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Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

**42 CFR Parts 405, 409, 410 et al.
Medicare Program; Payment Policies
Under the Physician Fee Schedule and
Other Revisions to Part B for CY 2011;
Final 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-FC]****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:** Final rule with comment period.

SUMMARY: This final rule with comment period addresses 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 finalizes the calendar year (CY) 2010 interim relative value units (RVUs) and issues interim RVUs for new and revised procedure codes for CY 2011. It also addresses, implements, or discusses certain provisions of both the Affordable Care Act (ACA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, this final rule with comment period discusses payments under the Ambulance Fee Schedule (AFS), the Ambulatory Surgical Center (ASC) payment system, and the Clinical Laboratory Fee Schedule (CLFS), payments to end-stage renal disease (ESRD) facilities, and payments for Part B drugs. Finally, this final rule with comment period also includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (CBP DMEPOS), and provider and supplier enrollment issues associated with air ambulances.

DATES: *Effective date:* These regulations are effective on January 1, 2011.*Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2011.**ADDRESSES:** In commenting, please refer to file code CMS-1503-FC. 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-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-1503-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 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:

Sara Vitolo, (410) 786-5714, for issues related to malpractice RVUs.

Erin Smith, (410) 786-0763, for issues related to end-stage renal disease-related services for home dialysis.

Michael Moore, (410) 786-6830, for issues related to geographic practice cost indices.

Ken Marsalek, (410) 786-4502, for issues related to the physician practice information survey, the multiple procedure payment reduction, and payment for the technical component of pathology services.

Regina Walker-Wren, (410) 786-9160, for issues related to outpatient mental health add-on provision and increased payment for certified nurse-midwife services.

Elizabeth Truong, (410) 786-6005, or Sara Vitolo, (410) 786-5714, for issues related to potentially misvalued services.

Elizabeth Truong, (410) 786-6005, for issues related to the sustainable growth rate or anesthesia or physician fee schedule conversion factors.

Dorothy Shannon, (410) 786-3396, for issues related to outpatient therapy services.

Pamela West, (410) 786-2302, for issues related to payment for diabetes self-management training programs and kidney disease education services.

Ryan Howe, (410) 786-3355, for issues related to direct practice expense inputs and telehealth services.

Sara Vitolo, (410) 786-5714, for issues related to pulmonary rehabilitation services, application of skin substitutes, canalith repositioning, intranasal/oral immunization, and the refinement panel.

Roberta Epps, (410) 786-4503, for issues related to portable x-ray and bone density tests.

Chava Sheffield, (410) 786-2298, for issues related to equipment utilization rate assumption for advanced imaging services.

Chava Sheffield, (410) 786-2298, or Larry Chan, (410) 786-6864, for issues related to the physician fee schedule practice expense methodology.

Stephanie Frilling, (410) 786-4507, or Erin Smith, (410) 786-0763, for issues related to the incentive payment programs for primary care and general surgery services, and payment for the annual wellness visit and preventive services.

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

Roehel 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.

hospital. Accordingly, we are finalizing the proposed revisions to § 415.130(d) to reflect this change.

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 stated in the CY 2011 PFS proposed rule (75 FR 40117) that 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 stated in the CY 2011 PFS proposed rule (75 FR 40118) that 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 stated in the CY 2011 PFS proposed rule (75 FR 40118) that 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 1-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.

A summary of the comments we received and our responses are included below.

Comment: Despite the extension of the ambulance payment add-ons under the ACA as discussed above, one commenter stated that “it has become increasingly difficult to continue to operate with the reimbursement cuts that went into effect January 1, 2010”. They expressed concern that Medicare payment rates for ambulance services are not keeping up with inflation in the industry. They were also concerned that this is the first time in nearly a decade that the ambulance industry will be experiencing negative growth.

Response: We are not sure what reimbursement cuts the commenter is referring to in 2010. As discussed above, pursuant to sections 3105 and 10311 of the ACA, we are required to extend certain ambulance payment add-ons through December 31, 2010. Thus, as discussed above, we are revising our regulations to conform the regulations to these statutory requirements. To date, Congress has not extended these payment add-ons beyond December 31, 2010, and thus we are not authorized to provide these add-ons beyond December 31, 2010.

Comment: One commenter stated that CMS must provide instructions to its contractors that direct them to reprocess claims paid at the original 2010 rates.

Response: Several provisions of the ACA require retroactive adjustments to Medicare claims, including claims for ambulance services, because these provisions have effective dates prior to the ACA’s enactment or shortly thereafter. We are currently developing the best course of action for addressing past claims that were processed under pre-ACA rules. The volume of claims that must be adjusted is unprecedented

and a careful process must be deployed to ensure that new claims coming into the Medicare program are processed timely and accurately, even as we address making retroactive adjustments. Once this process has been developed, we will provide instructions to our contractors regarding adjusting ambulance claims that were paid under the pre-ACA rules in order to apply the payment add-ons required by the ACA.

In this final rule with comment period, we are finalizing the revisions to § 414.610(c)(1)(i), (c)(5)(ii), and (h), as discussed above and in the CY 2011 PFS proposed rule, in order to conform the

regulations to the requirements set forth in sections 3105 and 10311 of the ACA. We note that in § 414.610(c)(1), we have made minor formatting revisions for clarification purposes. In addition, in § 414.610(c)(1)(i), we have corrected a typographical error that appeared in the CY 2011 PFS proposed rule (75 FR 40258) by changing “December 21” to “December 31” to conform with the ACA requirements. As we discuss above, sections 3105 and 10311 of the ACA are self-implementing and do not require any substantive exercise of discretion by the Secretary.

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

Section 3107 of the ACA amended 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 56, representing “specified services,” remains increased by 5 percent through December 31, 2010.

TABLE 56—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;)
90815 (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; with medical evaluation and management services)
Inpatient Hospital, Partial Hospital or Residential Care Facility
Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy:
90816 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;)
90817 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services)
90818 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient;)
90819 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services)
90821 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient;)
90822 (Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services)
Interactive Psychotherapy:
90823 (Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;)

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 [after application of any reduction in any update for failure to report on quality measures, if the Secretary implements a quality reporting program for ASCs] shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act” (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 proposed 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 an 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 62 provides illustrative examples of how we proposed the MFP adjustment would be applied to the ASC payment system. These examples show the implication of a positive CPI–U update factor with a smaller MFP adjustment, a positive CPI–U update factor with a large MFP adjustment, and a CPI–U update factor of zero. We discussed the application of the MFP adjustment to the CPI–U update factor for the ASC payment system under the OP/ASC CY 2011 proposed rule (75 FR 46359). We solicited comment on the specific mathematical calculation of the MFP adjustment and noted that comments on the application of the MFP adjustment to the CPI–U update factor under the ASC payment system should be made to the OP/ASC CY

2011 proposed rule (75 FR 46359). As discussed previously, we received and responded to comments on the calculation of the MFP adjustment and have finalized this methodology as described above. In the CY 2011 OP/ASC final rule with comment period, we respond to any comments received and finalize the methodology for applying the MFP adjustment to the CPI–U update factor for ASCs.

TABLE 62—MULTIFACTOR PRODUCTIVITY ADJUSTED PAYMENT UPDATE: ILLUSTRATIVE EXAMPLE

CPI–U (percent)	MFP Adjustment (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 rates are 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 subclause (C) which states that, for CY 2011 and each subsequent year, after determining the percentage increase under section 1834(l)(3)(B) of the Act (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) of the Act (as discussed previously). Section 3401(j) of the ACA further amends section 1834(l)(3) of the Act to state that the application of subclause (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 proposed 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 63 provides illustrative examples of how we proposed the MFP adjustment would be applied to the AFS. Finally, we proposed 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 previously discussed.

