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(1) * * *

(2) Responses to notices of irregularity under § 7.14, requests to note replacement under § 7.28, and requests for transformation under § 7.31, when filed by mail, will be accorded the date of receipt in the Office.

(c) *Hand-Delivered Correspondence.* International applications under § 7.11, subsequent designations under § 7.21, responses to notices of irregularity under § 7.14, requests to record changes in the International Register under § 7.23 and § 7.24, requests to note replacement under § 7.28, requests for transformation under § 7.31, and petitions to the Director to review an action of the Office's Madrid Processing Unit, may be delivered by hand during the hours the Office is open to receive correspondence. Madrid-related hand-delivered correspondence must be delivered to the Trademark Assistance Center, James Madison Building—East Wing, Concourse Level, 600 Dulany Street, Alexandria, VA 22314, Attention: MPU.

* * * * *

Dated: April 9, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-1321-F2]

RIN 0938-AN84

Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Correcting Amendment

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

ACTION: Correcting amendment.

SUMMARY: This correcting amendment corrects several technical and typographical errors in the final rule with comment period that appeared in the December 1, 2006 **Federal Register** (71 FR 69624). The final rule with comment period addressed Medicare Part B payment policy, including the physician fee schedule (PFS) that is applicable for calendar year (CY) 2007; payment for covered outpatient drugs and biologicals; payment for renal dialysis services; and policies related to independent diagnostic testing facilities (IDTFs). The final rule with comment period also updated the list of certain services subject to the physician self-referral prohibitions.

DATES: Effective Date: Pursuant to section 1871(e) of the Act, except for the corrections to § 410.33, this correcting amendment is effective January 1, 2007. The corrections to § 410.33 are effective April 16, 2007.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786-3355.

SUPPLEMENTARY INFORMATION:

I. Background

FR Doc. 06-9086 (71 FR 69624), the final rule with comment period entitled "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulance Inflation Factor Update for CY 2007" (hereinafter referred to as the CY 2007 PFS final rule with comment period), contained technical and typographical errors. Some of these technical and typographical errors were addressed in the correction notice that appeared in the December 8, 2006 **Federal Register** (71 FR 58415). Additional errors have been identified in the CY 2007 PFS final rule with comment period and are addressed in this correcting amendment.

II. Errors in the Preamble

A. Summary of Errors in the Preamble

In the preamble of the CY 2007 PFS final rule with comment period, there were a number of technical errors and omissions.

On page 69635, following the section heading titled, "(vi) Equipment Cost Per Minute," there was an error in the formula for calculating the equipment cost per minute.

On page 69647, language was inadvertently omitted from the response concerning cardiac monitoring services.

On page 69654, in Table 5, "Practice Expense Supply Item Additions for CY 2007", we incorrectly included a supply item and failed to include the unit price of another item.

On page 69663, the word "an" was incorrectly typed to read "as" in two places.

On page 69671, the word "not" was incorrectly included in a sentence.

On page 69677, the word "of" was missing from a sentence.

On page 69688, under the section heading titled, "d. "ESRD Wage Index Tables," the references to addenda were incorrect.

On page 69696, the word "supplier" was misspelled.

On page 69699 in the narrative concerning revisions to the performance standards for IDTFs, we inadvertently omitted language specifying that paragraphs (g) and (h) are not applicable to those services included in § 410.33(a)(2). We also inadvertently included language requiring IDTFs to list serial numbers and that was not our intention.

On pages 69744, the narrative concerning Table 17 contained several errors.

On pages 69746, certain CPT codes were incorrectly included in Table 17.

On page 69747, we incorrectly included a discussion about gold markers for CPT code 55876.

On page 69748, the word "radiology" was incorrectly stated as "radiation."

On page 69749, the word "of" should be removed from the phrase "radiology of and certain other imaging services."

On pages 69749 and 69750, in Table 18, under the subheading, "Radiology and certain other imaging services," we made errors in the descriptors for CPT codes 0174T and 0175T and HCPCS codes A9567, A9568, Q9952, and Q9953.

On page 69750, in Table 19, we omitted CPT codes 78350 and G0243.

On page 69760, language was omitted from the formula.

