for the service they actually provided. We thoroughly considered these concerns while reevaluating the procedure for reporting units for fractional mileage amounts.

Our first priority in considering the issues raised by ambulance providers and suppliers was to ascertain the basis for the current mileage reporting instructions. As previously discussed, the original instructions for reporting fractional mileage were published in Transmittal AB-00-88, issued on September 18, 2000. We instructed providers and suppliers to round fractional mileage amounts "up to the nearest whole mile" and to enter "1" for fractional mileage totaling less than one mile. This particular process had also been in place prior to issuance of the transmittal. The reason for the procedure was that our claims processing systems were not capable of accepting and processing claims submitted with fractional units of service—even if the service was commonly measured in fractional amounts, as with ambulance mileage.

We then explored whether a change in our procedure would be: (a) Appropriate, (b) possible considering our current system capabilities and industry standards of measurement, and (c) applicable to any service other than ambulance mileage. As to the appropriateness of changing the procedure for reporting units of service on provider claims for fractional ambulance mileage, we believe that we should make every effort to create and implement policies and processes that create the best opportunity for accuracy in billing. It is not our intention to put providers and suppliers in a position where they are required to bill inaccurately for the service they provide. We continue to strive toward ensuring that providers and suppliers bill and are paid only for services actually provided. We believe that changing our current procedure for reporting units of service to require reporting of fractional mileage will help to ensure that providers and suppliers can submit claims that more precisely reflect actual mileage, and are

reimbursed more accurately for the services they actually provided. We originally instituted a policy of accepting and processing only whole units because at that time, system limitations prevented us from accepting and processing fractional ambulance mileage.

Second, we considered whether it is currently possible for our claims processing systems to accept and process fractional unit amounts on both paper and electronic claims. Upon reevaluating our system capabilities, we found that technological advancements in Optical Character Recognition (OCR) and electronic claim submission have made it possible for our FFS systems to capture and accurately process fractional units on both paper and electronic claims. We note that our systems currently have the capability to accept fractional units with accuracy up to as much as one thousandth of a unit (that is, to 3 decimal places).

We also considered whether ambulance providers and suppliers have the capability to measure fractional mileage. This was an important point because if providers and suppliers are not able to measure mileage with any more specificity than the nearest whole number mile, then there would be no need to modify the current procedure for billing fractional mileage. In that case, providers and suppliers would continue to report mileage as whole numbers since they could measure no more accurately than that. However, both analog and digital motor vehicle odometers are designed to measure mileage accurately to within a minimum of a tenth of a mile. While we found that some vehicle odometers measure mileage more accurately than a tenth of a mile, most odometers are accurate to the nearest tenth of a mile. Additionally, aircraft geographic positioning system (GPS) technology provides the means to accurately determine billable mileage to the tenth of a mile.

Third, we considered whether a policy of billing fractional units would be applicable to any other service besides ambulance mileage. The units of service field on both the electronic and paper claim is used to report the quantity of services or supplies provided to Medicare beneficiaries and is used to report a wide range of services and supplies including, but not limited to: Number of office visits; anesthesia minutes; quantity of drugs administered; covered miles. Although Medicare currently makes payment based on fractional units for some services (for example, calculation of payment after conversion of anesthesia time reported in minutes to time units),

there is currently no requirement that providers bill fractional units on the claim. If we were to implement a policy of requiring reporting of fractional units for other types of services or supplies we would first need to evaluate whether it is possible to do so considering industry standards of measurement. As previously discussed, providers and suppliers of ambulance services have the capability to determine fractional mileage using standard onboard equipment, that is, an odometer, GPS, and/or other similar equipment used to measure distance traveled. This would enable us to readily implement a fractional unit billing policy for ambulance mileage; whereas applicability to other areas (such as anesthesia, drugs, *etc.*) would require more analysis to determine whether a fractional unit billing policy is feasible, efficacious, and cost effective. Additionally, this issue was first raised by ambulance suppliers who were concerned about overbilling and being overpaid by Medicare. Therefore, we believe it is most reasonable to first address the area where concerns have been raised (that is, ambulance mileage) and consider applicability of this procedure to other types of services and items in the future.

Finally, and perhaps most importantly, we considered that our claims processing system should be configured to process claims as accurately as possible so as to provide for more accurate payments and to safeguard Medicare dollars. As previously discussed, ambulance providers and suppliers currently have the capability to measure mileage accurately to within a minimum of a tenth of a mile using devices (for example, odometers, GPS technology, *etc.*) already equipped onboard their vehicles. We believe that requiring ambulance providers and suppliers to round (and report) fractional ambulance mileage up to the next tenth of a mile strikes a proper balance between ensuring that the claims processing system adjudicates a claim as accurately as the system will permit without unduly burdening the ambulance community.