TABLE 63—EXAMPLES OF THE APPLICATION OF THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT TO THE AMBULANCE FEE SCHEDULE

[In percent]

A CPI–U	B AIF	C MFP Adjustment	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

Comment: A few commenters stated that the payment rates for ambulances have consistently fallen further behind the actual cost of providing the service. One commenter stated that the annual update as adjusted by the MFP adjustment would create a permanent disparity between future increases in Medicare’s reimbursement for ambulance services and the increased costs of providing those services. The commenter stated that the two largest operational costs for ambulance services are personnel and fuel, neither of which readily lends itself to operational efficiencies. In particular, they claim that small and rural providers lack the volume of transports needed to obtain any meaningful economies of scale. These commenters acknowledge that the MFP adjustment is mandated by law, but they state that it will likely result in a net decrease in the already insufficient base reimbursement rate for air

ambulances. One commenter urged CMS to take whatever steps are within its authority to mitigate the potentially devastating effects of this new requirement.

Response: As discussed previously and in the CY 2011 PFS proposed rule (75 FR 40124), we are required by law to implement section 3401(j) of the ACA, which requires that for CY 2011 and each subsequent year, after determining the percentage increase under section 1834(l)(3)(B) of the Act (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) of the Act. In response to the request that we “mitigate” any potentially negative effects of the MFP adjustment, we reiterate that we are required to apply the MFP adjustment to the AIF in the manner specified by the ACA, and we are not authorized by statute to implement measures to mitigate the effects of this adjustment. We note that certain temporary payment add-ons, currently codified at section 1834(l)(12) and (13) of the Act and at section 146(b)(1) of the MIPAA, were extended by the ACA through December 31, 2010 (see section VI.F(1) and (3), of this final rule). To date, Congress has not extended these payment add-ons beyond December 31, 2010. Therefore, we are finalizing the methodology for applying the MFP adjustment to the AIF for the AFS as described in the

proposed rule. We did not receive any comments regarding the proposed changes to § 414.610(f) and § 414.620 as discussed above. Therefore, we are revising the regulation text in § 414.610(f) and § 414.620 as proposed, with the following minor technical change. In § 414.610(f), for clarification purposes, we have made a technical revision to refer to the definition of the productivity adjustment in section 1886(b)(3)(B)(xi)(II) of the Act.

c. Clinical Laboratory Fee Schedule

Section 1833(h)(2)(A)(i) of the Act, as amended by section 3401(l) of the ACA, states that the Secretary shall set the CLFS “for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv) [as added by the ACA], 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 adjustment to the fee schedule can be an increase or a decrease.

Section 3401(l) of the ACA also adds new clause (iv) that applies in CY 2011 and each subsequent year. This clause requires the Secretary to reduce the adjustment in clause (i): (1) By the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act for 2011 and each subsequent year and (2) by 1.75 percentage points for each year of

2011 through 2015 (the “percentage adjustment”). However, section 3401(l) of the ACA states that the MFP adjustment will not apply in a year where the adjustment to the fee schedule determined under clause (i) is zero or a percentage decrease for a year. Further, the application of the MFP adjustment shall not result in an adjustment to the fee schedule under clause (i) of less than zero for a year.

Therefore, we proposed to apply the MFP adjustment as follows:

- If the CPI-U update factor is positive, it would be reduced by the MFP adjustment. However, if application of the MFP adjustment would result in a negative update, the update would be held to zero.
- If the CPI-U update factor is zero or negative, the MFP adjustment would not be applied.

Section 3401(l) of the ACA also states that the application of the percentage adjustment may result in an adjustment to the fee schedule under clause (i) 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. Therefore, we are applying the percentage reduction of 1.75 percentage points to any adjustment to the fee schedule under the CLFS as directed by section 3401(l) of the ACA.

Table 64 provides illustrative examples of how we proposed these adjustments would be applied to fees under the CLFS.

TABLE 64—EXAMPLES OF THE APPLICATION OF THE MULTIFACTOR PRODUCTIVITY ADJUSTMENT TO THE CLINICAL LAB FEE SCHEDULE

A	B	C	D	E
CPI-U	MFP Adjustment	Productivity adjusted update	(- 1.75%) Percentage point reduction	Resultant change to CLFS
		Greater of 0.0% or (Col. A) - (Col. B)		Col. C - Col. D
2.0%	1.3%	0.7%	- 1.75%	- 1.05%
0.0%	N/A	0.0%	- 1.75%	- 1.75%
-2.0%	N/A	0.0%	- 1.75%	- 1.75%

We did not receive any public comments on the proposed methodology for applying the MFP adjustment and the percentage adjustment to the CPI-U update factor for the CLFS. Therefore, we are finalizing the methodology for applying the MFP adjustment and the percentage adjustment to the CPI-U update factor for the CLFS as described in the proposed rule.

d. DMEPOS Fee Schedule

Sections 1834(a)(14), 1834(h)(4), and 1842(s)(1) of the Act mandate annual updates to the fee schedule amounts established in accordance with these respective sections for covered items of durable medical equipment defined in section 1834(a)(13) of the Act, prosthetic devices, orthotics, and prosthetics defined in section 1834(h)(4)(B) and (C) of the Act, and parenteral and enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the

Act. The annual updates for 2011 for these sections are based on the percentage increase in the CPI-U for the 12-month period ending with June 2010. The annual updates for years subsequent to 2011 will be based on the percentage increase in the CPI-U for the 12-month period ending with June of the previous year (that is, June 2011 for 2012, June 2012 for 2013, etc.). Since 1990 for durable medical equipment, prosthetic devices, orthotics, and prosthetics and since 2003 for

AMP and manufacturer's ASP would affect comparisons between these two.

Comment: CMS received a number of comments pertaining to its proposals regarding the AMP threshold. Some commenters generally agreed that any proposal should be transparent, cautious, and should account for inter-quarter price fluctuations. Some commenters also supported our proposal to limit the price substitution to those HCPCS codes for which ASP and AMP comparisons are based on the same set of NDCs. One commenter requested that CMS specifically note that the volume used to calculate the volume-weighted AMP is identical to that used in the calculation of the volume-weighted ASP. Other commenters supported maintaining the applicable threshold at 5 percent for CY 2011.

Response: We appreciate the comments regarding our proposed AMP threshold policies. Since the publication of the PFS proposed rule, the preliminary injunction issued by the United States District Court for the 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 still in effect. Additionally, CMS continues to expect to develop regulations that will implement the provisions of section 2503 of the ACA, which amended the definition of AMP. Moreover, section 202 of the Federal Aviation Administration Air Transportation Modernization and Safety Improvement Act (Pub. L. 111–226), (enacted on August 10, 2010) has further amended section 1927(k) of the Act. Finally, on September 3, 2010, we proposed to withdraw certain provisions of the AMP final rule published on July 17, 2007 (75 FR 54073).

In light of these factors and comments received, we are finalizing our proposal that the AMP applicable threshold be 5 percent for CY 2011. However, we are not finalizing our proposed adjustments to the 5 percent AMP threshold that would specifically apply the applicable percentage such that comparisons of ASP to AMP will only be made when—

- The ASP exceeds the AMP by 5 percent in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter; and

- For those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, “complete” AMP data).

We appreciate the submitted comments and will take them into account when we revisit the price

substitution and AMP threshold issues in future rulemaking.

Comment: We received a number of comments regarding our price substitution proposed policies. Some commenters supported our proposal that any substitution would last only for a single quarter. The majority of commenters requested that any proposal should not be implemented until after CMS published regulations on the revised definition of AMP. A few commenters also recommended that CMS provide adequate notice to manufacturers prior to making a price substitution. One commenter suggested that additional OIG comparison studies are needed to examine the impact of the new definition of AMP. Several commenters requested clarification on and suggested changes to our proposed regulatory language. Another commenter requested clarification on the timing of price substitutions and suggested that any price substitution policies should not be implemented until the lag time between when the comparison is made and when the substitution would be implemented was decreased. One commenter noted that the OIG studies are not a reliable indicator of predicted savings since the substitution timeframes within the studies differed from that in our proposal. All commenters agreed that any price substitution policy should not be implemented until after the preliminary injunction is vacated.