On pages 69769 and 69770, in Table 36, "Impact of Final Rule with Comment Period and Estimated Physician Update on 2007 Payment for Selected Procedures", we identified errors in the new payment amounts for the following CPT and HCPCS codes: 27130, 27244, 27447, 33533, 35301, 43239, 77056, 77056-26, 77057, 77057-26, 92980, 93000, 93015 and G0317.

Corrections to these errors are reflected in section II.B. of this correcting amendment.

B. Correction of Errors in the Preamble

1. On page 69635, in the 3rd column, under the discussion titled, "(vi)

Equipment Cost Per Minute,” the calculation for the equipment cost per minute contained an error. The formula is corrected to read as follows:

“The equipment cost per minute is calculated as: (1/(minutes per year * usage)) * price * ((interest rate/(1-(1/(1+interest rate)^{life of equipment}))) + maintenance).”

2. On page 69647, in the 3rd column, in the 1st full paragraph, after the 3rd sentence, insert the following language: “We also added the holter monitor to CPT codes 93226 and 93232 and assigned the equipment a time of 1440 minutes for these codes and reduced the holter monitor equipment time for CPT codes 93225 and 93231 to 42 minutes to correspond with the clinical staff associated with these services.”

3. On page 69654, in Table 5, the supply item, “Kit, gold markers, fiducial, 3 per kit” is deleted from the table. In addition, the unit price “\$1290” for “Agent, embolic” is added to the table.

4. On page 69663, in the 2nd column, lines 5 through 12 of the third full paragraph, the language in the discussion with respect to items “(1) and (2)” is corrected to read as follows: “(1) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (IPPE) (as defined in section 1861(w)(1) of the Act); (2) who has not been previously furnished such an ultrasound screening under this title; and”.

5. On page 69671, in the 2nd column, line 24, delete the second occurrence of the word “not”. This sentence is revised to read as follows: “Given the range of comments, we do not believe it is advisable to mandate the use of the methodology, which we proposed at § 414.804(a)(4)(iii), for excluding lagged exempt sales.”

6. On page 69677, the 3rd column, line 2, insert the word “of” between “number” and “units.” The sentence is revised to read as follows: “One commenter asked that we clarify the number of units to be reported are the number of units sold excluding exempted sales.”

7. On page 69688, in the 1st column, under the section heading titled, “d. ESRD wage Index Tables,” the paragraph is revised to read as follows:

“Addenda G and H show the CY 2007 ESRD wage index, including the BNF adjustment, for urban areas (Addendum G) and rural areas (Addendum H).”

8. On page 69696, in the 1st column, 2nd paragraph, line 4, the spelling of the word “supplier” is corrected.

9. On page 69699—

a. In the 1st column, the 5th full paragraph, the following sentence is added to the end of the paragraph: “Additionally, we do not intend to require IDTFs to list the serial numbers of all diagnostic equipment used by IDTFs in their comprehensive liability insurance. We recognize that it is infeasible for IDTFs to comply with this requirement and that such a requirement would inadvertently change the comprehensive liability insurance policy into a different type of insurance policy. Therefore, we are revising the language in § 410.33(g)(6) of our regulations to remove the serial number requirement.”

b. In the 3rd column, the 2nd full paragraph, the following language is added at the end of the paragraph: “In addition, we are clarifying that these performance standards are not applicable to the diagnostic tests listed under the exceptions in § 410.33(a)(2).”

10. On page 69744, in the 3rd column, in the paragraph following the section heading, “F. Additional Pricing Issue,” the narrative concerning the table is corrected to read as follows:

“We are carrier-pricing the global and TC for the codes listed in Table 17. The TC is not paid in the facility setting under the PFS and for the majority of these services the RUC recommended that these be designated as NA in the non-facility setting. Work RVUs will continue to be used to establish payment for the PC.”

11. On page 69746, the following CPT codes are deleted from Table 17: 93503, 93539, 93540, 93541, 93542, 93543, 93544 and 93545.

12. On page 69747, the 1st column, the final paragraph that continues into the 2nd column is removed in its entirety.

13. On page 69748, in the 1st column, the 3rd paragraph, line 4, the word, “radiation” is corrected to read as, “radiology.”