Based on all of the above considerations, we have decided that our claims processing instructions for submission of claims for ambulance mileage should be revised to reflect the current functionality of our claims processing systems so as to maximize the accuracy of claims payment, as further discussed below in this section.

c. Billing of Fractional Units for Mileage

It is both reasonable and prudent that, in order to ensure accuracy of payment, we facilitate and allow submission of the most accurate information on all Medicare ambulance claims. Furthermore, since our claims processing systems are currently capable of accepting and processing fractional units of service, we believe that ambulance mileage should be billed to and paid by Medicare in fractional amounts to enhance payment accuracy. Based on all the considerations discussed above, we are proposing to require that claims for mileage submitted by ambulance providers and suppliers for an ambulance transport (ground and air) be billed in fractional units, by rounding up to the nearest tenth of a mile (with the exception discussed below). As discussed above, we believe that requiring ambulance providers and suppliers to round (and report) fractional mileage up to the next tenth of a mile would allow us to provide for more accurate claims payment without unduly burdening the ambulance community.

Therefore, we are proposing that, effective for claims with dates of service on and after January 1, 2011, ambulance providers and suppliers would be required to report mileage rounded up to the nearest tenth of a mile for all claims for mileage totaling up to 100 covered miles. Providers and suppliers would submit fractional mileage using a decimal in the appropriate place (for example, 99.9). Since standard vehicle mileage (analog, digital, and GPS) is or can be calculated accurately to the nearest tenth of a mile, we are proposing that the mileage billed to Medicare by ambulance providers and suppliers be reported by rounding up to the next tenth of a mile.

Although the electronic claim formats can accommodate fractional mileage when mileage is equal to or greater than 100 covered miles (for example, 100.0), the paper claim cannot. Because the Form CMS-1500 paper claim currently only supports four characters (including the decimal point) in the units field (Item 24G), we also propose that mileage equal to or greater than 100 covered miles continue to be reported in whole number miles on both paper and electronic claims. We propose that providers and suppliers would round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the units' field. We would revise the instructions set forth in our Claims Processing Manual to reflect the revised procedures for

submitting and paying claims for fractional ambulance.

C. Clinical Laboratory Fee Schedule: Signature on Requisition

In the March 10, 2000 **Federal Register**, we published the "Medicare Program; Negotiated Rulemaking; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services" proposed rule (65 FR 13082) announcing and soliciting comments on the results of our negotiated rulemaking committee tasked to establish national coverage and administrative policies for clinical diagnostic laboratory tests under Part B of Medicare. In our final rule published in the November 23, 2001 **Federal Register** (66 FR 58788), we explained our policy on ordering clinical diagnostic laboratory services and amended § 410.32 to make our policy more explicit. Our regulation at § 410.32(a) states the requirement that "[a]ll diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary." In the November 23, 2001 final rule, we added paragraph (d)(2) to § 410.32 to require that the physician or qualified nonphysician practitioner (NPP) (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners (NPs), and physician assistants (PAs)) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record (66 FR 58809). In the preamble discussions to the March 10, 2000 proposed rule and November 23, 2001 final rule (65 FR 13089 and 66 FR 58802, respectively), we noted that "[w]hile the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered." In those preambles, we described the policy of not requiring physician signatures on requisitions for clinical diagnostic laboratory tests, but implicitly left in place the existing requirements for a written order to be signed by the ordering physician or NPP for clinical diagnostic laboratory tests, as well as other types of diagnostic tests. We further stated in the preambles of the proposed and final rules that we would publish an instruction to Medicare contractors clarifying that the signature of the ordering physician is not required for Medicare purposes on a requisition for a clinical diagnostic laboratory test (65 FR 13089 and 66 FR 58802).

On March 5, 2002, we published a program transmittal implementing the administrative policies set forth in the

final rule, including the following instruction: "Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record." (Transmittal AB-02-030, Change Request 1998, dated March 5, 2002).

On January 24, 2003, we published a program transmittal in order to manualize the March 5, 2002 Transmittal. (Transmittal 1787, Change Request 2410, dated January 24, 2003). The cover note to the transmittal states, "Section 15021, Ordering Diagnostic Tests, manualizes Transmittal AB-02-030, dated March 5, 2002. In accordance with negotiated rulemaking for outpatient clinical diagnostic laboratory services, no signature is required for the ordering of such services or for physician pathology services." In the manual instructions in that transmittal in a note, we stated: "No signature is required on orders for clinical diagnostic services paid on the basis of the physician fee schedule or for physician pathology services." The manual instructions did not explicitly reference clinical diagnostic laboratory tests as the cover note did. Rather, the transmittal seemed to extend the policy set forth in the **Federal Register** (that no signature is required on requisitions for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS)) to also apply to clinical diagnostic tests paid on the basis of the Physician Fee Schedule (PFS) and physician pathology services. In addition, the manual instructions used the term "order" instead of "requisition," which some members of the industry have asserted caused confusion.