Moreover, several commenters provided additional information related to the comparison between ASP and AMP, including:

- How ASP and AMP each encompass different sales and rebate data and are calculated based on differing statutory definitions;
- The impact of restated AMP data on comparisons; and
- The effect of price substitutions on physician acquisition of drugs.

Response: We appreciate the comments submitted regarding our price substitution proposal. As discussed above, recent legislative and regulatory changes have further affected this issue.

After careful review and consideration of the comments received, we will not be finalizing our price substitution proposal at this time and thus we will not be finalizing the proposed regulation text at section 414.904(d). Specifically, we are not finalizing our proposal for a policy to substitute 103 percent of AMP for 106 percent of ASP for both multiple and single source drugs and biologicals as defined respectively at section 1847(A)(c)(6)(C) and (D) of the Act. This proposal specifically would have—

- Occurred when the applicable percentage had been satisfied for a number of calendar quarters as discussed elsewhere in this rule;
- Permitted for a final comparison between the OIG's volume-weighted 103 percent of AMP for a billing code (calculated from the prior quarter's data) and the billing code's volume weighted 106 percent ASP, as calculated by CMS, for the current quarter to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy; and

- Had the duration of the price substitution lasting for only one quarter.

We are finalizing the portion of our proposal that sets the AMP threshold at 5 percent CY2011 and have revised the regulations text accordingly. We remain committed to proceeding cautiously as we continue to evaluate the impact of any future policy developments in this area.

6. Out of Scope Comments

We received comments pertaining to: (1) Part B payment for insulin; (2) bona fide service fees; (3) price concessions and bundled arrangements in the calculation of manufacturer ASP data; (4) updating supplying and dispensing fees for Part B drugs; (5) developing standards for manufacturers to not submit related ASP data; (6) low reimbursement in a HCPCS-based claims systems for pharmacies; (7) claims processing, claims rejection, and payment delays in Medicare Part B as compared to Part D; and (8) publishing reimbursement rates for radiopharmaceuticals on contractor Web sites. These comments are outside the scope of this rule, and therefore are not addressed in this final rule with comment period.

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—Provisions of the CY 2011 Proposed Rule

In the CY 2011 PFS proposed rule (75 FR 40159–40161, issued July 13, 2010), we proposed 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 on all claims for mileage totaling up to 100 covered miles, as further discussed below. We stated that we would revise the instructions set forth in our Claims Processing Manual to reflect the revised billing procedures. In this section, we describe our proposals in the CY 2011 PFS proposed rule, including the background and current process for reporting ambulance mileage, the proposed fractional mileage billing policy, and our reasons for proposing revisions to the current mileage reporting policy.

a. Background and Current Process for Reporting Ambulance Mileage

Historically, the Medicare 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 ambulance transports, as it is now possible for our FFS systems to capture and accurately process fractional units on both paper and electronic forms.

Based on our prior 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 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. Based on our current instructions, 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. Because of those instructions, a provider or supplier is required to bill as much as 0.9 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.

As we stated in the CY 2011 PFS proposed rule (75 FR 40160), 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.

In the CY 2011 PFS proposed rule (75 FR 40160), we then explored whether a change in our procedure would be: (1) Appropriate; (2) possible considering our current system capabilities and industry standards of measurement; and (3) 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 stated in the proposed rule (75 FR 40160) that 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. In the CY 2011 PFS proposed rule (75 FR 40160), we stated that 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 in the CY 2011 PFS proposed rule (75 FR 40160) 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 in the CY 2011 PFS proposed rule (75 FR 40160) 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. We stated in the proposed rule that 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. We stated that 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 discussed in the CY 2011 PFS proposed rule (75 FR 40160), we found that 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. We stated that 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 stated in the proposed rule (75 FR 40160) that 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, we found that 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, and GPS technology, etc.) already equipped onboard their vehicles. We stated in the CY 2011 PFS proposed rule (75 FR 40160) that 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 considerations noted previously, we proposed 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 in this section (75 FR 40160).

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 previously, in the CY 2011 PFS proposed rule (75 FR 40161), we proposed 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 previously discussed, 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, in the CY 2011 PFS proposed rule (75 FR 40161), we proposed 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 proposed that the mileage billed to Medicare by ambulance providers and suppliers be reported by rounding up to the next tenth of a mile.

We also stated in the proposed rule (75 FR 40161) that 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 proposed 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 proposed 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 stated that 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 mileage.

3. Analysis of and Responses to Public Comments

We received approximately 131 comments in response to the proposed rule. We received comments from, among others, public and private ambulance companies, national ambulance organizations, local fire and EMS departments as well as other interested parties such as attorneys and consultants. The responses we received pertained primarily to the proposed rule's financial and administrative impact, the impact on patient care, and the overall impact on the ambulance services industry. A summary of the comments and our responses are included below.

a. Basis for Reconsideration of the Ambulance Mileage Reporting Requirements

Comment: A few commenters believed that the concerns discussed in the proposed rule regarding certain suppliers' belief that the current mileage reporting requirement forced them to bill inaccurately, were an attempt by CMS to achieve budgetary savings by using the concerns of a few companies as justification. These commenters stated that CMS should have addressed the suppliers' concerns by educating providers and suppliers about its current policy of rounding up to the next whole mile so that they would be aware that this billing practice is appropriate, and suggested that CMS include the current whole mile billing policy in the regulations to further reinforce this, rather than implement the new fractional mileage policy. They stated that any change to the ambulance mileage reporting requirement would be unreasonable and unfounded. The commenters believed that if accuracy was a priority, then CMS should have implemented the fractional mileage billing policy in Transmittal AB-00-88, issued September 18, 2000.

Response: While the impetus for reconsidering our policy on ambulance mileage billing was the concerns raised by ambulance suppliers wishing to bill accurately, our basis for moving forward with the proposed policy was that the conditions that dictated the original mileage billing policy have now changed. As we stated in the proposed rule (75 FR 40160), technological advancements in our system capabilities enabled us to reconsider our policy for reporting ambulance mileage. We were originally not capable of receiving or processing fractional unit amounts on electronic or paper claims, and thus, initially, it was necessary to implement a policy that required providers and suppliers to round mileage up to the nearest whole mile—even though that amount exceeded the miles actually traveled. As discussed in the CY 2011 PFS proposed rule (75 FR 40159), under the current policy, the result could be overpayment for mileage of up to 0.9 of a mile.

Therefore, this change to our policy regarding ambulance mileage billing represents a reasonable and appropriate change to improve payment accuracy. The fact that we did not implement such a policy in the Transmittal cited by commenters does not negate the fact that the change is both needed and appropriate. Again, the original policy for rounding mileage up to the nearest whole number mile was based on the fact that we could not capture and process fractional mileage on a Medicare claim. To ignore the current systems' capability to more accurately process claims than what was possible 10 years ago would unnecessarily perpetuate a less accurate method of processing claims and would result in less accurate payments than is possible with current system capabilities.

For the reasons discussed previously and in the CY 2011 PFS proposed rule, we continue to believe that it is reasonable and appropriate to revise our claims processing instructions as discussed in the proposed rule to require that ambulance mileage be reported in fractional amounts by rounding up to the next tenth of a mile.

b. Appropriateness of Fractional Mileage Reporting Policy

As we discussed in the CY 2011 PFS proposed rule (75 FR 40160), we believe that reporting of and payment based on fractional ambulance mileage is appropriate because it permits ambulance providers and suppliers to submit claims that more precisely reflect actual mileage and to be reimbursed more accurately for the services they provide. Although many

commenters agreed that billing and payment accuracy are important, commenters cited various concerns regarding the appropriateness of the policy.