14. On page 69749, in the 1st column, the 1st full paragraph, line 4, in the

phrase, “radiology of and certain other imaging services,” delete the word, “of.” The phrase is corrected to read “radiology and certain other imaging services.”

15. On pages 69749 and 69750, in Table 18, the following descriptors are corrected as follows:

TABLE 18.—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT¹/HCPCS CODES

Radiology and Certain Other Imaging Services	
0174T	Cad cxr with interp.
0175T	Cad cxr remote.
A9567	Technetium TC-99m aerosol.
A9568	Technetium tc99m arcitumomab.
Q9952	Inj Gad-base MR contrast, 1ml.
Q9953	Inj Fe-base MR contrast, 1ml.

¹ CPT codes and descriptions only are copyright 2006 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

16. On page 69750, in Table 19, the following CPT and HCPCS codes and their descriptors are added:

TABLE 19.—DELETIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT¹/HCPCS CODES

Radiation and Certain Other Imaging Services	
78350	Bone mineral, single photon.

Radiation Therapy Services and Supplies	
G0243	Multisour photon stereo treat.

¹ CPT codes and descriptions only are copyright 2006 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

17. On page 69760, the payment formula at the top of the 3rd column is corrected to read as follows:

“(((Work RVU × BN adjustor (0.8994)) (round product to two decimal places) × Work GPCI) + (PE RVU × PE GPCI) + (MP RVU × MP GPCI)) × CF.”

18. On pages 69769 through 69770 in Table 36, the following corrections are made:

TABLE 36.—IMPACT OF FINAL RULE WITH COMMENT PERIOD AND ESTIMATED PHYSICIAN UPDATE ON 2007 PAYMENT FOR SELECTED PROCEDURES

CPT/HCPCS	MOD	Description	FACILITY			NON-FACILITY		
			OLD	NEW	Percent change	OLD	NEW	Percent change
27130		Total hip arthroplasty	\$1,399.55	\$1,292.21	-8%	\$1,399.55	na	na
27244		Treat thigh fracture	\$1,137.68	\$1,045.36	-8%	\$1,137.68	na	na
27447		Total knee arthroplasty	\$1,511.35	\$1,391.17	-8%	\$1,511.35	na	na
33533		CABG, arterial, single	\$1,933.53	\$1,812.55	-6%	\$1,933.53	na	na
35301		Rechanneling of artery	\$1,128.97	\$1,018.01	-10%	\$1,128.97	na	na
43239		Upper GI endoscopy, biopsy	\$162.20	\$147.18	-9%	\$334.26	\$309.11	-8%
77056		Mammogram, both breasts	\$97.40	na	na	\$97.40	\$92.48	-5%
77056	26	Mammogram, both breasts	\$45.10	\$39.22	-13%	\$45.10	\$39.22	-13%
77057		Mammogram, screening	\$85.65	na	na	\$85.65	\$77.73	-9%
77057	26	Mammogram, screening	\$36.38	\$31.67	-13%	\$36.38	\$31.67	-13%
92980		Inser intracoronary stent	\$830.71	\$756.04	-9%	\$830.71	na	na
93000		Electrocardiogram, complete	\$26.91	na	na	\$26.91	\$23.39	-13%
93015		Cardiovascular stress test	\$108.01	na	na	\$108.01	\$99.32	-8%
G0008		Admin influenza virus vac	na	na	na	\$18.57	\$18.35	-1%
G0317		ESRD related svcs 4+mto 20+yrs.	\$308.11	\$268.11	-13%	\$308.11	\$268.11	-13%

III. Errors in the Regulation Text

A. Summary of Errors in the Regulation Text

On page 69784, in § 410.33, we erroneously omitted a cross-reference in (a)(2) to include paragraphs (g) and (h). In addition, in § 410.33(g), Application certification standards, an editing error resulted in language being included on page 69785 in § 410.33(g)(6) that required IDTFs to list the serial numbers of all their diagnostic equipment in their comprehensive liability insurance policy.