When we transitioned from paper manuals to the current electronic Internet Only Manual system, these manual instructions were inadvertently omitted from the new Benefit Policy Manual (BPM).

In August 2008, we issued a program transmittal (Transmittal 94, Change Request 6100, dated August 29, 2008) to update the BPM to incorporate language that was previously contained in section 15021 of the Medicare Carriers Manual. The reissued language states, "No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or

beneficiaries in situations where they relocate near the end of a capped rental payment period. With regard to oxygen equipment, suppliers in general have not demonstrated a willingness to accommodate beneficiaries in similar situations. Therefore, it is necessary to revisit this rule in order to protect beneficiaries in these situations. This proposal would allow either a new supplier in the beneficiary's new service area or a supplier in the old service area to receive at least half of the 36 monthly payments allowed for under the current statutory payment rule for oxygen equipment. We believe this approach would be fair to suppliers in either scenario since the same minimum number of payments applies. Based on current 2010 Medicare allowed fee schedule amounts for stationary oxygen equipment, total payments for 18 months is \$3,117.06. We believe this new rule would provide greater financial incentive to suppliers in areas where beneficiaries relocate to furnish oxygen equipment in these situations. We also believe that this proposal would not disadvantage suppliers required to continue furnishing oxygen equipment or make arrangements for furnishing oxygen equipment to beneficiaries that relocate outside their normal service area since these suppliers would receive 18 or more monthly payments. Most of the cases that have been reported regarding problems encountered by beneficiaries in obtaining access to oxygen equipment after relocating during the 36-month rental cap period have been situations where the beneficiary has relocated during the second half of the 36-month rental cap period. Therefore, we believe that this rule would largely address access problems associated with relocations during the 36-month rental cap period because the supplier that received payments during the first half of the 36-month rental cap period would be obligated to continuing furnishing the equipment during the second half of the 36-month rental cap period.

H. Provider and Supplier Enrollment Issue: Air Ambulance Provision

The National Transportation Safety Board (NTSB) is an independent Federal agency charged by the Congress with investigating transportation accidents, determining their probable cause and making recommendations to prevent similar accidents from occurring. Based on information derived from testimony provided at the NTSB public hearing and investigations into recent Helicopter Emergency Medical Services (HEMS) accidents, the NTSB made several specific recommendations to the

Secretary of Health and Human Services on September 24, 2009.

Specifically, the NTSB recommended that the Secretary develop minimum safety accreditation standards for HEMS operators that augment the operating standards of 14 CFR part 135 by including for all flights with medical personnel on board: (a) Scenario-based pilot training; (b) implementation of preflight risk evaluation programs; and (c) the installation of FAA-approved terrain awareness warning systems, night vision imaging systems, flight data recording systems for monitoring and autopilots if a second pilot is not used.

In response to the NTSB concerns, the Secretary noted that the recommendations to CMS were similar to those being made to the Federal Aviation Administration (FAA). While we have expertise to regulate health and safety requirements that suppliers and providers of healthcare should meet, we do not have the expertise to determine aircraft safety requirements. The Secretary stated that, "we believe the FAA should determine the minimum level of safety that HEMS operators should meet and CMS should adopt regulations that require any HEMS operator that enrolls in Medicare to meet those requirements." The Secretary also added that, "while we do not believe CMS should augment FAA regulations, we do believe that CMS' regulations should ensure that only those HEMS operators that maintain the minimum level of requirements established by the FAA through its regulations are enrolled or maintain enrollment in the Medicare program."

In the April 21, 2006 **Federal Register**, we published the "Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment" final rule. This final rule implemented section 1866(j)(1)(A) of the Act. In this final rule, we required that all providers and suppliers (other than physicians or practitioners who have elected to "opt-out" of the Medicare program) must complete an enrollment form and submit specific information to CMS in order to obtain Medicare billing privileges. Section 424.515 required that ambulance service providers continue to resubmit enrollment information in accordance with § 410.41(c)(2), which states, "Upon a carrier's request, complete and return the ambulance supplier form designated by CMS and provide Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws." This final rule also established

§ 424.510(d)(2)(iii) which states, "Submission of all documentation, including all applicable Federal and State licensure and regulatory requirements that apply to the specific provider or supplier type that related to providing health care services, required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to establish the provider or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program."