(1) Statutory Compliance and Financial Impact of Fractional Mileage Policy

Comment: Many commenters believed that the fractional mileage reporting policy does not adhere to the “budget neutrality principles” set forth in 42 U.S.C. 1395m(l)(3)(B). These commenters interpreted 42 U.S.C. 1395m(l)(3)(B) as requiring that CMS pay the same amount for ambulance services after implementation of the fee schedule as it did prior to the fee schedule with an inflation adjustment, and stated that in order to comply with this statute, the fractional mileage policy must be implemented in a manner such that any savings generated by this policy are reinvested in the ambulance fee schedule.

Furthermore, commenters asked that CMS comply with the “requirement and commitment made during negotiated rulemaking to ensure that no money is taken out of the system.” Commenters cited to the February 27, 2002 final rule implementing the ambulance fee schedule, in which we stated that we would monitor payment data and make adjustments to the conversion factor (CF) if the actual experience under the fee schedule is significantly different from the assumptions used to establish the original CF. (67 FR 9102 and 9102). Several commenters stated that the fractional mileage policy alters the fee schedule and therefore requires reconsideration of the conversion factor (CF) used to set the ambulance fee schedule payment amounts so that no money is removed from the system. Some commenters believed that the policy will have a greater effect on ground ambulance services and recommended a greater proportional increase to the CF for ground ambulance transports versus air ambulance rates.

Response: Section 1834(l)(3)(B) of the Act (42 U.S.C. 1395m(l)(3)(B)) does not require that we pay the same aggregate amount for ambulance services after implementation of the fee schedule as we did before implementation of the ambulance fee schedule, or that we ensure that any savings generated by the fractional mileage policy be put back into the ambulance fee schedule. Rather, this statutory section sets forth the ambulance inflation factor to be used to update the ambulance fee schedule rates each year. Section 1834(l)(3)(B) of the Act requires that we set the ambulance fee schedule rates each year at the same

level as the previous year increased by the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending in June of the previous year (as discussed in section VI.P. of this final rule with comment period, effective January 1, 2011, the annual update to the fee schedule rates is subject to a productivity adjustment). We have interpreted this provision at § 414.610(f) as requiring that the CF, the air ambulance rates and the mileage rates be updated annually by the ambulance inflation factor set forth in the statute. The fractional mileage billing policy does not alter the payment rates set under the ambulance fee schedule; rather, it is a change to our operational instructions for reporting ambulance mileage intended to improve billing and payment accuracy. After implementation of the fractional mileage billing policy, we will continue to update the rates each year as required by section 1834(l)(3)(B) of the Act, and thus we believe this policy is consistent with section 1834(l)(3)(B) of the Act. Furthermore, we note that while section 1834(l)(3)(A) of the Act required the Secretary to ensure that the aggregate amount of payments made for ambulance services during 2000 (originally expected to be the first year of the ambulance fee schedule) did not exceed the aggregate amount of payments that would have been made for such services during such year absent the fee schedule, it did not set forth a budget neutrality requirement for subsequent years.

While some commenters stated that the fractional mileage billing policy alters the fee schedule and therefore requires reconsideration of the conversion factor (CF) used to set the ambulance fee schedule payment amounts so that no money is removed from the system (citing to the February 27, 2002 final rule implementing the ambulance fee schedule), we believe that commenters have misunderstood our statements in the February 27, 2002 final rule. In the February 27, 2002 final rule, we stated that we would monitor payment data and make adjustments to the conversion factor (CF) if the actual experience under the fee schedule is significantly different from the assumptions used to establish the original CF as discussed in the February 27, 2002 final rule (67 FR 9102 and 9103).

As stated previously, the fractional ambulance mileage billing policy does not change the rates under the ambulance fee schedule. Rather, it is a change to our operational procedures for reporting ambulance mileage intended to improve billing and payment

accuracy. We do not believe that it is appropriate to adjust the CF or air ambulance rates as a result of this policy, as further discussed below.

In the February 27, 2002 final rule implementing the ambulance fee schedule (67 FR 9102–9103, 9127, 9134), we stated that we would monitor the payment data and adjust the CF and the air ambulance rates if actual experience under the fee schedule proved to be significantly different from the assumptions used to determine the initial CF and air ambulance rates (for example, the relative volumes of the different levels of service (service mix) and the extent to which providers and suppliers charge below the fee schedule (low billers)). Thus, in the February 27, 2002 final rule, we finalized § 414.610(g), which at that time stated, in part, that the “Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates.”

In each of the 4 years following implementation of the ambulance fee schedule, we reevaluated the effects of the relative volume of different levels of ambulance service (service mix) and the extent to which ambulance providers and suppliers bill less than the ambulance fee schedule (low billers) to determine whether the assumptions used to set the CF were accurate when compared to actual billing data. We found only insignificant differences in the observed data versus our assumptions. The differences observed in any single year were not significant enough to warrant a change to the CF in any of the years we monitored. (See 71 FR 69624, 69717, and 69718). Consequently, in the December 1, 2006 final rule (71 FR 69717–69718), we discontinued our annual review of the original CF assumptions and the air ambulance rates, and revised § 410.610(g) to state, in part, that the “Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates *as appropriate* to reflect actual practices under the fee schedule.”

We do not believe that adjustments to the CF or the air ambulance rates are appropriate as a result of the fractional mileage billing policy. First, as discussed previously, the fractional mileage billing policy has no effect on the fee schedule rates; rather, it is an operational procedure for reporting ambulance mileage. Second, the purpose of this policy is to improve billing and payment accuracy for ambulance mileage. As discussed

previously, under the current whole mile reporting policy, ambulance providers and suppliers are billing as much as 0.9 of a mile more than what is actually traveled. Commenters suggest that adjustments to the CF and the air ambulance rates are necessary to make up for the fact that ambulance providers and suppliers will be permitted to round up only to the nearest tenth of a mile rather than the nearest whole mile, resulting in lower mileage reimbursement on some claims compared to under the current policy. The purpose of the fractional mileage billing policy is to provide for more accurate billing and payment for ambulance transports, which we do not believe can be achieved if we were to make the adjustments suggested by commenters. Furthermore, we note that the current regulation at § 410.610(g) requires us to monitor billing and payment data and adjust the CF and air ambulance rates “as appropriate” to reflect actual practices under the fee schedule. This regulation does not require that we adjust the fee schedule rates prospectively each time we adopt operational procedures that differ from those in place prior to implementation of the fee schedule.

Furthermore, we believe that the policy does not have a significant bearing on the original CF assumptions that were discussed in the February 27, 2002 final rule (67 FR 9102–03, 9115–16), and for this reason too, we do not believe that adjustments to the CF and air ambulance rates would be appropriate. Having reevaluated the CF during the 4 years after implementation of the ambulance fee schedule and finding no significant differences in the observed data versus our original assumptions, we believe that we will continue to find insignificant differences, if any at all, after implementation of the fractional mileage billing policy, such that changing the CF or air ambulance rates would be unnecessary.

However, as required by § 410.610(g), we will continue to monitor the billing and payment data on an ongoing basis, and will consider adjusting the CF and air ambulance rates in the future if (and to the extent) we determine appropriate to reflect actual experience under the fee schedule after the policy is implemented.

Comment: The commenters believed that the proposed rule would lower ambulance reimbursement that is already too low and noted that the fee schedule rates have not been increased in the last 2 years. Most of the same commenters cited a May 2007 Government Accountability Office

(GAO) report detailing GAO’s research findings which indicated that Medicare’s reimbursement for ambulance services averages between 6 percent and 17 percent less than the cost to ambulance companies for the services they provide.

Response: We reiterate that the fractional ambulance mileage billing policy does not change the ambulance fee schedule rates. The base payment rate and mileage reimbursement rate will not be changed by the fractional mileage billing policy. The fractional mileage billing policy is strictly an effort to improve billing and payment accuracy, and as such, we believe that it is both reasonable and appropriate to implement this policy.