On page 69785, § 411.15(o) contained erroneous revisions. Due to an editing error, changes to § 411.15(o) were improperly included in the August 22, 2006 proposed rule (71 FR 49081). There was no explanation given for these changes in the preamble, no public comments were received on the proposed changes, and the changes to the regulation text were inadvertently included in the final rule without any explanation. The erroneous language suggests that Medicare may pay for a category A device in certain clinical trials. Currently, however, the statute does not authorize payment for the costs of the category A device, but only for "routine costs of care" (section 1862(m) of the Act; § 405.207(b)(2)). Thus, we are correcting this final rule by restoring the language in § 411.15(o) to the language from the 2006 version of the CFR.

On pages 69787 and 69788, language was incorrectly included concerning

non-lagged price concessions in the example.

B. Correction of Errors in the Regulation Text

The correction of errors for the regulation text appear after section V. of this correcting amendment.

IV. Errors in the Addenda

A. Summary of Errors in the Addenda

The following errors in Addenda B, G and J are revised under this correcting amendment. These addenda will not appear in the Code of Federal Regulations.

In Addendum B, pages 69796 through 70011, we are making the following corrections:

(1) Incorrect RVUs were listed for the following CPT codes: 36478, 37210, 44180, 44186, 77056, 77056-TC, 77422, 77423, 78351, 93225, 93226, 93231, 93232, 95991, 98960, 98961, 98962, G9041, G9042, G9043 and G9044.

(2) Incorrect status indicators and RVUs were listed for CPT codes 93503, 93539, 93540, 93541, 93542, 93543, 93544 and 93545.

In Addendum G, pages 70022 through 70043, we are making the following corrections:

(1) The title of the Addendum was missing a word.

(2) On page 70037, the wage index value for CBSA code "39820, Redding CA" was incorrect.

In Addendum J, pages 70248 through 70251, we note the following errors:

(1) On page 70247, CPT codes 78267 and 78268 are not in numerical order.

(2) On page 70248, in the 2nd column, we made typographical errors in the code descriptors for CPT codes 0174T and 0175T.

(3) On page 70250, in the 1st column, we incorrectly listed CPT code 78350. That code (single-photon absorptiometry) is non-covered beginning in 2007 under the policy changes discussed on page 69691 of the CY 2007 PFS final rule with comment period.

(4) On page 70250, in the 3rd column, we made typographical errors in the descriptors for HCPCS codes A9567, A9568, Q9952, and Q9953.

(5) On page 70251, in the 2nd column, we did not include the correct descriptor for HCPCS code G0173. Also, in that column, we incorrectly included HCPCS G0243, which was terminated effective December 31, 2006.

(6) On page 70251, in the second footnote at the bottom of the page, we gave an incorrect Web site address.

These corrections are reflected in section IV.B. of this correcting amendment.

B. Correction of Errors in Addenda

1. On pages 69796 through 70011, in Addendum B: Relative Value Units (RVUs) and Related Information the following entries are corrected to read as follows:

ADDENDUM B.—RELATIVE VALUE UNITS (RVUS) AND RELATED INFORMATION—CORRECTIONS

CPT-1/ HCPCS ²	Mod	Status	Description	Physician Work RVUs ³	Fully Im- plemented Non-Facil- ity PE RVUs	Year 2007 Transi- tional Non- Facility PE RVUs	Fully Im- plemented Facility PE RVUs	Year 2007 Transi- tional Fa- cility PE RVUs	Mal-Prac- tice RVUs	Fully Im- plemented Non-Facil- ity Total	Year 2007 Transi- tional Non- Facility Total	Fully Im- plemented Facility Total	Year 2007 Transi- tional Fa- cility Total	Global
36478	A	Endovenous laser, 1st vein.	6.72	26.53	41.71	2.03	2.41	0.37	33.62	48.80	9.12	9.50	000
37210	A	Embolization uterine fibroid.	10.60	79.88	79.88	3.13	3.13	0.60	91.08	91.08	14.33	14.33	000
44180	A	Lap, enterolysis	15.19	NA	NA	5.65	6.09	1.86	NA	NA	22.70	23.14	090
44186	A	Lap, jejunostomy	10.30	NA	NA	4.43	4.70	1.27	NA	NA	16.00	16.27	090
77056	A	Mammogram, both breasts.	0.87	1.96	1.68	NA	NA	0.11	2.94	2.66	NA	NA	XXX
77056 ..	TC ..	A	Mammogram, both breasts.	0.00	1.72	1.41	NA	NA	0.07	1.79	1.48	NA	NA	XXX
77422	A	Neutron beam tx, simple	0.00	5.31	2.61	NA	NA	0.13	5.44	2.74	NA	NA	XXX
77423	A	Neutron beam tx, complex.	0.00	7.51	3.57	NA	NA	0.13	7.64	3.70	NA	NA	XXX
78351	N	Bone mineral, dual photon.	0.30	0.47	1.41	0.07	0.11	0.01	0.78	1.72	0.38	0.42	XXX
93225	A	ECG monitor/record, 24 hrs.	0.00	0.85	1.14	NA	NA	0.08	0.93	1.22	NA	NA	XXX
93226	A	ECG monitor/report, 24 hrs.	0.00	1.18	1.93	NA	NA	0.14	1.32	2.07	NA	NA	XXX
93231	A	Ecg monitor/record, 24 hrs.	0.00	0.71	1.32	NA	NA	0.11	0.82	1.43	NA	NA	XXX
93232	A	ECG monitor/report, 24 hrs.	0.00	1.34	1.97	NA	NA	0.13	1.47	2.10	NA	NA	XXX
93503	A	Insert/place heart catheter.	2.91	NA	NA	0.47	0.63	0.20	NA	NA	3.58	3.74	000
93539	A	Injection, cardiac cath	0.40	NA	NA	0.22	0.18	0.01	NA	NA	0.63	0.59	000
93540	A	Injection, cardiac cath	0.43	NA	NA	0.24	0.19	0.01	NA	NA	0.68	0.63	000
93541	A	Injection for lung angiogram.	0.29	NA	NA	0.15	0.12	0.01	NA	NA	0.45	0.42	000
93542	A	Injection for heart x-rays	0.29	NA	NA	0.15	0.12	0.01	NA	NA	0.45	0.42	000
93543	A	Injection for heart x-rays	0.29	NA	NA	0.16	0.12	0.01	NA	NA	0.46	0.42	000
93544	A	Injection for aortography	0.25	NA	NA	0.13	0.11	0.01	NA	NA	0.39	0.37	000
93545	A	Inject for coronary x-rays	0.40	NA	NA	0.22	0.18	0.01	NA	NA	0.63	0.59	000
95991	A	Spin/brain pump refill & main.	0.77	1.63	1.53	0.18	0.17	0.06	2.46	2.36	1.01	1.00	XXX
98960	B	Self-mgmt educ & train, 1 pt.	0.00+	0.57	0.57	NA	NA	0.01	0.58	0.58	NA	NA	XXX
98961	B	Self-mgmt educ/train, 2-4 pt.	0.00+	0.27	0.27	NA	NA	0.01	0.28	0.28	NA	NA	XXX
98962	B	Self-mgmt educ/train, 5-8 pt.	0.00+	0.20	0.20	NA	NA	0.01	0.21	0.21	NA	NA	XXX
G9041	A	Low vision rehab occupationa.	0.44	0.29	0.29	0.29	0.29	0.01	0.74	0.74	0.74	0.74	XXX
G9042	A	Low vision rehab orient/mobi.	0.10	0.29	0.29	0.29	0.29	0.01	0.40	0.40	0.40	0.40	XXX
G9043	A	Low vision lowvision therapi.	0.10	0.29	0.29	0.29	0.29	0.01	0.40	0.40	0.40	0.40	XXX
G9044	A	Low vision rehabilitate teache.	0.10	0.23	0.23	0.23	0.23	0.01	0.40	0.40	0.40	0.40	XXX

¹ CPT codes and descriptions only are copyright 2006 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
³ + Indicates RVUs are not used for Medicare payment.

2. On pages 70022 through 70043, the title of Addendum G is corrected to read as follows: "CY 2007 ESRD WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS."