While the Airline Deregulation Act (Pub. L. 95-504) preempts a State, political subdivision of a State, or political authority of at least 2 States from enacting or enforcing a law, regulation, or other provision having the force and effect of law related to a price, route, or service of an air carrier that may provide air transportation, air ambulances remain subject to Federal laws and regulations. In accordance with § 424.516(a)(2), providers and suppliers must adhere to all Federal regulations and State laws and regulations, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare.

In § 424.510(d)(iii), we are proposing to clarify that ambulance suppliers and other providers and suppliers include documentation regarding all applicable Federal and State certifications. Accordingly we are proposing to revise § 424.510(d)(iii) from "Submission of all documentation, including all applicable Federal and State licenses and regulatory requirements that apply to the specific provider or supplier type that relate to providing health care service, required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to establish the provider or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program," to "Submission of all documentation, including all applicable Federal and State licenses, certifications (including, but not limited to Federal Aviation Administration and Clinical Laboratory Improvement Act certifications), and regulatory requirements that apply to the specific provider or supplier type that relate to providing health care service, required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to establish the provider or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program."

We are also proposing to revise § 424.516(e)(2) and add new paragraph

(e)(3) to clarify that Medicare enrolled providers and suppliers must report a revocation or suspension of a Federal or State license or certification, including but not limited to FAA and Clinical Laboratory Improvement Act (CLIA) certifications. This revision will clarify that fixed-wing ambulance operators and HEMS operators are responsible for notifying the designated Medicare contractor for their State when FAA revokes or suspends any license or certification. Moreover, fixed-wing ambulance operators and HEMS operators must maintain all requirements as specified in 14 CFR part 135.

We believe that requiring fixed-wing ambulance and HEMS operators to notify their Medicare contractor of a suspension or revocation of a license or certification will ensure that any action taken by the FAA or other regulating authority will have a direct linkage to the operator's ability to maintain their Medicare enrollment. We believe that such a policy will help improve aircraft safety for operators that are enrolled in Medicare and providing services to Medicare beneficiaries. In addition, since the FAA is responsible for the issuance and enforcement of regulations and minimum standards covering manufacturing, operating, and maintaining aircraft, we will work with the FAA to confirm that fixed-wing ambulance operators and HEMS operators remain in compliance with FAA safety regulations (including, but not limited to Federal Aviation Administration and certifications) to the Medicare contractor within 30 days of the revocation or suspension of the license or certification, the provider or supplier is making the decision to voluntarily terminate its Medicare billing privileges because the provider or supplier is no longer in compliance with the applicable licensing or certification requirements for their provider or supplier type. We believe that allowing providers and suppliers to self-report licensure or certification revocations and suspensions within a 30 day period via the Medicare enrollment application (such as, the Internet-based Provider Enrollment Chain and Ownership System (PECOS) or the paper CMS-855) promotes compliance with the Medicare reporting requirements found in § 424.516. In addition, by reporting a licensure or certification revocation or suspension within 30 days, the provider or supplier avoids the Medicare contractor bringing an action to revoke its Medicare billing privileges and establishing and Medicare enrollment bar, see

§ 424.535(c). Thus, by complying with the reporting responsibilities found in § 424.516 and voluntarily terminating from the Medicare program, the air ambulance supplier can submit an initial application to enroll in the Medicare program as soon as the licensure or certification revocation or suspension action is resolved with the applicable licensing or certification organization.

In § 424.502, we are proposing to define the term, "voluntary termination" as it is currently used in the Medicare program and throughout this regulation in the context of the provider enrollment requirements: We are proposing that the term, "voluntary termination" to mean an air ambulance supplier, that submits written confirmation to CMS of its decision to discontinue enrollment in the Medicare program.

Furthermore, we believe that an air ambulance supplier, can make the decision to voluntarily terminate their business relationship with the Medicare program at any time, including when the provider or supplier makes the decision that they will no longer furnish services to Medicare beneficiaries.

In those situations, where an air ambulance supplier does not meet their reporting responsibilities and notify the Medicare program of a Federal or State licensure or certification revocation or suspension within 30 days of the reportable event, we believe that it is appropriate to that CMS or the Medicare contractor revoke the supplier's Medicare billing privileges using § 424.535(a)(1). We believe that this change will clarify that CMS or our Medicare contractor may revoke Medicare billing privileges when these types of suppliers do not report a revocation or suspension of a Federal or State license or certification.