In response to the comment that the fee schedule rates have not been increased in the past 2 years, we note that the ambulance inflation factor for CY 2008 was 2.7 percent and in CY 2009 it was increased to 5 percent, and thus the CF, air ambulance rates and mileage rates were increased by 2.3 percent over the previous calendar year in accordance with the section 1834(l)(3)(B) of the Act. However, we recognize that the fee schedule rates were not increased in CY 2010 because the CPI-U for the 12 month period ending with June 2009 was negative, resulting in no increase to the rates under the statutory formula set forth in section 1834(l)(3)(B) of the Act.

The 2007 GAO report cited by commenters estimated that between 39 percent and 56 percent of ambulance providers and suppliers will realize a profit under the ambulance fee schedule after expiration of the temporary payment provisions in the MMA. The GAO also noted in the same report that providers’ expected Medicare margins will vary greatly depending on their ability to keep their operating cost low, and because of that variance, they were not able to conclude with any certainty whether providers and suppliers would see a decrease, increase, or no change in their profitability as it relates to the Medicare reimbursement rates after expiration of the temporary payment provisions in the MMA.

We seriously considered the findings in the May 2007 GAO report and, although we were not bound to the GAO findings, we agreed with their recommendation that CMS monitor utilization of ambulance transports to ensure that Medicare payments are adequate to provide for beneficiary access to ambulance services, particularly in “super rural” areas. We note that in the years since the May 2007 GAO report, certain temporary payment provisions originally set forth

in § 414 of the MMA have been increased and extended in subsequent legislation to address these issues. Specifically, § 414(d) of the MMA added section 1834(l)(13) of the Act which set forth payment increases of 1 percent and 2 percent for urban and rural ground transports, respectively. Section 146(a) of the MIPPA modified section 1834(l)(13) of the Act to increase these percentages to 2 percent and 3 percent for urban and rural transports, respectively, and to extend these increases through December 31, 2009. Subsequently, sections 3105(a) and 10311(a) of the ACA extended these increases through December 31, 2010. Furthermore, section 414(c) of the MMA added section 1834(l)(12) of the Act which provided a “super rural” bonus for certain ground transports that originate in qualified rural areas effective through December 31, 2009. Sections 3105(c) and 10311(c) of the ACA extended this super rural bonus through December 31, 2010. Finally, we note that section 146(b)(1) of the MIPPA, as amended by sections 3105(b) and 10311(b) of the ACA, provides that any area that was designated as a rural area for purposes of making payment for air ambulance services furnished on December 31, 2006, shall continue to be treated as a rural area for purposes of making payment for air ambulance services furnished during the period July 1, 2008 through December 31, 2010. We have implemented these payment add-ons in § 414.610(c)(1), (c)(5)(ii) and (h), respectively.

Comment: Several commenters stated that cutting already low reimbursement rates for ambulance providers and suppliers would result in cutbacks that would make it difficult to stay in business and would, therefore, have a negative impact on patient care. Many commenters also noted that smaller companies would be impacted the most by lowered reimbursement rates, stating that small companies need the extra revenue to stay in business. Some commenters suggested that mileage charges are the only means ambulance providers and suppliers have of recovering increasing, variable costs for ancillaries—such as oxygen supplies, disposable supplies, etc.—that are not separately payable under the fee schedule. Other commenters believed that reporting mileage more accurately will be too costly and would increase the cost of doing business. Another commenter responded that the payment made for mileage represents payment for the variable cost of transporting patients and that even short trips have a cost associated with them. The same

commenter pointed out that lowering the mileage reimbursement would not adequately reimburse ambulance providers and suppliers for the cost of transporting their patients.

Response: As previously stated, the fractional mileage billing policy is an effort to improve billing and payment accuracy. The policy does not modify the reimbursement rates under the ambulance fee schedule. While we remain cognizant of the need for ambulance providers and suppliers to remain financially solvent, we must also ensure that providers and suppliers bill accurately and that we pay accurately. We believe the payment implications of the fractional mileage billing policy are modest when considering the difference in reimbursement on a claim by claim basis, and should not have a significant impact on the overall financial viability of individual ambulance providers and suppliers or on patient care. We recognize that there is a cost of doing business. However, as discussed previously, we believe that it is both reasonable and appropriate to implement the policy to provide for more accurate billing and payment for ambulance mileage under Medicare. We do not believe that it is appropriate to continue the current whole mileage reporting procedure, which results in less accurate billing and payment, in order to provide extra revenue for providers and suppliers.

Comment: One commenter responded that the lower reimbursement would “trickle down” to other payers. In other words, the commenter believes that other payers would follow CMS’ lead by adopting similar mileage reporting requirements, thereby potentially lowering reimbursement from other payers as well.

Response: While other payers may choose to adopt similar requirements for reporting ambulance mileage, we would not have any involvement in that decision. As previously discussed, we believe that it is reasonable and appropriate to implement the fractional mileage billing policy under Medicare to provide for more accurate billing and payment for Medicare ambulance services.

c. Administrative Impact

Comment: Many commenters stated that the fractional mileage policy would be administratively burdensome for medical and billing staff and would distract their medical staff from their first priority which is caring for the patient. The same commenters also suggested that the policy would be particularly burdensome for small ambulance companies. One commenter

stated that imposing a requirement to capture fractional mileage would complicate the already overwhelming documentation requirements that they face. Another commenter believed that the fractional mileage billing policy creates undue hardship on an ambulance industry which is already overburdened and underfunded.

Response: We believe that capturing fractional mileage amounts in trip documentation and on claims will not create any undue burden on the ambulance industry. Proper documentation of trip details, including mileage traveled, is already a longstanding Medicare requirement that remains unchanged and, we believe, uncompromised by the requirement to capture the additional digit beyond the decimal point. As we stated in the proposed rule, we believe that implementation of the policy is a reasonable and appropriate measure to ensure that claims are adjudicated and paid as accurately as possible.

Comment: Many commenters responded that the fractional mileage billing policy would make it difficult for ambulance providers and suppliers to comply with State and local laws which prohibit billing fractional mileage. Several commenters cited the City of Los Angeles as an example of a locality requiring that mileage be rounded to a whole number.

Response: We are not aware of any State or local law(s) that regulate how claims must be submitted to Medicare. We did not find any language in the City of Los Angeles or the Los Angeles County ordinances that governs claims submission to other payers, including Medicare. Further, even if there were a State or local law that specified a billing requirement that differed from Medicare’s requirement, the Medicare requirement would, nevertheless, be controlling for claims submitted for Medicare payment. We note that the fractional mileage billing policy applies only to claims submitted to Medicare and does not dictate how a provider or supplier reports mileage to other payers. Thus, while we recognize the possibility that the requirements for billing ambulance mileage to State-funded or other payers may differ, we believe that the fractional mileage billing policy is reasonable and appropriate to ensure that claims submitted to Medicare more accurately reflect the service(s) rendered and that our payments to providers and suppliers are as accurate as possible.

Comment: Several commenters stated that, if the fractional mileage billing policy is implemented, the requirements for billing ambulance mileage to Medicare will be different than for other

payers, and it would make it difficult for ambulance providers and suppliers to maintain compliance with the differing billing requirements. One commenter stated that since other payers allow whole number reporting of mileage, their ambulance company would be forced to manually change claims in order to submit fractional mileage to Medicare.

Response: We understand that payer requirements may, and often do, vary, and that providers and suppliers may need to comply with different payer billing requirements. Each payer sets its own requirements for billing and payment. We believe that most billing systems are capable of accommodating the reality of varying billing requirements amongst different payers. While additional changes to billing systems or procedures may be necessary in some cases to enable mileage to be reported differently for different payers, as we stated previously, we continue to believe that implementation of the fractional mileage billing policy is reasonable and appropriate to ensure more accurate reporting and payment of ambulance mileage under Medicare.

After considering the comments, for the reasons discussed previously and in the CY 2011 PFS proposed rule, we continue to believe that it is reasonable and appropriate to revise our claims processing instructions to require reporting of and payment based on fractional mileage, as further discussed below.