3. On page 70037, the wage index value for CBSA code 39820, Redding CA is corrected to read "1.3895".

4. In Addendum J:

a. On page 70247, in the 3rd column, the entries for CPT codes 78267 and 78268 and their respective descriptors are corrected by placing them in numerical order.

b. On page 70248, in the 2nd column, the descriptors for CPT codes 0174T and 0175T are corrected by revising "crx" to read "cxr".

c. On page 70250, in the 1st column, the entry for CPT code 78350 is removed.

d. On page 70250, in the 3rd column, the descriptors for HCPCS codes A9567, A9568, Q9952 and Q9953 are corrected to read as follows:

ADDENDUM J.—LIST OF CPT¹/HCPCS CODES USED TO DESCRIBE CERTAIN DESIGNATED HEALTH SERVICE CATEGORIES² UNDER SECTION 1877 OF THE SOCIAL SECURITY ACT
[Effective Date January 1, 2007]

RADIATION THERAPY SERVICES AND SUPPLIES

CPT code	Descriptor
A9567	Technetium TC-99m aerosol.
A9568	Technetium tc99m arcitumomab.
Q9952	Inj Gad-base MR contrast, 1ml.
Q9953	Inj Fe-base MR contrast, 1ml.

¹ CPT codes and descriptions only are copyright 2006 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

² This list does not include codes for the following designated health service (DHS) categories: 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; and inpatient and outpatient hospital services. For the definitions of these DHS categories, refer to §411.351. For more information, refer to <http://cms.hhs.gov/PhysicianSelfReferral/>.

e. On page 70251, in the 2nd column, the descriptor for HCPCS code G0173 is corrected to read, "Linear acc stereo radsur com", and HCPCS code G0243 and its descriptor are removed.

f. On page 70251, in the 3rd column, the Web site in the last sentence of the second footnote is corrected to read <http://www.cms.hhs.gov/PhysicianSelfReferral/>.

V. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal**

Register to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive the notice and comment procedures if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule.

Section 553(d) of the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

This correcting amendment addresses technical errors and omissions made in FR Doc. 06-9086, entitled "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulance Inflation Factor Update for CY 2007," which appeared in the December 1, 2006 **Federal Register** (71 FR 69624), and was effective January 1, 2007. This correcting amendment identifies errors and technical correction that are in addition to those identified in the correction notice that appeared in the December 8, 2006 **Federal Register** (71 FR 58415). The provisions of this final rule with comment period have been previously subjected to notice and comment procedures. Except as noted below, these corrections are consistent with the discussion and text of the final rule with comment period, and do not make substantive changes to the CY 2007 published rule. As such, this correcting amendment is intended to ensure the CY 2007 PFS final rule with comment period accurately reflects the policies adopted in that rule. With respect to most of the corrections in this correcting amendment, we find, therefore, that it is unnecessary and would be contrary to the public interest to undertake further notice and comment procedures to incorporate these corrections into the final rule with comment period.

Except as noted below, for the same reasons, we are also waiving the 30-day delay in effective date for this correcting

amendment. We believe that it is in the public interest to ensure that the CY 2007 PFS final rule with comment period accurately states our policies relating to the PFS and other Part B payment policies. Therefore, except as noted otherwise, we find that delaying the effective date of these corrections beyond the January 1, 2007 effective date of the final rule with comment period would be contrary to the public interest. In so doing, we also find good cause to waive the 30-day delay in the effective date.

With respect to the corrections to pages 69699 and 69785 concerning revisions to the performance standards for IDTFs, we find that it would be impracticable and contrary to the public interest to seek public comments before correcting this regulation. The current regulatory language is erroneous because it would require IDTFs to list the serial numbers for all diagnostic equipment in its comprehensive liability insurance policy. This requirement would be impracticable for several reasons. For one, most IDTFs would be unable to comply with this requirement because only some of their diagnostic equipment is onsite. Secondly, this requirement would have the unintended effect of changing the comprehensive liability insurance policy into a different type of insurance policy. For the same reasons, we are waiving the 30-day delay in effective date for these corrections. The corrections to pages 69699 and 69785 concerning revisions to the performance standards for IDTFs are effective April 16, 2007.

With respect to the corrections to §411.15(o), we find it would be contrary to the public interest to seek public comments before correcting this regulation. The current regulatory language is erroneous and misleading for it suggests that Medicare payment could be made for certain category A devices for which questions of safety and effectiveness have not been resolved (§405.201). Moreover, payment for category A devices in these circumstances would be inconsistent with Congressional intent in enacting section 1862(m) of the Act. Section 1871(e)(1)(A) of the Act, as amended by section 903(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), generally prohibits the Secretary from making retroactive substantive changes in policy unless retroactive application of the change is necessary to comply with statutory requirements, or failure to apply the change retroactively would be contrary to the public interest. We are making the

corrections to § 411.15(o) retroactive because failure to apply the change retroactively to January 1, 2007 would be contrary to the public interest because it would fail to preserve the public fisc. *OPM v. Richmond*, 496 U.S. 414 (1990). Moreover, retroactivity is necessary to comply with statutory requirements in section 1862(m) of the Act which did not authorize payment for category A devices.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 5, 2007.

Ann C. Agnew,

Executive Secretary to the Department.

■ Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395m, and 1395hh).

Subpart B—Medical and Other Health Services

■ 2. Section 410.33 is amended by—

- A. Revising paragraph (a)(2).
- B. Revising paragraph (g)(6).

The revisions read as follows:

§ 410.33 [Amended]

(a) * * *

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.

* * * * *

(g) * * *

(6) Have a comprehensive liability insurance policy of at least \$300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 is amended to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social

Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

Subpart A—General Exclusions and Exclusion of Particular Services

■ 4. Section 411.15 is amended by revising paragraph (o) to read as follows:

§ 411.15 [Amended]

* * * * *

(o) Experimental or investigational devices, except for certain devices.

(1) Categorized by the FDA as a non-experimental/investigational (Category B) device defined in § 405.201(b) of this chapter; and

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 5. The authority citation for Part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

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

■ 6. Section 414.804(a)(3)(iv) is revised to read as follows:

§ 414.804 [Amended]

(a) * * *

(3) * * *

(iv) *Example.* After adjusting for exempted sales, the total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal \$200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals \$600,000. The lagged price concessions percentage for this period equals 200,000/600,000 = 0.33333. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported, equals \$50,000 for 10,000 units sold. The manufacturer’s average sales price calculation for this National Drug Code for this quarter is: \$50,000 – (0.33333 × \$50,000) = \$33,334 (net total sales amount); \$33,334/10,000 = \$3.33 (average sales price).

* * * * *

[FR Doc. E7–6989 Filed 4–13–07; 8:45 am]

BILLING CODE 4120–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 801

Public Availability of Information

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Final rule.

SUMMARY: The NTSB is updating its regulations regarding the availability of information. This amendment updates the NTSB regulations that implement the Freedom of Information Act (FOIA) and Privacy Act, notifies the public of changes in the NTSB’s Freedom of Information Act processing procedures and, in general, advises the public on the availability of information from NTSB accident investigations.

DATES: This final rule will become effective May 23, 2007.

ADDRESSES: A copy of the notice of proposed rulemaking (NPRM), published in the **Federal Register**, is available for inspection and copying in the Board’s public reading room, located at 490 L’Enfant Plaza, SW., Washington, DC 20594–2000. Alternatively, a copy of the NPRM is available on the Board’s Web site, at <http://www.nts.gov>.

FOR FURTHER INFORMATION CONTACT: Gary L. Halbert, General Counsel, (202) 314–6080.

SUPPLEMENTARY INFORMATION:

Regulatory History

On November 22, 2006, the NTSB published a notice of proposed rulemaking entitled, “Public Availability of Information,” in the **Federal Register** (71 FR 67523). This NPRM set forth amendments to the Board’s regulations regarding the availability of information, and provided updated information regarding how the public may obtain NTSB records. The NPRM also set forth an updated fee schedule to apply to requests for NTSB records.

Discussion of Comments and Changes

The NTSB did not receive any comments regarding the aforementioned NPRM. The NTSB also did not receive any requests for a public meeting; therefore, the NTSB did not hold a public meeting on the NPRM.

In the interest of ensuring that all provisions of 49 CFR part 801 are accurate and complete, the Board’s final rule herein will include one minor revision to § 801.60(a) that the NTSB did not include in the NPRM: In the final sentence of § 801.60(a), the rule will now advise requesters to “pay fees in accordance with the instructions