I. Technical Corrections

1. Physical Therapy, Occupational Therapy and Speech-language Pathology

We are proposing to revise § 409.23(c) by making a minor technical correction to remove an extraneous cross-reference which was initially proposed in the CY 2008 PFS proposed rule (72 FR 38122, 72 FR 38193, and 72 FR 38221). This cross-reference refers the reader to "paragraph (c)(1)(ii) of this section," a paragraph also proposed in the CY 2008 PFS proposed rule, but never finalized. In the CY 2008 PFS final rule with comment period, we inadvertently neglected to remove the associated cross-reference from the regulations text. Accordingly, we now propose to rectify that oversight by making an

appropriate correction in the regulations text, along with other minor formatting revisions. We are also proposing to make a minor clarification to the section heading and introductory text of § 409.23 (along with a conforming revision to the corresponding regulations text at § 409.20(a)(3)) by revising the existing phrase "speech therapy" to read "speech-language pathology services," so that it more accurately reflects the currently used terminology for this type of therapeutic treatment.

In addition, we are also proposing to make a minor wording change in the provision at § 409.17(d) (which is incorporated by reference in § 409.23(c)(2)), in order to clarify that the former provision's reference to "hospital" policies and procedures can alternatively refer, depending on the particular context, to SNF policies and procedures.

2. Scope of Benefits

In § 410.3, we are proposing a technical correction to paragraph (b)(2). Currently, § 410.3(b)(2) states that the specific rules on payment are set forth in subpart E of part 410. However, the specific payment rules are actually listed in subpart I of part 410. Therefore, we are proposing to correct § 410.3(b)(2) in this proposed rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

(4) This decision is final and binding.
 (1) *Effect of contract termination.*
 (1) A contract supplier whose contract has been terminated may no longer furnish competitive bid items to beneficiaries within a CBA and be reimbursed by Medicare for these items after the effective date of the termination.

(2) A contract supplier whose contract has been terminated must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract. The notice to the beneficiary from the supplier whose contract was terminated must be provided within 5 days of receipt of the final notice of termination. The notification to the beneficiaries must inform the beneficiaries that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay these items.

(m) *Effective date of the contract termination.*

(1) A supplier's DMEPOS CBP contract is terminated effective on the termination date specified in the CBIC notice to the supplier, unless the supplier timely requests a hearing with the HO or the supplier has submitted a CAP under paragraph (x) of this section.

(2) If a supplier requests an HO review of the CMS decision to terminate its contract, and CMS based upon on the HO recommendation terminates the supplier's contract, the effective date of the termination will be the date specified in the CBIC notice to the supplier.

(3) For violations of the terms of the supplier's DMEPOS CBP contract that may harm beneficiaries, such as a supplier providing an inferior product that causes harm to the beneficiary, no delays of the effective date of the termination will be allowed.

Subpart H—Fee Schedule for Ambulance Services

39. Section 414.610 is amended by revising paragraphs (c)(1)(i), (c)(5)(ii), (f), and (h) to read as follows:

§ 414.610 Basis of payments.

(c) * * *
 (1) *Ground ambulance service levels.*
 (i) The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. For services furnished during the period July 1, 2004 through December 31, 2006, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is one percent higher than otherwise is

applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is two percent higher than otherwise is applicable under this section. For services furnished during the period July 1, 2008 through December 21, 2010, ambulance services originating in urban areas (both base rate and mileage) are paid based on a rate that is two percent higher than otherwise is applicable under this section, and ambulance services originating in rural areas (both base rate and mileage) are paid based on a rate that is three percent higher than otherwise is applicable under this section.

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2010, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is 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 and, as of January 1, 2011, is reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period.)

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services

furnished during the period July 1, 2008 through December 31, 2010.

40. Section 414.620 is revised to read as follows:

§ 414.620 Publication of the ambulance fee schedule.

(a) Changes in payment rates resulting from incorporation of the annual inflation factor and the multi-factor productivity adjustment as described in § 414.610(f) will be announced by CMS by instruction and on the CMS Web site.

(b) CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than those described in § 414.610(f).

Subpart J—Submission of Manufacturer's Average Sales Price Data

41. Section 414.804 is amended by—
 A. Redesignating paragraph (a)(6) as (a)(7).
 B. Adding new paragraph (a)(6).
 The addition reads as follows:

§ 414.804 Basis of payment.

(a) * * *
 (6) The manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label as defined by section 201(k) of the Food, Drug, and Cosmetic Act.

* * * * *

Subpart K—Payment for Drugs and Biologicals Under Part B

42. Section 414.902 is amended by adding the definitions of "Biosimilar biological product" and "Reference biological product" in alphabetical order to read as follows:

§ 414.902 Definitions.

* * * * *

Biosimilar biological product means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act.

* * * * *

Reference biological product means the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product as defined at section 1847A(c)(6)(I) of the Act.

* * * * *

43. Section 414.904 is amended by—

A. Adding paragraphs (a)(3), (i), and (j).

B. Revising paragraph (d)(3).

The revisions and additions read as follows:

§ 414.904 Average sales price as the basis for payment.