(2) Technical and Other Considerations (A) Ability To Measure Fractional Miles

Comment: Many commenters responded that most ambulance companies do not have the ability to measure fractional mileage because their odometer does not show tenths of a mile. These commenters stated that 67 percent of all new ambulances are Ford models which do not have a tenths display on the odometer. One commenter stated that digital odometers, in particular, only show whole miles. Another commenter asked that CMS prove its assertion that most vehicle odometers display tenths of a mile. Yet another commenter suggested that we provide guidance for ambulances that do not display tenths of a mile on the odometer. We also received a response from a commenter who believed that GPS can sometimes be unreliable.

Response: Based on the statement from many commenters that most new ambulances are Ford models, we reviewed owner’s manuals for the Ford E250, E350, E450 as well as the F350

and F450 vehicles. Our research revealed that Ford E series and F series vehicle (typically trucks or vans) chassis typically provide the base for the Ford ambulance prep package. We reviewed Ford's gauge specifications for model years 1996 through 2010. In model years prior to 2004, the standard analog odometer reflected tenths of a mile. Model years 2004 and later include standard digital odometers that show fractional miles as well as a separate trip odometer that also displays mileage to the tenth of a mile. Additionally, the ambulance prep package includes an optional onboard trip computer and navigation system.

We also researched other vehicle chassis models that may provide the base for other ambulance prep packages and may currently be in use by some providers or suppliers. We reviewed owner's manuals for the Dodge Ram 3500 and 4500 for model years 2008 and 2009 and we also researched GM/Chevrolet G4500 and 3500 for model years 2009 and 2010. We found that both Dodge and Chevrolet model vehicle gauges include odometers and/or trip odometers that display fractional mileage. Chevrolet models also include a retroactive reset feature on the trip odometer that will calculate the distance traveled since the engine was last started in the event the trip odometer is not reset at the beginning of the trip.

We found through our research that in many cases, trip odometers are mentioned as separate devices from the basic odometer, particularly in newer model cars that utilize both digital gauges. We also found that in some cases, the basic digital odometer does not, in fact, have a tenths display. In those cases, we found that the tenths display appears only on the trip odometer. In the proposed rule, we did not specify the types of odometers that that may be used to measure fractional mileage, and thus we are clarifying in this final rule with comment period that mileage may be measured using a separate trip odometer as well.

In light of our review of Ford vehicle chassis and the assertion that most new ambulances are Ford vehicles as well as our review of the other vehicle chassis models as discussed above, we believe that most ambulance companies have the ability to measure fractional mileage to the tenth of a mile. However, we recognize that there may be some ambulance companies that have a small number of vehicles wherein the gauges are damaged, missing, or otherwise unusable, or that may be using non-standard vehicles that do not have a fractional mileage display on the

odometer, trip odometer, GPS navigation, trip computer, or other onboard device that measures distance traveled. We believe that tools used to measure distance traveled (such as GPS navigation equipment) are readily available to the average consumer at a low cost. As such, ambulance providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile, and ensuring that onboard vehicle gauges measuring trip mileage are in working order. If they are not able to repair said gauges, they are responsible for ensuring that they have the necessary equipment to measure mileage accurately to the tenth of a mile. Additionally, for those ambulance providers and suppliers who have vehicles that include a separate trip odometer, ambulance providers and suppliers are still responsible for ensuring that trip mileage is measured and reported accurately—even if they fail to reset the trip odometer at the beginning of a trip. For example, if the driver fails to reset the trip odometer at the beginning of the trip, he or she would simply document the mileage at the end of the trip and subtract the mileage for the previous trip from the total which would leave a remaining balance that should correspond to the distance of the current trip.

With regard to the statement that GPS can sometimes be unreliable, CMS is not aware of data that confirms or refutes this statement. However, in order to continue to provide ambulance providers and suppliers with flexibility in how they can measure fractional mileage, use of GPS devices will continue to be acceptable for the purpose of measuring fractional mileage.

(B) Ambulance Provider Versus Supplier Billing

Comment: We received responses from several commenters who believe that the fractional mileage billing policy establishes different requirements for Part A versus Part B ambulance providers and suppliers. These commenters stated that neither electronic nor paper institutional claims can accommodate fractional unit amounts. They cited 42 U.S.C. 1395m(l)(1) which requires that all ambulance services be paid under the same fee schedule. Many commenters believed that Part A providers and Part B suppliers, respectively, will be treated differently under the fractional mileage billing policy and will, therefore, be paid differently.

Response: Per the version 4010A1 Implementation Guide and the version

5010 TR3 specifications, the ANSI 8371 (institutional) electronic claim format has the capability to accept fractional unit amounts up to 3 decimal places, and thus both ambulance providers and suppliers will be able to bill fractional mileage on electronic claims. The commenters are correct that the Form UB-04 paper institutional claim does not currently support fractional unit amounts. However, the National Uniform Billing Committee (NUBC) has recently approved a change to the Form UB-04 that will allow fractional unit billing, and this change is scheduled to take effect in July 2011. Currently, less than 0.5 percent of all institutional providers bill Medicare using the paper Form UB-04. Based on the low number of providers billing ambulance services on the Form UB-04 and the fact that the form is expected to be capable of accepting fractional unit amounts in July 2011, we are delaying the implementation date for ambulance providers billing on the paper Form UB-04. If the Form UB-04 is capable of accepting fractional mileage unit amounts by the end of July 2011 as scheduled, ambulance providers billing on the paper Form UB-04 will be required to submit fractional mileage in accordance with this final rule with comment period for dates of service on and after August 1, 2011. If paper Form UB-04 is not capable of accepting fractional mileage by July 31, 2011, then implementation of the fractional mileage policy for these ambulance providers will be further delayed until January 1, 2012 to allow ample time for any changes to the UB-04 to be implemented. As with other claim types, ambulance providers billing on the paper Form UB-04 will report fractional mileage on all claims for mileage totaling up to 100 miles.

We note that delayed implementation of the fractional mileage billing policy for the small number of providers using Form UB-04 does not result in suppliers and providers receiving different rates under the ambulance fee schedule. As discussed previously, the fractional mileage billing policy does not change the rates under the ambulance fee schedule for providers or suppliers. It is strictly a change to our operational instructions for reporting ambulance mileage intended to improve billing and payment accuracy. Thus, after implementation of the fractional mileage billing policy, providers and suppliers will continue to be paid under the same fee schedule and there will be no differentiation in rates between providers and suppliers.

(C) Billing Software

Comment: We received a few comments stating that billing systems will need to be modified to accommodate the fractional mileage billing policy. Three commenters stated that modification of billing software would be too costly, with one commenter further stating that the change would create a hardship for the billing software developer. Another commenter believed that changing their billing system would mean that they would have to report fractional mileage to all payers, not just Medicare.

Response: While minor changes to billing software may be required, any billing software that is compliant with ANSI 837 electronic claim standards should have the capability to accept and submit fractional unit amounts in the appropriate field. For providers and suppliers using paper claim forms to submit claims to Medicare, again, we believe that only minor changes to the units field will be required in order to submit fractional mileage amounts.

As discussed previously, we understand that payer requirements may—and often do—vary, and that providers and suppliers may need to comply with different payer billing requirements. However, the requirement to bill fractional mileage to Medicare does not necessarily mean that providers and suppliers will have to also submit fractional mileage to other payers. Each payer sets its own requirements for billing and payment. We believe that most billing systems are capable of accommodating the reality of varying billing requirements amongst different payers. While additional changes to billing systems or procedures may be necessary in some cases to enable mileage to be reported differently for different payers, as we stated previously, we continue to believe that implementation of the fractional mileage billing policy is reasonable and appropriate to ensure more accurate reporting of and payment for ambulance mileage under Medicare.