(a) * * *

(3) For purposes of this section—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment shall be made for amounts of product in excess of that reflected on the FDA-approved label.

* * * * *

(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 the applicable threshold percentage specified in paragraph (d)(3)(iii) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted by the lesser of the widely available market price or 103 percent of the average manufacturer price as subject to the following adjustments:

(i) The payment amount substitution will be applied at the next ASP payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about drugs or biologicals that have exceeded the applicable threshold percentage, and will remain in effect for one quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when:

(A) The threshold for making price substitutions, as defined in section (iii) is met; and,

(B) When 103 percent of the AMP is less than the 106 percent of the ASP during the quarter in which the average manufacturer price would be applied.

(iii) The applicable threshold for AMP comparisons for calendar years 2005, 2006, 2007, 2008, 2009, 2010, is 5 percent. For CY 2011, the threshold for ASP comparisons is reached when:

(A) The ASP for the billing code has exceeded the AMP for the billing code

by 5 percent or more in two consecutive quarters, or three of the last four quarters; immediately preceding the quarter to which the price substitution recommendation would apply; and,

(B) The average manufacturer price for the billing code is calculated using the same set of NDCs used for the average sales price calculation as per this section for the billing code;

(iv) The applicable threshold for WAMP comparisons for calendar years 2005 through 2011 is 5 percent.

(v) No payment amount substitutions will occur before the preliminary injunction issued on December 19, 2007, by the United States District of Columbia in *National Association of Chain Drug Stores et al. v. Health and Human Services*, Civil Action No. 1:07-cv-02017 (RCL), is vacated.

* * * * *

(i) If manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits, the payment limit is calculated by carrying over the most recent available manufacturer ASP price from a previous quarter for an NDC, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported during both the most recently available quarter and the current quarter.

(j) *Biosimilar biological products.* Effective July 1, 2010, the payment amount for a biosimilar biological drug product (as defined in § 414.902 of this subpart) is the sum of the average sales price of all NDCs assigned to the biosimilar biological product as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in § 414.902 of this subpart).

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

44. 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

45. Section 415.130 is amended by revising paragraph (d) to read as follows:

§ 415.130 Conditions for payment: Physician pathology services.

* * * * *

(d) *Physician pathology services furnished by an independent laboratory.*

(1) The technical component of physician pathology services furnished by an independent laboratory to a hospital inpatient or outpatient on or before December 31, 2010, may be paid to the laboratory by the contractor under the physician fee schedule if the Medicare beneficiary is a patient of a covered hospital as defined in paragraph (a)(1) of this section.

(2) For services furnished after December 31, 2010, an independent laboratory may not bill the Medicare contractor for the technical component of physician pathology services furnished to a hospital inpatient or outpatient.

(3) For services furnished on or after January 1, 2008, the date of service policy in § 414.510 of this chapter applies to the TC of specimens for physician pathology services.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

46. 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 B—Certification and Plan of Treatment Requirements

47. Section 424.20 is amended by revising paragraph (e)(2) to read as follows:

§ 424.20 Requirements for posthospital SNF care.

* * * * *

(e) * * *

(2) A physician extender (that is, a nurse practitioner, a clinical nurse specialist, or a physician assistant as those terms are defined in section 1861(aa)(5) of the Act) who does not have a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section—

(i) *Collaboration.*

(A) Collaboration means a process whereby a physician extender works with a doctor of medicine or osteopathy to deliver health care services.

(B) The services are delivered within the scope of the physician extender's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the physician extender and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

(ii) *Types of employment relationships.*

(A) *Direct employment relationship.* A direct employment relationship with the facility is one in which the physician extender meets the common law definition of the facility's "employee," as specified in 20 CFR 404.1005, 404.1007, and 404.1009. When a physician extender meets this definition with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(B) *Indirect employment relationship.*

(1) When a physician extender meets the definition of a direct employment relationship in paragraph (e)(2)(ii)(A) of this section with respect to an entity other than the facility itself, and that entity has an agreement with the facility for the provision of nursing services under § 409.21 of this subchapter, the facility is considered to have an indirect employment relationship with the physician extender.

(2) An indirect employment relationship does not exist if the agreement between the entity and the facility involves only the performance of delegated physician tasks under § 483.40(e) of this chapter.

* * * * *

Subpart C—Claims for Payment

48. Section 424.44 is amended by revising paragraphs (a), (b), and (e) to read as follows:

§ 424.44 Time limits for filing claims.

(a) *Time limits.*

(1) For services furnished on or after January 1, 2010, except as provided in paragraphs (b) and (e) of this section, the claim must be filed no later than the close of the period ending 1 calendar year after the date of service.

(2) For services furnished before January 1, 2010, except as provided in paragraphs (b) and (e) of this section, the claim must be filed on or before December 31 of the following year for services that were furnished during the first 9 months of a calendar year, and on or before December 31st of the second following year for services that were furnished during the last 3 months of the calendar year, except that for services furnished during the last 3 months of 2009 all claims must be filed no later than December 31, 2010.

(b) *Exceptions to time limits.*

Exceptions to the time limits for filing claims include the following:

(1) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section was caused by error or misrepresentation of an employee, Medicare contractor (including Medicare Administrative Contractor, intermediary, or carrier), or agent of the Department that was performing Medicare functions and acting within the scope of its authority.

(2) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(3) The time for filing a claim will be extended if CMS or one of its contractors determines that a failure to meet the deadline in paragraph (a) of this section is caused by all of the following conditions:

(i) At the time the service was furnished the beneficiary was not entitled to Medicare.

(ii) The beneficiary subsequently received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) A State Medicaid agency recovered the Medicaid payment for the furnished service from a provider or supplier 11 months or more after the service was furnished.

(4) *Extension of time.* (i) The time to file a claim will be extended through the last day of the 6th calendar month following the month in which the error or misrepresentation referenced in paragraph (b)(1) of this section, is corrected. However, no extension of time will be granted for paragraph (b)(1) when the request for that exception is made to CMS or one of its contractors more than 4 years after the date of service.

(ii) If CMS or one of its contractors determines that both of the conditions are met in paragraph (b)(2) of this section but that all of the conditions in paragraph (b)(3) are not satisfied, the time to file a claim will be extended through the last day of the 6th calendar month following the month in which the beneficiary received notification of Medicare entitlement effective retroactively to or before the date of the furnished service.

(iii) If CMS or one of its contractors determines that all of the conditions are

met in paragraph (b)(3) of this section, the time to file a claim will be extended through the last day of the 6th calendar month following the month in which the State Medicaid agency recovered the Medicaid payment for the furnished service from the provider or supplier.

* * * * *

(e) As specified in §§ 424.520 and 424.521 of this subpart, there are restrictions on the ability of the following newly-enrolled suppliers to submit claims for items or services furnished prior to the effective date of their Medicare billing privileges:

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

* * * * *

Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

49. Section 424.502 is amended by adding a definition of "Voluntary termination" in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Voluntary termination means that a provider or supplier, including an individual physician or non-physician practitioner, submits written confirmation to CMS of its decision to discontinue enrollment in the Medicare program.

50. Section 424.510 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(1) * * *

(iii) Submission of all documentation, including all applicable Federal and State licenses, certifications (including, but not limited to Federal Aviation Administration and Clinical Laboratory Improvement Act certifications), and regulatory requirements that apply to the specific provider or supplier type that relate to providing health care service, required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to establish the provider or supplier's eligibility to furnish Medicare covered items or services to beneficiaries in the Medicare program.

* * * * *

51. Section 424.516 is amended by adding paragraph (e)(3) to read as follows:

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

* * * * *

(e) * * * (3) Within 30 days any revocation or suspension of a Federal or State license or certification (including Federal Aviation Administration and Clinical Laboratory Improvement Act certifications), an air ambulance supplier must report a revocation or suspension of its license or certification to the applicable Medicare contractor.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: June 18, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: June 24, 2010.

Kathleen Sebelius,

Secretary.

ADDENDUM A: Explanation and Use of Addendum B

The Addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in CY 2011. Addendum B contains the RVUs for work, nonfacility PE, facility PE, and malpractice expense, and other information for all services included in the PFS.

In previous years, we have listed many services in Addendum B that are not paid under the PFS. To avoid publishing as many pages of codes for these services, we are not including clinical laboratory codes or the alpha-numeric codes (Healthcare Common Procedure Coding System (HCPCS) codes not included in CPT) not paid under the PFS in Addendum B.

Addendum B contains the following information for each CPT code and alpha-numeric HCPCS code, except for: Alpha-numeric codes beginning with B (enteral and parenteral therapy); "E" (durable medical equipment); "K" (temporary codes for nonphysicians' services or items); or "L" (orthotics); and codes for anesthesiology. Please also note the following:

- An "NA" in the "Nonfacility PE RVUs" column of Addendum B means that CMS has not developed PE RVUs in the nonfacility setting for the service because it is typically performed in the hospital (for example, an open heart surgery is generally performed in the hospital setting and not a physician's office). If there is an "NA" in the nonfacility PE RVU column, and the contractor determines that this service can be performed in the nonfacility setting, the service will be paid at the facility PE RVU rate.

- Services that have an "NA" in the "Facility PE RVUs" column of Addendum B

are typically not paid under the PFS when provided in a facility setting. These services (which include "incident to" services and the technical portion of diagnostic tests) are generally paid under either the hospital outpatient prospective payment system or bundled into the hospital inpatient prospective payment system payment. In some cases, these services may be paid in a facility setting at the PFS rate (for example, therapy services), but there would be no payment made to the practitioner under the PFS in these situations.

1. **CPT/HCPCS code.** This is the CPT or alpha-numeric HCPCS number for the service. Alpha-numeric HCPCS codes are included at the end of this Addendum.

2. **Modifier.** A modifier is shown if there is a technical component (modifier TC) and a professional component (PC) (modifier-26) for the service. If there is a PC and a TC for the service, Addendum B contains three entries for the code, specifically a code for: The global values (both professional and technical); modifier—26 (PC); and modifier—TC. The global service is not designated by a modifier, and physicians must bill using the code without a modifier if the physician furnishes both the PC and the TC of the service. Modifier-53 is shown for a discontinued procedure, for example a colonoscopy that is not completed. There will be RVUs for a code with this modifier.

3. **Status indicator.** This indicator shows whether the CPT/HCPCS code is included in the PFS and whether it is separately payable if the service is covered.

A = Active code. These codes are separately payable under the PFS if covered. There will be RVUs for codes with this status. The presence of an "A" indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for coverage decisions in the absence of a national Medicare policy.

B = Bundled code. Payments for covered services are always bundled into payment for other services not specified. If RVUs are shown, they are not used for Medicare payment. If these services are covered, payment for them is subsumed by the payment for the services to which they are incident (an example is a telephone call from a hospital nurse regarding care of a patient).

C = Contractors price the code. Contractors establish RVUs and payment amounts for these services, generally on an individual case basis following review of documentation, such as an operative report.

E = Excluded from the PFS by regulation. These codes are for items and services that CMS chose to exclude from the PFS by regulation. No RVUs are shown, and no payment may be made under the PFS for these codes. Payment for them, when covered, continues under reasonable charge procedures.

I = Not valid for Medicare purposes. Medicare uses another code for the reporting of, and the payment for these services. (Codes not subject to a 90-day grace period.)

M = Measurement codes, used for reporting purposes only. There are no RVUs and no payment amounts for these codes. CMS uses them to aid with performance measurement.

No separate payment is made. These codes should be billed with a zero ((\$0.00) charge and are denied) on the MPFSDB.

N = Noncovered service. These codes are noncovered services. Medicare payment may not be made for these codes. If RVUs are shown, they are not used for Medicare payment.

R = Restricted coverage. Special coverage instructions apply. If the service is covered and no RVUs are shown, it is contractor-priced.

T = There are RVUs for these services, but they are only paid if there are no other services payable under the PFS billed on the same date by the same provider. If any other services payable under the PFS are billed on the same date by the same provider, these services are bundled into the service(s) for which payment is made.

X = Statutory exclusion. These codes represent an item or service that is not within the statutory definition of "physicians' services" for PFS payment purposes. No RVUs are shown for these codes, and no payment may be made under the PFS. (Examples are ambulance services and clinical diagnostic laboratory services.)

4. **Description of code.** This is an abbreviated version of the narrative description of the code.

5. **Physician work RVUs.** These are the RVUs for the physician work in CY 2011.

6. **Fully implemented nonfacility PE RVUs.** These are the fully implemented resource-based PE RVUs for nonfacility settings.

7. **CY 2011 transitional nonfacility PE RVUs.** These are the CY 2011 resource-based PE RVUs for nonfacility settings.

8. **Fully implemented facility PE RVUs.** These are the fully implemented resource-based PE RVUs for facility settings.

9. **CY 2011 Transitional facility PE RVUs.** These are the CY 2011 resource-based PE RVUs for facility settings.

10. **Malpractice expense RVUs.** These are the RVUs for the malpractice expense for CY 2011.

Note: The BN reduction resulting from the chiropractic demonstration is *not* reflected in the RVUs for CPT codes 98940, 98941 and 98942. The required reduction will only be reflected in the files used for Medicare payment.

11. **Global period.** This indicator shows the number of days in the global period for the code (0, 10, or 90 days). An explanation of the alpha codes follows:

MMM = Code describes a service furnished in uncomplicated maternity cases, including antepartum care, delivery, and postpartum care. The usual global surgical concept does not apply. See the Physicians' Current Procedural Terminology for specific definitions.

XXX = The global concept does not apply.

YYY = The global period is to be set by the contractor (for example, unlisted surgery codes).

ZZZ = Code related to another service that is always included in the global period of the other service. (Note: Physician work and PE are associated with intra-service time and, in some instances, with the post-service time.)