(D) Enforcement and Compliance

Comment: One commenter stated that the fractional mileage billing policy would be impossible to verify and/or enforce.

Response: Upon implementation of the fractional mileage billing policy, ambulance providers and suppliers will still be subject to the same statutory and regulatory requirements regarding documentation, fraudulent billing, and pre- and post-payment review.

Comment: One commenter requested guidance for providers and suppliers

who cannot comply with the fractional mileage billing policy.

Response: We believe that providers and suppliers are capable of complying with the new policy. As discussed above, we believe that most ambulance companies have the ability to measure fractional mileage using standard onboard devices. Furthermore, we believe that tools used to measure distance traveled (such as GPS navigation) are readily available to the average consumer at a low cost. Thus, in those instances where gauges are damaged, missing or otherwise unusable, or where companies are using non-standard vehicles that do not include a device to measure fractional mileage, ambulance providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile. Furthermore, billing software that is compliant with the ANSI 837 electronic claim format is capable of capturing and submitting fractional unit amounts, and fractional mileage units can be captured on paper claims (with the exception of paper Form UB04 claims as discussed previously). We believe that implementing the fractional mileage policy is a reasonable and appropriate measure to ensure more accurate billing and payment of Medicare ambulance transports and thus, ambulance providers and suppliers (except for providers billing on Form UB-04 as discussed previously) are expected to comply effective January 1, 2011 with the fractional mileage billing policy finalized in this final rule with comment period.

(E) Air Ambulance

Comment: One commenter responded that the air ambulance segment of the ambulance industry is overpaid by Medicare and suggested that we look to generate savings by changing the reimbursement for air ambulance mileage to be based on nautical miles instead of statutory miles.

Response: As we stated in the proposed rule, our claims processing system should be configured to process claims as accurately as possible so as to provide more accurate Medicare payments. Thus, we believe that the fractional mileage billing policy is a reasonable and appropriate measure to enhance billing and payment accuracy for both air and ground transports. The issue of basing air ambulance reimbursement on nautical miles versus statutory miles was not discussed or proposed in the CY 2011 PFS proposed rule, and thus we are not addressing this

issue in this final rule with comment period.

Comment: A few commenters suggested that the fractional mileage billing policy will affect ground ambulance transports but not air ambulance transports.

Response: The fractional mileage billing policy will be applied in the same manner to, and will affect, both ground and air ambulance transports. However, since the fractional mileage billing policy does not apply to mileage exceeding 100 miles, we recognize that it may impact a greater percentage of ground transports than air transports, as a larger percentage of air transports may exceed 100 miles. We analyzed claim payment data for all Part B ambulance claims paid in 2008. If the fractional mileage billing policy had been implemented in 2008, approximately 92 percent of all claims for air ambulance mileage would have been impacted versus 99 percent of all claims for ground ambulance mileage. However, since air ambulance companies receive higher mileage reimbursement rates, we found that the average financial impact per claim would have been greater for air ambulance versus ground ambulance transports. Thus, when we consider both factors together, it is not clear whether the overall impact will be greater for ground ambulance companies than for air ambulance companies. Regardless of any potential differential impact, we believe that implementation of the fractional mileage billing policy is a reasonable and appropriate measure to ensure more accurate reporting of mileage and more accurate payments under Medicare for both ground and air transports.

(F) Miscellaneous Comments

Comment: One commenter questioned whether the new rounding rule would create no reimbursement for 0.49 miles.

Response: No. The correct rounding, based on the fractional mileage billing policy, would be to always round up the hundredths place. Therefore, the provider or supplier in the commenter's example would bill 0.5 miles. Likewise, if the provider or supplier traveled 0.43 miles, they would bill 0.5 miles on their claim. CMS would apply the normal calculations for determining the payment amount using the fractional mileage units reported.

4. Applicability of the Fractional Billing Policy to Other Services

We received no comments regarding the applicability of the fractional unit billing policy to other services. Therefore, for the reasons discussed in the CY 2011 PFS proposed rule (75 FR

40160), we are applying the fractional unit billing policy only to ambulance mileage.

5. Final Fractional Mileage Billing Policy

For the reasons discussed above and in the CY 2011 PFS proposed rule (75 FR 40159), we believe that it is reasonable and appropriate to implement the fractional mileage billing policy as proposed in the CY 2011 PFS proposed rule effective for claims with dates of service on and after January 1, 2011 (with the exception discussed below relating to providers billing on paper Form UB-04).

Therefore, effective for claims with dates of service on and after January 1, 2011, ambulance providers and suppliers (except for providers billing on paper Form UB-04) are required to report mileage rounded up to the nearest tenth of a mile on all claims for mileage totaling up to 100 covered miles. Providers and suppliers must submit fractional mileage using a decimal in the appropriate place (for example, 99.9). For example, if the total miles traveled equals 1.59 miles, then the provider or supplier must report "1.6" on the claim for mileage. Likewise, if the total mileage equals 1.53 miles, the provider or supplier must report "1.6" on the claim.

Although the electronic claim formats can accommodate fractional mileage when mileage is equal to or greater than 100 covered miles (for example, 100.0), as discussed in the proposed rule, the paper claim cannot. The Form CMS-1500 paper claim currently only supports four characters (including the decimal point) in the units field (Item 24G). Therefore, we are finalizing our proposal that mileage equal to or greater than 100 covered miles must continue to be reported in whole number miles on both paper and electronic claims. Providers and suppliers must round up fractional mileage to the next whole number for mileage that exceeds 100 covered miles and report the resulting whole number in the unit field. The instructions set forth in our Claims Processing Manual will be updated to reflect the revised procedures for submitting and paying claims for fractional ambulance mileage.

Because the changes to the paper Form UB-04 necessary to accommodate fractional units are scheduled to be completed in July 2011, implementation of this policy for ambulance providers that are permitted to bill using the Form UB-04 is delayed until August 1, 2011 (that is, ambulance providers permitted to bill on paper form UB-04 will be required to report fractional mileage in

accordance with this final rule with comment period for dates of service on and after August 1, 2011). If the paper Form UB-04 is not capable of accepting fractional mileage by July 31, 2011, then implementation of this policy for these ambulance providers will be further delayed until January 1, 2012. As with other claim types, upon implementation of the fractional mileage policy for providers billing on the paper Form UB-04, these providers will report fractional mileage on all claims for mileage totaling up to 100 miles.

As discussed previously, providers and suppliers are responsible for ensuring that they have the necessary equipment to measure fractional mileage to the tenth of a mile, and ensuring that onboard vehicle gauges measuring trip mileage are in working order. If they are not able to repair said gauges, they are responsible for ensuring that they have the necessary equipment to measure mileage accurate to the tenth of a mile. Tools that may be used to measure trip mileage include, but are not limited to: Digital or analog odometers, trip odometers, GPS navigation, onboard trip computers or navigation systems.

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 order 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

rental DME payment category in section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–203), representatives of the DME industry indicated that suppliers would be able to accommodate beneficiaries in these situations, and this has proven to be true for capped rental items. In fact, we have found this to be the case to this day.

For this reason, we believed that beneficiaries would not encounter problems obtaining access to oxygen and oxygen equipment in similar situations, that is, following the 36-month cap imposed by section 144(b) of MIPPA. However, since the changes to the payment rules for oxygen and oxygen equipment mandated by the DRA became effective in 2006 and the 36-month rental cap imposed by MIPPA was reached for the first time in January 2009, we have received many reports of beneficiaries relocating prior to the end of the 36-month rental payment cap period and having difficulty finding an oxygen supplier in the new location. We have learned that many suppliers are unwilling to provide services in situations where there are a few number of months left in the 36-month rental payment period.

We do not believe that beneficiaries have encountered similar issues following the 36-month rental cap, which most likely is the result of different statutory requirements for these two periods (that is, during and after the 36-month rental period). Section 1834(a)(5)(F)(ii) of the Act requires the supplier that furnishes the oxygen equipment during the 36-month rental payment period to continue furnishing the equipment after the 36-month rental payment period. Consistent with this requirement, we established regulations at § 414.226(f)(1) that require the supplier to furnish the equipment or make arrangements for furnishing the equipment in situations where the beneficiary relocates outside the supplier's normal service area. Since no such requirement currently applies in situations where the beneficiary relocates prior to the end of the 36-month rental payment period, and in fact current regulations at § 414.226(g)(1)(ii) absolve the supplier of the obligation to continue furnishing oxygen equipment in these situations, beneficiaries are experiencing difficulties finding suppliers of oxygen equipment in their new locations that are willing to accommodate them. As noted above, we have not seen this problem in the capped rental DME context. The requirement at § 414.226(g)(1) to furnish oxygen equipment for the entire 36-month

rental cap period was established in the course of implementing section 5101(b) of the DRA in order to safeguard the beneficiary from situations where suppliers might discontinue service and pick up oxygen equipment prior to the end of the 36-month rental cap in order to avoid losing title to the equipment. As mentioned earlier, the transfer of title of oxygen and oxygen equipment after the 36th paid rental month was repealed. The exception to this rule at § 414.226(g)(1)(ii) was established based on our experience that suppliers of capped rental DME have accommodated beneficiaries in these situations, which, unfortunately, has not been our experience in the context of oxygen equipment.

In order to address this vulnerability facing beneficiaries as a result of regulations currently in effect, we proposed to revise the exception at § 414.226(g)(1)(ii) to apply only to situations where the beneficiary relocates before the 18th paid rental month to an area that is outside the normal service area of the supplier that initially furnished the equipment. We proposed to revise the regulation to require the supplier that furnishes the oxygen equipment and receives payment for month 18 or later to either furnish the equipment for the remainder of the 36-month rental payment period or, in the case where the beneficiary has relocated outside the service area of the supplier, make arrangements for furnishing the oxygen equipment with another supplier for the remainder of the 36-month rental payment period. The supplier that is required to furnish the equipment on the basis of this requirement must also furnish the equipment after the 36-month rental payment period in accordance with the requirements of section 1834(a)(5)(F)(ii) and § 414.226(f).

The proposed revision would mean that a supplier does not have to continue to furnish the oxygen equipment if the beneficiary relocates outside the normal service area before the 18th paid rental month during a period of continuous use. Under the current rule, a supplier does not have to furnish the oxygen equipment if the beneficiary relocated before the 36th paid rental month during a period of continuous use. The current rule was established based on the long term, demonstrated ability of suppliers of capped rental DME to accommodate beneficiaries in situations where they relocate near the end of a capped rental payment period.

Comment: We received a total of 8 comments on our proposal to require oxygen suppliers to continue to furnish

medically necessary oxygen equipment for the remainder of the reasonable useful lifetime of the equipment to beneficiaries who relocate on or after the 18th rental month. All the comments were opposed to the proposed requirement. Some of the commenters questioned whether the statute gives us the authority to establish this requirement before the 36th month rental payment. Others objected to the financial and coordination-of-benefits burden they believe that this requirement would cause for suppliers. Other objections were that the proposed requirement did not consider the effect on beneficiaries who relocate on a temporary basis during winter months (“snow birds”), or the access problems that it might cause in rural areas. Recommended alternatives included starting the rental period over at the time of relocation or keeping the current policy that only requires suppliers to continue furnishing oxygen equipment to beneficiaries who relocate outside of their service area if 36 rental amounts have already been paid.

Response: In addition to considering the comments on the proposed rule, we analyzed complaint data from beneficiaries from January 2009 to September 2010 which is data collected by the regional offices. In the limited situations where beneficiaries receiving oxygen equipment for less than 36 months relocated during this time and initially had trouble locating an oxygen supplier in their new location, CMS caseworkers in the CMS Regional Offices and the Office of the Medicare Beneficiary Ombudsman were able to locate suppliers to serve each and every beneficiary, usually within a matter of days. This means that, although supply arrangements and/or access to oxygen and oxygen equipment in these situations may have been briefly delayed, suppliers stepped forward to provide access to oxygen and oxygen equipment in these situations. Based on this information and certain comments received, we have decided not to finalize this proposed revision at this time. If in the future, beneficiaries' access to oxygen equipment becomes a problem following the relocation of beneficiaries, we may consider this proposal or similar proposals.

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 air ambulance accidents, the NTSB made several specific recommendations to the Secretary on September 24, 2009.

Specifically, the NTSB recommended that the Secretary develop minimum safety accreditation standards for helicopter air ambulance operators that augment the operating standards of 14 CFR 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.” The FAA proposed Federal regulations to address the NTSB’s concerns in their October 12, 2010 proposed rule (75 FR 62640) entitled “Air Ambulance and Commercial Helicopter Operations, Part 91 Helicopter Operations, and Part 135 Aircraft Operations; Safety Initiatives and Miscellaneous Amendments.”

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 the 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 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 two 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 proposed to clarify that ambulance suppliers and other providers and suppliers include documentation regarding all applicable Federal and State certifications. Accordingly we proposed 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 FAA 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.” When revoked or suspended, we are requiring that the specific pilot certifications (for example, instrumentation and medical), and the airworthiness certifications be reported. We proposed to 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 certifications. The certifications, when revoked, that need to be reported are the specific pilot certifications, such as instrument and medical certified; as well as airworthiness certificates. This revision will clarify that fixed-wing ambulance operators and helicopter air ambulance 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 helicopter air ambulance operators must maintain all requirements as specified in 14 CFR parts 91, 119, and 135.

We stated our belief that requiring fixed wing ambulance and helicopter air ambulance 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 link to the operator’s ability to maintain their Medicare enrollment. We also stated that such a policy will help improve aircraft safety for operators that are enrolled in Medicare and providing services to Medicare beneficiaries. 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 a 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. If the supplier does not self-report a licensure, certification revocation or a suspension action, then the supplier's enrollment in the Medicare program will be automatically revoked for a period of one to three years.

In § 424.502, we proposed 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 proposed that the term, "voluntary termination" means an air ambulance supplier that submits written confirmation to CMS of its decision to discontinue enrollment in the Medicare program.

Furthermore, we stated our belief 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 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.

Comment: Several comments received agreed with CMS' enrollment requirements and believe the FAA has the appropriate resources to develop, monitor, and enforce aviation or aviation safety related standards. The commenters believe that the sole authority of the FAA to regulate matters of aviation safety assures continuity in regulations and further believe any change to the authority would have serious consequences for safe operations since CMS lacks the expertise and resources to develop and enforce such standards.

Response: We agree with the commenters; and therefore, are

finalizing the proposal without modification.

Comment: Several commenters believe CMS missed an opportunity through this proposed rule to improve system safety for Medicare beneficiaries through an accreditation process.

Response: Currently, we do not have the statutory authority to establish an accreditation program for fixed-wing air ambulance operators and air ambulance operators.

Comment: Several commenters noted that the preamble language might cause confusion as stated, "fixed-wing air ambulance operators and HEMS operators must maintain all requirements as specified in 14 CFR part 135."

Response: We are clarifying that all fixed-wing air ambulance operators and helicopter air ambulance operators must adhere to all applicable FAA regulations as specified in 14 CFR parts 91, 119 and 135 or risk having their Medicare enrollment revoked or suspended.

I. Technical Corrections

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

We proposed 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. Therefore, we proposed to rectify that oversight by making an appropriate correction in the regulations text, along with other minor formatting revisions by making the following changes:

- 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.

- 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.

We did not receive public comment on this proposal; and therefore, are finalizing this proposal without modification.

2. Scope of Benefits

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 proposed correct this referencing error by making a technical correction to § 410.3(b)(2).

We did not receive public comment on this proposal; and therefore, are finalizing this proposal without modification.

J. Physician Self-Referral Prohibition: Annual Update to the List of CPT/ HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS