

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 419**

**[CMS-1371-IFC]**

**RIN 0938-AM96**

**Medicare Program; Hospital Outpatient Prospective Payment System  
Payment Reform for Calendar Year 2004**

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

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (DIMA) of 2003 that affect the Medicare outpatient prospective payment system (OPPS) that become effective January 1, 2004. Sections 303 and 621 of the DIMA include provisions that alter the methods for drug payment in hospital outpatient departments, some of which become effective January 1, 2004. These provisions affect the methodology for paying for pass-through and non-pass-through drugs under the OPPS. Further, the new law includes a requirement that all brachytherapy sources be paid separately. Section 411 of the DIMA reinstates the hold-harmless protection for small rural

hospitals with fewer than 100 beds and extends that protection to sole community hospitals in rural areas.

**DATES:** Effective date: January 1, 2004.

Comment date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on [Insert 60 days after the date of publication].

**ADDRESSES:** In commenting, please refer to file code CMS-1371-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,

Attention: CMS-1371-IFC,  
P.O. Box 8018,  
Baltimore, MD 21244-8018.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201, or  
Room C5-14-03,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

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

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

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

**FOR FURTHER INFORMATION CONTACT:**

Dana Burley, (410) 786-0378.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call (410) 786-7195.

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## **I. Background**

### A. Authority for the Outpatient Prospective Payment System

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted on December 21, 2000, made further

changes in the OPSS. The OPSS was first implemented for services furnished on or after August 1, 2000.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) (Pub. L. 108-173), enacted on December 8, 2003, made additional changes to the Act relating to the OPSS and calendar year 2004 payment rates to be implemented January 1, 2004.

We would ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We find good cause to waive notice and comment procedures for this correction notice as set forth in section IV, "Waiver of Proposed Rulemaking and Waiver of 30-Day Delay in the Effective Date," below.

#### B. Summary of Relevant Provisions of the DIMA

The DIMA, enacted December 8, 2003, made the following changes to the Act that relate to the OPSS:

##### 1. Transitional Corridor Payments Extended

Section 411 of the DIMA amends section

1833(t)(7)(D)(i) of the Act and extends the hold-harmless provision for small rural hospitals. The hold harmless transitional corridor payments will continue through December 31, 2005 for small rural hospitals having 100 or fewer beds. Section 411 of the DIMA further amends section 1833(t)(7) of the Act to provide that hold-harmless transitional corridor payments shall apply to sole community hospitals as defined in section 1886(d)(5)(D)(iii) of the Act and will continue through December 31, 2005.

## 2. Payment for "specified covered outpatient drugs"

Section 621(a)(1) of the DIMA amends the Act by adding section 1833(t)(14) that requires classification of separately paid radiopharmaceutical agents and drugs or biologicals that had transitional pass-through status on or before December 31, 2002, into 3 categories: innovator multiple source drugs; noninnovator multiple source drugs; and sole source drugs. Payment levels based on the reference average wholesale price are specified for each category.

## 3. Payment for drug or biological before HCPCS code assigned

Section 621(a)(1) of the DIMA amends the Act by adding section 1833(t)(15), which requires that payment be made at 95

percent of the average wholesale price (AWP) for new drugs and biologicals until a HCPCS code is assigned.

#### 4. Payment for pass-through drugs

Section 303(b) of the DIMA amends section 1842(o) of the Act. As a result, certain pass-through drugs are to be paid at 95 percent, and others at 85 percent, of the AWP. Drugs and biologicals furnished during 2004 for which pass-through payment was first made on or after January 1, 2003 (which removes them from application of section 621 of the DIMA) and were approved by the FDA for marketing as of April 1, 2003, will be paid 85 percent of AWP pursuant to section 1842(o)(1)(B) and 1842(o)(4)(A), unless sections 1842(o)(4)(B), (C) or (D) apply. Blood clotting factors furnished during 2004, drugs or biologicals furnished during 2004 that were not available for payment as of April 1, 2003, vaccines furnished on or after January 1, 2004, and drugs or biologicals furnished during 2004 in connection with the renal dialysis services if billed by renal dialysis facilities, are paid at 95 percent of the reference AWP. Drugs or biologicals that were paid on a pass-through basis under the OPPS on or after January 1, 2003 and that were available for payment as of April 1, 2003 are paid at

85 percent of the reference AWP rather than 95 percent as was previously the policy under section 1842(o) of the Act.

5. Exclude separately payable drugs and biologicals from outlier payments

Section 621(a)(3) amends section 1833(t)(5) of the Act to require that separately paid drugs and biologicals be excluded from outlier payments.

6. Brachytherapy sources are to be paid separately

Section 621(b) amends the Act by adding section 1833(t)(16)(C) which requires that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) be paid based on the hospital's charge for each device adjusted to cost. Also included in the new provision is a requirement that all such brachytherapy sources be excluded from outlier payments.

**Payment methodology that applied prior to enactment:**

In the hospital outpatient prospective payment update final rule published in the **Federal Register** on November 7, 2003, CMS announced payments for 2004 under the Medicare hospital outpatient prospective payment system (68 FR 63398). The provisions of that final rule with regard to payment for brachytherapy sources, for separately payable drugs, biologicals and radiopharmaceutical agents and for pass-through drugs and

biologicals is superceded in part with enactment of the DIMA, effective for services furnished on or after January 1, 2004. This interim final rule with comment presents the payment amounts that apply in 2004 that result from the changes made by DIMA.

The following is a summarization of the payment policies that we published for the 2004 OPSS before enactment of the new law.

Drugs and biologicals that were within the 2-3 year pass-through payment period were paid amounts as specified in section 1842(o) of the Act. Under the November 7 final rule, that payment was 95 percent of AWP.

Under the provisions of the November 7 OPSS final rule, payment for non-pass-through drugs, biologicals and radiopharmaceutical agents with per day median costs greater than \$50 was based on data compiled from hospital claims submitted on or after April 1, 2002 through December 31, 2002. Those data were used to set median costs which were converted to relative weights, scaled for budget neutrality, and multiplied by the 2004 conversion factor, the same methodology used to set relative weights for procedural ambulatory payment classifications (APCs) under the OPSS. A detailed discussion of

the rate setting methodology for the 2004 OPPS update is provided in the November 7, 2003 final rule (68 FR 63416).

Payment for drugs, biologicals and radiopharmaceutical agents that had per day median costs less than \$50 and drugs, biologicals and radiopharmaceutical agents for which there was no HCPCS code, was included in the rate for the service in which the item was used. There were no separate payments for these drugs, biologicals and radiopharmaceutical agents.

#### **Changes Required Under the DIMA**

1. Changes in Payment for "specified covered outpatient drugs": radiopharmaceutical agents and drugs or biologicals that were paid as pass-throughs under the OPPS on or before December 31, 2002

The DIMA amends the Act by adding section 1833(t)(14) which states that payment for specified covered outpatient drugs is to be based on its "reference average wholesale price," that is, the average wholesale price for the drug as determined under section 1842(o) of the Act as of May 1, 2003 (1833(t)(14)(G)).

Under new section 1833(t)(14)(B)(i) a "specified covered outpatient drug" is a covered outpatient drug as defined in 1927(k)(2) of the Act, for which a separate ambulatory payment classification group (APC) exists and that is a

radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions, which are not included in the definition of "specified covered outpatient drugs." These exceptions are the following:

- A drug or biological for which payment is first made on or after January 1, 2003 under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(i) specifies payment limits for 3 categories of "specified covered outpatient drugs" in 2004. Section 1833(t)(14)(F) defines the 3 categories of "specified covered outpatient drugs" based on sections 1861(t)(1) and 1927(k)(7)(A)(ii), (iii) and (iv) of the Act. The categories of drugs are "sole source drugs", "innovator multiple source drugs" and "noninnovator multiple source drugs."

2. Definitions and payment rates for DIMA-specified categories for drugs, biologicals, and radiopharmaceutical agents

Section 1927(k) of the Act pertains to the Medicaid drug rebate program. In order to administer the Medicaid drug rebate program, CMS gathers information from manufacturers and classifies drugs into categories that are defined in sections 1927(k)(7)(A)(ii), (iii) and (iv) of the Act. We are using these category designations to guide our classification of covered OPPS drugs in order to implement the changes in payment under the OPPS that are required by DIMA in section 1833(t)(14) of the Act. The classifications are listed in the Medicaid average manufacturer price (AMP) database, which can be found at [www.cms.gov/medicaid/drugs/drug6.asp](http://www.cms.gov/medicaid/drugs/drug6.asp). In cases when the AMP database does not provide a classification for an affected drug or biological, we relied on our clinical and pharmaceutical experts to determine the appropriate classification. Further, when there are conflicting or incomplete designations in the AMP, we assigned drugs to the noninnovator multiple-source category for payment effective January 1, 2004, until we can resolve the conflicts and make a definitive classification. Classification changes will be implemented April 1, 2004 effective for services furnished on or after January 1, 2004.

We invite comments regarding the appropriate classification of the drugs listed in Table 2.

The Medicaid AMP database is updated on a quarterly basis. However, we believe that midyear changes in the classification of drugs could be confusing and burdensome for providers to administer. Therefore, the final category designations used to determine 2004 OPPS drug payments for the "specified covered outpatient drugs" to which section 1833(t)(14)(A)(i) of the Act applies, will remain in effect through December 31, 2004. We will update the category designations through rulemaking as part of the annual OPPS update for 2005.

The sole source category is defined in section 1833(t)(14)(F)(i) of the Act as a biological product (as defined under section 1861(t)(1) of the Act) or a single source drug (as defined in section 1927(k)(7)(A)(iv)) of the Act). Section 1927(k)(7)(A)(iv) of the Act defines the term "single source drug" to mean a covered outpatient drug which is produced or distributed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Based on this definition, in effect, single source drugs are brand name drugs for which

there is no FDA generic approval, and the term is used interchangeably with "sole source drug" in this preamble.

Section 621(a) of the DIMA, amends the Act by adding section 1833(t)(14)(A)(i)(I), which provides that a sole source drug shall, in 2004, be paid no less than 88 percent and no more than 95 percent of the reference AWP.

Innovator multiple source drugs are defined in section 1833(t)(14)(F)(ii) of the Act according to the definition provided in section 1927(k)(7)(A)(ii) of the Act. Section 1927(k)(7)(A)(ii) of the Act defines an innovator multiple source drug as a multiple source drug that was originally marketed under an original NDA approved by the FDA. Under this definition, these drugs were originally sole source drugs for which FDA subsequently approved a generic alternative(s). An innovator multiple source drug first must be a sole source drug.

Section 621(a) of the DIMA, amends the Act by adding section 1833(t)(14)(A)(i)(II), which provides that an innovator multiple source drug shall, in 2004, be paid no more than 68 percent of the reference AWP.

Section 1833(t)(14)(F)(III) defines a noninnovator multiple source drug according to the definition of the term in 1927(k)(7)(A)(iii). Section 1927(k)(7)(A)(iii) defines

noninnovator multiple source drug as a multiple source drug that is not an innovator multiple source drug. Under this definition, noninnovator multiple source drugs are, in effect, generic drugs approved by the FDA.

Section 621(a) of the DIMA, amends the Act by adding section 1833(t)(14)(A)(i)(III), which provides that a noninnovator multiple source drug shall, in 2004, be paid no more than 46 percent of the reference AWP.

There are several drugs that are classified in the AMP database as qualifying for all three categories. A drug that meets the criteria for all 3 categories has FDA approval as an innovator drug. A generic version of the drug, the noninnovator, also has received FDA approval. In addition, there is an FDA approval for a different indication for use under a different NDA for which the drug is the sole source. When a single drug, biological or radiopharmaceutical agent that meets the definition of a single HCPCS code qualifies for all of the 3 categories in the AMP file, we are recognizing the product only as an innovator multiple source and noninnovator multiple source drug. That is, once a drug qualifies as a multiple source drug, we will not recognize it as a sole source drug for payment under the OPSS. We believe that it would be impossible

to operationalize a system in which the same drug would be paid differently according to the clinical indication for its use. Medicare makes payment for a drug or biological that is reasonable and necessary to treat an illness or disease. Medicare does not base payment for drugs and biologicals according to their indicated uses, except when required by a national coverage decision. Further, to do so would circumvent the payment limitation that the law requires for drugs, biologicals and radiopharmaceutical agents that have generic competition by allowing payment for a drug that has generic competition at the sole source rate (88 to 95 percent of AWP) rather than at the limit for innovator multiple source (68 percent of AWP) or noninnovator multiple source (46 percent of AWP) drugs.

### 3. Definition of "reference AWP" and determination of payment amounts.

Section 1833(t)(14)(G) of the Act defines reference AWP as the AWP determined under section 1842(o) as of May 1, 2003. We interpret this to mean the AWP set under the CMS single drug pricer (SDP) based on prices published in the Red Book on May 1, 2003.

We determined the payment amount for specified covered outpatient drugs under the provisions of the DIMA by comparing the payment amount calculated under the median cost methodology in effect prior to enactment of the DIMA to the percentages specified in new section 1833(t)(14)(A) of the Act.

Specifically, for sole source drugs, we compared the payments established in the November 7, 2003 final rule for the HCPCS code for the drug to its reference AWP. When the payment fell below 88 percent of the reference AWP, we increased the payment to 88 percent of the reference AWP. When the payment exceeded 95 percent of the reference AWP, we reduced the payment to 95 percent of the reference AWP. When the payment was no lower than 88 percent and no higher than 95 percent of reference AWP, we made no change. To receive payment for sole source drugs on or after January 1, 2004, hospitals should continue to bill the appropriate HCPCS code for the drug. Table 1 lists the payment amounts for sole source drugs, biologicals and radiopharmaceutical agents effective January 1, 2004 through December 31, 2004.

There are a few drugs for which we cannot find an AWP rate. We are working to resolve this on a case-by-case basis for each of the drugs. The drugs are: Technetium TC 99M Sodium

Glucosheptonate (C1200), Cobalt Co 57 cobaltous chloride (C9013), I-131 tositumomab, diagnostic (C1080) and I-131 tositumomab, therapeutic (C1081).

With regard to C1080 and C1081, there is no AWP available because this drug did not receive FDA approval until June, 2003 and so could not be in the May 1, 2003 **Red Book** (AWP) that we have identified as the source of the reference AWP. We presented an in-depth discussion of our policy for payment of this drug, Bexxar, in our November 7 final rule. In that rule we explain our rationale for making payment for Bexxar parallel to that for another radiopharmaceutical called Zevalin. In order to set the payment rate for Bexxar in accordance with DIMA, we also have adhered to the policy regarding the pricing of Bexxar established in the November 7 final rule.

For the remaining drugs for which we could not identify a May 1, 2003 AWP amount, we will continue our research to find an AWP. If we are able to identify the AWP established on dates other than May 1, 2003, we will use whichever is closest to May 2003. In the interim, we will implement the payment rates published in the November 7 final rule to make payments for these drugs for January 1, 2004 through March 31, 2004. We will

address our findings regarding development of payment rates for these drugs in our April update.

APC 9024 is made up of 3 sole source drugs: Amphotericin B lipid complex (J0287); Amphotericin B cholesteryl sulfate (J0288); and Amphotericin B liposome injection (J0289). To comply with the statute, these 3 drugs must all be paid separately under the OPPS and that will require that we create an APC for each of the drugs. Due to the limited time available to implement the changes required for January 1, 2004, we will not be able to implement the new APCs until April 1, 2004. We will continue to pay for these drugs in APC 9024 at the rate published in the November 7 final rule. The new APCs will be implemented April 1, 2004 and will be effective for services furnished on or after January 1, 2004.

**Table 1 Sole Source Drugs**

<b>HCPCS</b>	<b>Status Indicator</b>	<b>Description</b>	<b>APC</b>	<b>OPPS CY 2004 November 7, 2003 rate</b>	<b>DIMA Final rate</b>
A4642	K	Satumomab pentetide per dose	0704	\$124.46	\$1,474.00
A9500	K	Technetium TC 99m sestamibi	1600	\$64.28	\$112.73
A9502	K	Technetium TC99M tetrofosmin	0705	\$58.06	\$665.28

A9507	K	Indium/111 capromab pendetid	1604	\$687.71	\$2,030.60
A9511	K	Technetium TC 99m depreotide	1095	\$37.87	\$704.00
A9521	K	Technetiumtc-99m exametazine	1096	\$210.65	\$825.00
A9524	K	Iodinated I-131 serumalbumin, per 5uci	9100	\$0.36	\$48.58
A9600	K	Strontium-89 chloride	0701	\$402.85	\$892.43
C1079	K	CO 57/58 per 0.5 uCi	1079	\$68.51	\$235.14
C1080	K	I-131 tositumomab, dx	1080	\$2,260.00	\$2,565.55
C1081	K	I-131 tositumomab, tx	1081	\$19,565.00	\$22,210.19
C1082	K	In-111 ibritumomab tiuxetan	9118	\$2,260.00	\$2,565.55
C1083	K	Yttrium 90 ibritumomab tiuxetan	9117	\$19,565.00	\$22,210.19
C1092	K	IN 111 pentetate per 0.5 mCi	1092	\$217.45	\$237.60
C1122	K	Tc 99M ARCITUMOMAB PER VIAL	1122	\$534.77	\$1,144.00
C1166	K	CYTARABINE LIPOSOMAL, 10 mg	1166	\$278.99	\$344.08
C1167	K	EPIRUBICIN HCL, 2 mg	1167	\$20.43	\$25.60
C1178	K	BUSULFAN IV, 6 Mg	1178	\$299.70	\$27.87
C1200	K	TC 99M Sodium Glucoheptonat	1200	\$30.28	\$30.28
C1201	K	TC 99M SUCCIMER, PER Vial	1201	\$80.24	\$125.66
C1305	K	Apligraf	1305	\$822.19	\$1,199.00
C9003	K	Palivizumab, per 50 mg	9003	\$344.15	\$611.24
C9008	K	Baclofen Refill Kit-500mcg	9008	\$6.90	\$73.92
C9009	K	Baclofen Refill Kit-2000mcg	9009	\$40.92	\$40.92
C9010	K	Baclofen Refill Kit--4000mcg	9010	\$42.22	\$79.82
C9109	K	Tirofiban hcl, 6.25 mg	9109	\$118.60	\$218.33
C9202	K	Octafluoropropane	9202	\$118.60	\$137.28
J0130	K	Abciximab injection	1605	\$289.44	\$475.22
J0207	K	Amifostine	7000	\$289.40	\$419.59
J0287	K	Amphotericin b lipid complex	9024	\$20.86	\$20.86
J0288	K	Ampho b cholesteryl sulfat	9024	\$20.86	\$20.86

J0289	K	Amphotericin b liposome inj	9024	\$20.86	\$20.86
J0350	K	Injection anistreplase 30 u	1606	\$1,516.46	\$2,495.31
J0585	K	Botulinum toxin a per unit	0902	\$3.21	\$4.58
J0587	K	Botulinum toxin type B	9018	\$6.98	\$8.14
J0637	K	Caspofungin acetate	9019	\$29.64	\$30.52
J0850	K	Cytomegalovirus imm IV /vial	0903	\$291.18	\$659.60
J1327	K	Eptifibatide injection	1607	\$7.99	\$11.88
J1438	K	Etanercept injection	1608	\$102.37	\$143.73
J1440	K	Filgrastim 300 mcg injection	0728	\$123.48	\$172.20
J1441	K	Filgrastim 480 mcg injection	7049	\$175.96	\$290.93
J1565	K	RSV-ivig	0906	\$48.61	\$16.55
J1626	K	Granisetron HCl injection	0764	\$5.70	\$17.18
J1830	K	Interferon beta-1b / .25 MG	0910	\$100.51	\$67.22
J1950	K	Leuprolide acetate /3.75 MG	0800	\$182.92	\$479.20
J2020	K	Linezolid injection	9001	\$15.12	\$34.09
J2353	K	Octreotide injection, depot	1207	\$65.74	\$73.62
J2354	K	Octreotide inj, non-depot	7031	\$1.44	\$3.94
J2788	K	Rho d immune globulin 50 mcg	9023	\$1.69	\$32.21
J2790	K	Rho d immune globulin inj	0884	\$10.16	\$92.93
J2792	K	Rho(D) immune globulin h, sd	1609	\$9.76	\$19.03
J2820	K	Sargramostim injection	0731	\$16.32	\$26.92
J2941	K	Somatropin injection	7034	\$41.18	\$297.79
J2993	K	Retepase injection	9005	\$568.33	\$1,263.90
J3100	K	Tenecteplase injection	9002	\$1,296.75	\$2,492.60
J3245	K	Tirofiban hydrochloride	7041	\$227.85	\$436.66
J3305	K	Inj trimetrexate glucuronate	7045	\$61.36	\$132.00
J3395	K	Verteporfin injection	1203	\$897.20	\$1,350.80
J7191	K	Factor VIII (porcine)	0926	\$1.52	\$1.89
J7195	K	Factor IX recombinant	0932	\$1.01	\$1.04
J7320	K	Hylan G-F 20 injection	1611	\$123.46	\$215.97
J7504	K	Lymphocyte immune globulin	0890	\$127.89	\$258.17
J7505	K	Monoclonal antibodies	7038	\$320.84	\$792.33
J7507	K	Tacrolimus oral per 1 MG	0891	\$1.34	\$3.24

J7511	K	Antithymocyte globuln rabbit	9104	\$163.56	\$331.23
J7520	K	Sirolimus, oral	9020	\$2.89	\$6.60
J7525	K	Tacrolimus injection	9006	\$5.72	\$110.04
J8510	K	Oral busulfan	7015	\$1.57	\$1.93
J8520	K	Capecitabine, oral, 150 mg	7042	\$1.65	\$3.14
J8700	K	Temozolmide	1086	\$3.76	\$6.81
J9001	K	Doxorubicin hcl liposome inj	7046	\$256.34	\$364.49
J9010	K	Alemtuzumab injection	9110	\$424.88	\$541.46
J9017	K	Arsenic trioxide	9012	\$26.91	\$34.32
J9020	K	Asparaginase injection	0814	\$16.13	\$58.00
J9045	K	Carboplatin injection	0811	\$86.47	\$137.79
J9098	K	Cytarabine liposome	1166	\$278.99	\$344.08
J9151	K	Daunorubicin citrate liposom	0821	\$163.55	\$64.60
J9170	K	Docetaxel	0823	\$220.97	\$331.53
J9178	K	Inj, epirubicin hcl, 2 mg	1167	\$20.43	\$25.60
J9185	K	Fludarabine phosphate inj	0842	\$205.74	\$329.83
J9201	K	Gemcitabine HCl	0828	\$80.43	\$112.09
J9202	K	Goserelin acetate implant	0810	\$285.16	\$413.59
J9206	K	Irinotecan injection	0830	\$100.55	\$135.00
J9213	K	Interferon alfa-2a inj	0834	\$20.61	\$32.31
J9214	K	Interferon alfa-2b inj	0836	\$10.93	\$13.78
J9215	K	Interferon alfa-n3 inj	0865	\$79.65	\$8.17
J9216	K	Interferon gamma 1-b inj	0838	\$180.15	\$290.70
J9217	K	Leuprolide acetate suspnsion	9217	\$312.37	\$576.47
J9219	K	Leuprolide acetate implant	7051	\$3,666.71	\$5,001.92
J9245	K	Inj melphalan hydrochl 50 MG	0840	\$254.90	\$389.14
J9268	K	Pentostatin injection	0844	\$965.98	\$1,784.64
J9270	K	Plicamycin (mithramycin) inj	0860	\$15.42	\$86.89
J9293	K	Mitoxantrone hydrochl / 5 MG	0864	\$173.68	\$332.87
J9310	K	Rituximab cancer treatment	0849	\$306.40	\$464.20
J9320	K	Streptozocin injection	0850	\$65.19	\$131.05
J9350	K	Topotecan	0852	\$433.41	\$739.80
J9355	K	Trastuzumab	1613	\$40.56	\$53.85
J9357	K	Valrubicin, 200 mg	1614	\$461.78	\$487.87
J9390	K	Vinorelbine tartrate/10 mg	0855	\$64.79	\$100.97

J9600	K	Porfimer sodium	0856	\$1,594.30	\$2,411.82
Q0136	K	Non esrd epoetin alpha inj	0733	\$9.83	\$11.76
Q0137	K	Darbepoetin alfa, non esrd	0734	\$3.24	\$3.88
Q0166	K	Granisetron HCl 1 mg oral	0765	\$34.49	\$171.78
Q0180	K	Dolasetron mesylate oral	0763	\$41.00	\$152.38
Q0187	K	Factor viia recombinant	1409	\$1,083.93	\$1,495.30
Q2003	K	Aprotinin, 10,000 kiu	7019	\$1.17	\$13.26
Q2005	K	Corticorelin ovine triflutat	7024	\$224.91	\$375.00
Q2006	K	Digoxin immune fab (ovine)	7025	\$271.14	\$1.79
Q2007	K	Ethanolamine oleate 100 mg	7026	\$27.82	\$67.10
Q2008	K	Fomepizole, 15 mg	7027	\$7.23	\$10.65
Q2009	K	Fosphenytoin, 50 mg	7028	\$4.88	\$5.63
Q2011	K	Hemin, per 1 mg	7030	\$0.64	\$6.86
Q2013	K	Pentastarch 10% solution	7040	\$26.40	\$139.94
Q2017	K	Teniposide, 50 mg	7035	\$137.41	\$238.49
Q2018	K	Urofollitropin, 75 iu	7037	\$63.48	\$63.48
Q3000	K	Rubidium-Rb-82	9025	\$143.89	\$162.63
Q3003	K	Technetium tc99m biccisate	1620	\$183.69	\$392.93
Q3005	K	Technetium tc99m mertiatide	1622	\$20.63	\$1,650.00
Q3008	K	Indium 111-in pentetretotide	1625	\$449.84	\$1,144.00
Q4052	K	Octreotide injection, depot	1207	\$65.74	\$73.62

**Table 2 Multisource Drugs**

<b>HCPCS</b>	<b>Status Indicator</b>	<b>Description</b>	<b>APC</b>	<b>OPPS CY 2004 November 7, 2003 rate</b>	<b>DIMA Final rate</b>
A9505	K	Thallous chloride TL 201/mci	1603	\$19.89	\$18.29
A9508	K	Iobenguane sulfate I-131, per 0.5 mCi	1045	\$165.82	\$165.82
A9517	K	Th I131 so iodide cap millic	1064	\$5.48	\$5.48
A9528	K	Dx I131 so iodide cap millic	1064	\$5.48	\$5.48
A9529	K	Dx I131 so iodide sol millic	1065	\$6.49	\$6.49
A9530	K	Th I131 so iodide sol millic	1065	\$6.49	\$6.49
A9605	K	Samarium sm153 lexicronamm	0702	\$874.44	\$493.89
C1091	K	IN111 oxyquinoline,per0.5mCi	1091	\$224.52	\$224.52
C1775	K	FDG, per dose (4-40 mCi/ml)	1775	\$324.48	\$324.48
C9013	K	Co 57 cobaltous chloride	9013	\$56.67	\$56.67

C9105	K	Hep B imm glob, per 1 ml	9105	\$71.33	\$65.58
J1190	K	Dexrazoxane HCl injection	0726	\$112.48	\$112.48
J1563	K	Immune globulin, 1 g	0905	\$43.96	\$37.95
J1564	K	Immune globulin 10 mg	9021	\$0.44	\$0.41
J1745	K	Infliximab injection	7043	\$38.86	\$31.81
J1825	K	Interferon beta-1a	0909	\$184.79	\$123.77
J2430	K	Pamidronate disodium /30 MG	0730	\$174.32	\$128.74
J7190	K	Factor viii	0925	\$0.51	\$0.42
J7192	K	Factor viii recombinant	0927	\$1.01	\$0.61
J7193	K	Factor IX non-recombinant	0931	\$0.51	\$0.51
J7194	K	Factor ix complex	0928	\$0.51	\$0.18
J7198	K	Anti-inhibitor	0929	\$1.01	\$0.69
J7310	K	Ganciclovir long act implant	0913	\$86.54	\$86.54
J7317	K	Sodium hyaluronate injection	7316	\$138.78	\$67.16
J7502	K	Cyclosporine oral 100 mg	0888	\$2.56	\$2.41
J7517	K	Mycophenolate mofetil oral	9015	\$2.04	\$1.36
J8560	K	Etoposide oral 50 MG	0802	\$27.37	\$21.91
J9000	K	Doxorubic hcl 10 MG vl chemo	0847	\$6.61	\$4.69
J9031	K	Bcg live intravesical vac	0809	\$103.75	\$77.54
J9040	K	Bleomycin sulfate injection	0857	\$160.56	\$88.32
J9060	K	Cisplatin 10 MG injection	0813	\$21.74	\$7.73
J9065	K	Inj cladribine per 1 MG	0858	\$37.82	\$24.84
J9070	K	Cyclophosphamide 100 MG inj	0815	\$4.74	\$2.77
J9093	K	Cyclophosphamide lyophilized	0816	\$4.50	\$2.36
J9100	K	Cytarabine hcl 100 MG inj	0817	\$5.07	\$1.55
J9130	K	Dacarbazine 100 mg inj	0819	\$5.31	\$5.31
J9150	K	Daunorubicin	0820	\$73.97	\$35.94
J9181	K	Etoposide 10 MG inj	0824	\$4.56	\$0.83
J9200	K	Floxuridine injection	0827	\$114.19	\$66.24
J9208	K	Ifosfomide injection	0831	\$106.04	\$72.81
J9209	K	Mesna injection	0732	\$28.43	\$17.66
J9211	K	Idarubicin hcl injection	0832	\$178.21	\$178.21
J9218	K	Leuprolide acetate injeciton	0861	\$43.60	\$14.48
J9265	K	Paclitaxel injection	0863	\$112.14	\$79.04
J9280	K	Mitomycin 5 MG inj	0862	\$53.03	\$30.91
J9340	K	Thiotepa injection	0851	\$59.93	\$45.31
Q2022	K	VonWillebrandFactrCmplxperIU	1618	\$1.01	\$0.46

Q3002	K	Gallium ga 67	1619	\$11.22	\$11.22
Q3007	K	Sodium phosphate p32	1624	\$70.61	\$66.44
Q3011	K	Chromic phosphate p32	1628	\$98.52	\$81.27
Q3012	K	Cyanocobalamin cobalt co57	1089	\$57.07	\$47.38
Q3025	K	IM inj interferon beta 1-a	9022	\$61.60	\$13.36

#### Coding for specified outpatient drugs

In order to implement these provisions timely on January 1, 2004, we are instructing hospitals to use the existing HCPCS code that describes the drug for services furnished on or after January 1, 2004. For sole source drugs, the existing HCPCS code is priced in accordance with the provisions of section 1833(t)(14)(A)(i) of the Act as indicated in Table 1. However, existing HCPCS codes do not allow us to differentiate payment amounts for innovator multiple source and noninnovator multiple source forms of the drug.

Therefore, for implementation January 1, 2004, we set payment rates for all multiple source innovator and noninnovator drugs, biologicals and radiopharmaceutical agents at the lower of the payment rate in the November 7, 2003 final rule or 46 percent of the reference AWP. These rates are shown in Table 2.

Initially, we will implement sections 1833(t)(14)(A)(i)(II) and (III) of the Act in this manner because we are unable to compile a definitive list of the innovator multiple source drugs

in time for January 1, 2004 implementation. On April 1, 2004, CMS will implement new HCPCS codes that providers may use to bill for innovator multiple source drugs in order to receive appropriate payment in accordance with section 1833(t)(14)(A)(i)(II) of the Act, that is, the payment amount established in the November 7, 2003 final rule or 68 percent of the reference AWP, whichever is lower. The new codes will be effective January 1, 2004 so that providers may submit adjustment bills after April 1, 2004 to receive appropriate payment for multiple source innovator drugs furnished on or after January 1, 2004 through March 31, 2004.

Beginning April 1, 2004, innovator multiple source drugs will be paid at the statutory rate as long as the new codes are used. The multiple source noninnovator rate will be the default payment rate for the existing HCPCS code assigned to the drug, and providers will continue to use the current HCPCS codes to bill for noninnovator multiple source drugs after March 31, 2004. The new HCPCS codes will be very similar to the current codes with only the distinction that the drug being billed is an innovator multiple source drug eligible for payment of as much as 68 percent of the AWP.

We recognize that creation and use of a new code to designate a drug to be an innovator multiple source drug creates burden for hospitals. However, the law provides different payment rules based on the category into which the drug falls and therefore, to ensure correct payment, hospitals must report a code for the drug that identifies the category into which it falls. We request comments on ways that we can reduce the reporting burden on hospitals that results from the law's imposing different payment limitations on brand name and generic versions of the same drug.

Table 2 lists the drugs for which the new HCPCS codes will be implemented April 1, 2004 to distinguish innovator multiple source from noninnovator multiple source drugs.

**Other changes in payment methodology effective January 1, 2004  
as a result of enactment of the Medicare Prescription Drug,  
Improvement and Modernization Act of 2003**

Payment for pass-through drugs, biologicals, and  
radiopharmaceuticals:

Drugs and biologicals that are within the 2-3 year pass-through payment period in 2004 continue to be paid pursuant to section 1842(o) of the Act. However, section 1842(o) of the Act

has been revised by section 303(b) of the DIMA and those revisions change the way that these drugs are paid.

Drugs and biologicals furnished during 2004 that are approved for pass-through payment under the OPPS and that were not approved by the FDA for marketing as of April 1, 2003 will be paid 95 percent of AWP pursuant to section 1842(o)(1)(A)(iii). See Table 3b for a list of these pass-through drugs.

Drugs and biologicals furnished during 2004 for which pass-through payment was first made on or after January 1, 2003 (which removes them from application of section 621 of the DIMA) and were approved by the FDA for marketing as of April 1, 2003, will be paid 85 percent of AWP pursuant to section 1842(o)(1)(B) and 1842(o)(4)(A), unless sections 1842(o)(4)(B), (C) or (D) apply. See Table 3a for a list of these pass-through drugs.

Table 3c lists 10 drugs and biologicals with pass-through status in 2004 that also meet the criteria for "specified covered outpatient drugs" under section 1833(t)(14). That is, the drugs in Table 3c are pass-through drugs in 2004 that were available for payment before April 1, 2003 and would therefore be paid 85 percent of AWP (determined as of April 1, 2003) under the cross reference in section 1833(t)(6)(D)(i) to section

1842(o). Separate APCs have been established for these drugs and they were paid as pass-through drugs on or before December 31, 2002. Therefore, these pass-through drugs qualify under section 1833(t)(14)(B) as "specified covered outpatient drugs." As specified covered outpatient drugs, the ten drugs would be categorized as "sole source" drugs.

Sole source drugs, under section 1833(t)(14)(A)(i)(I) are paid no less than 88 percent nor more than 95 percent of the reference AWP. To the extent that the ten drugs listed in Table 3c qualify as both pass-through drugs and sole source drugs under the DIMA, it appears that they are subject to two different payment provisions. We have reconciled the two apparently conflicting payment provisions in a way that we believe results in the fewest anomalies. The drugs will retain their pass-through status, and therefore, the rules and policies that otherwise apply to pass-through drugs continue to apply to them. They will also be considered sole source drugs for purposes of section 1833(t)(14). We will pay for the drugs as follows.

First, because the drugs are pass-through drugs, we will give them pass-through payments. The pass-through payments will equal 85 percent of AWP (determined as of April 1, 2003) under

section 1833(t)(6)(D)(i). However, because the drugs are also sole source drugs, we will also apply the payment methodology set forth in section 1833(t)(14)(A)(i)(I), and raise the payment to 88 percent of the reference AWP (the AWP determined as of May 1, 2003).

Under the payment methodology that we are applying to sole source drugs, we look at the payment that would otherwise be made and if it is less than 88 percent or greater than 95 percent of reference AWP, we adjust it as minimally as necessary to ensure that it is within the required range. In the case of these drugs, absent the provisions of 1833(t)(14)(i)(I), we would pay 85 percent of AWP (determined as of April 1, 2003). Therefore adjusting the payment that would otherwise be made results in payment at 88 percent of reference AWP.

In light of the total revamping of the methodology for payment for drugs and biologicals under OPPS, we revisited the adjustment that we made under our authority in section 1833(t)(2)(E) of the Act to ensure equitable payments in 2003 and in the November 7 final rule for the 2004 update of the OPPS. After considering the nature of the DIMA payment changes, we have concluded that it is still appropriate to apply this adjustment to the methodology discussed in the previous two

paragraphs for the reasons we stated in the OPPS rulemaking during the past two years. Therefore, for darbepoetin alpha (Q0137 and C1774), we are making an adjustment in accordance with section 1833(t)(2)(E) of the Act (which was unaffected by DIMA) to the combined pass-through amount and 3 percent additional payment provided under section 1833(t)(14)(A)(i)(I) of DIMA, resulting in a payment rate of \$3.88 per unit. This payment rate is budget neutral.

**Table 3a--Pass-through Drugs Reimbursed at  
85% of AWP**

HCPCS	APC	Long Description	2004 Payment Amount	2004 Co-Payment Amount
J9395	9120	Injection, Fulvestrant, per 25 mg	\$78.36	\$13.09
C9121	9121	Injection, Argotroban, per 5 mg	\$14.63	\$2.44
C9123	9123	TransCyte, per 247 sq cm	\$689.78	\$115.23
C9205	9205	Injection, Oxaliplatin, per 5 mg	\$8.45	\$1.41
C9203	9203	Injection, Perflexane lipid microspheres, per single use vial	\$127.50	\$21.30
J3315	9122	Injection, Triptorelin pamoate, per 3.75 mg	\$356.66	\$59.58
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg	\$18.60	\$3.11
C9211	9211	Injection, IV, Alefacept, per 7.5 mg	\$595.00	\$99.40
C9212	9212	Injection, IM, Alefacept, per 7.5 mg	\$422.88	\$70.65

**Table 3b--Pass-Through Drugs Paid at 95% of AWP**

HCPGS	APC	Long Description	Amount	Amount
C9207	9207	Injection, IV, Bortezomib, per 3.5 mg	\$1,039.68	\$155.40
C9208	9208	Injection, IV, Agalsidase beta, per 1 mg	\$123.78	\$18.50
C9209	9209	Injection, IV, Laronidase, per 2.9 mg	\$644.10	\$96.28
C9210	9210	Injection, IV, Palonosetron HCl, per 0.25 mg (250 micrograms)	\$307.80	\$46.01

**Table 3c Pass-Through Drugs Paid As Sole Source Drugs at 88% of  
AWP**

<b>HCPCS</b>	<b>APC</b>	<b>Long Description</b>	<b>OPPS CY2004 November 7 Rate</b>	<b>DIMA Final Rate</b>
J0583	9111	Injection, Bivalirudin, per 1 mg	\$1.43	\$1.61
C9112	9112	Injection, Perflutren lipid microsphere, per 2 ml	\$132.60	\$137.28
C9113	9113	Injection, Pantoprazole sodium, per vial	\$22.44	\$23.23
J1335	9116	Injection, Ertapenem sodium, per 500 mg	\$21.24	\$21.99
J2505	9119	Injection, Pegfilgrastim, per 6 mg single dose vial	\$2,507.50	\$2,596.00
C9200	9200	Orcel, per 36 sqare centimeters	\$1,015.75	\$1,051.60
C9201	9201	Dermagraft, per 37.5 square centimeters	\$516.80	\$535.04
J2324	9114	Injection, Nesiritide, per 0.5 mg	\$135.66	\$140.45
J3487	9115	Injection, Zoledronic acid, per 1 mg	\$194.52	\$211.07

**Payment for new drugs and biologicals before a HCPCS code is  
assigned**

Under new section 1833(t)(15) of the Act, as added by section 621(a)(1) of the DIMA a drug or biological that is furnished as part of covered outpatient department services for which a HCPCS codes has not been established, is to be paid at 95 percent of the AWP for the drug or biological.

We are in the process of determining how hospitals would bill Medicare for a drug prior to assignment of a HCPCS code. We will issue instructions once we have determined how to make this requirement operational.

#### **Payment for orphan drugs as designated by the Secretary**

Section 1833(t)(14)(C) as added by section 621(a)(1) of the DIMA, provides that the amount of payment for orphan drugs designated by the Secretary shall, for 2004 and 2005, equal the amount the Secretary shall specify. We have determined that single indication orphan drugs as designated by the Secretary will be paid at the rates published in the November 7, 2003 **Federal Register** (68 FR 63398). Neither the definition nor the 2004 payment amounts for single indication orphan drugs under the OPPS have changed from what was published in the November 7 final rule.

#### **Brachytherapy**

Section 621(b)(1) of the DIMA of 2003 amends the Act by adding section 1833(t)(16)(C) and section 1833(t)(2)(H) which establish separate payment for devices of brachytherapy consisting of a seed or seeds (or radioactive source) based on a hospital's charges for the service, adjusted to cost. Further, charges for the brachytherapy devices shall not be used in determining any outlier payments and consistent with our

practice under OPPS to exclude items paid at cost from budget neutrality consideration, these items will be excluded from budget neutrality as well. The period of payment under this provision is for brachytherapy sources furnished from January 1, 2004 through December 31, 2006.

We will pay for the brachytherapy sources listed in Table 4 on a cost basis, as required by the statute. The status indicator for brachytherapy sources is changed to "H." The definition of status indicator "H" is currently for pass-through payment for devices, but the brachytherapy sources affected by new sections 1833(t)(16)(C) and 1833(t)(2)(H) are not pass-through device categories. Therefore, we are also changing, for 2004, the definition of payment status indicator "H" to include non-pass-through brachytherapy sources paid for on a cost basis. This use of status indicator "H" is a pragmatic decision that allows us to pay for brachytherapy sources in accordance with new section 1833(t)(16)(C) effective January 1, 2004 without having to modify our claims processing systems. We will revisit the use and definition of status indicator "H" for this purpose for the OPPS update for 2005. Table 4 provides a complete listing of the HCPCS codes, descriptors, APC assignments and status indicators for brachytherapy sources.

**Table 4: Brachytherapy sources to be paid separately, using charges reduced to cost**

HCPCS	Descriptor	APC	APC title	NEW Status Indicator
C1716	Brachytx source, Gold 198	1716	Brachytx source, Gold 198	H
C1717	Brachytx source, HDR Ir-192	1717	Brachytx source, HDR Ir-192	H
C1718	Brachytx source, Iodine 125	1718	Brachytx source, Iodine 125	H
C1719	Brachytx sour, Non-HDR Ir-192	1719	Brachytx source, Non-HDR Ir-192	H
C1720	Brachytx source, Paladium 103	1720	Brachytx source, Paladium 103	H
C2616	Brachytx source, Yttrium-90	2616	Brachytx source, Yttrium-90	H
C2632	Brachytx solution, I-125, per mCi	2632	Brachytx sol, I-125, per mCi	H
C2633	Brachytx source, Cesium-131	2633	Brachytx source, Cesium-131	H
C2632	Brachytx sol, I-125, per mCi	2632	Brachytx sol, I-125, per mCi	H

As indicated in Table 4, brachytherapy source in HCPCS code C1717 will be paid based on the hospital's charge reduced to cost beginning January 1, 2004. Prior to enactment of DIMA, these sources were paid as packaged services in APC 0313. As a result of the requirement to pay for C1717 separately, we are adjusting the payment rate for APC 0313 to reflect the unpackaging of the brachytherapy source. The new rate is listed in Addendum A.

Section 1833(t)(2)(H) is added by section 621(b)(2)(C) of DIMA, mandating the creation of separate groups of covered OPD services that classify brachytherapy devices separately from other services or groups of services. The additional groups shall be created in a manner reflecting the number, isotope and radioactive intensity of the devices of brachytherapy furnished, including separate groups for palladium-103 and iodine-125.

We invite the public to submit recommendations for new codes to describe brachytherapy sources in a manner reflecting the number, radioisotope, and radioactive intensity of the sources. We request that commenting parties provide a detailed rationale to support recommended new codes. We will propose appropriate changes in codes for brachytherapy sources in the 2005 OPPS update.

#### **Continuation of Transitional Corridor Payments for CY 2004**

Since the inception of the OPPS, providers have been eligible to receive additional transitional payments if the payments they received under the OPPS were less than the payments they would have received for the same services under the payment system in effect before the OPPS. Under 1833(t)(7) of the Act, most hospitals that realize lower payments under the OPPS received transitional corridor payments based on a percent of the decrease in payments. However, rural hospitals having

100 or fewer beds, as well as cancer hospitals and children's hospitals described in section 1886(d)(1)(B)(iii) and (v) of the Act, were held harmless under this provision and paid the full amount of the decrease in payments under the OPFS.

Transitional corridor payments were intended to be temporary payments to ease providers' transition from the prior cost-based payment system to the prospective payment system. In accordance with section 1833(t)(7) of the Act, transitional corridor payments were to be eliminated January 1, 2004, for all providers other than cancer hospitals and children's hospitals. Cancer hospitals and children's hospitals are held harmless permanently under the transitional corridor provisions of the statute.

Section 411 of the DIMA amends section 1833(t)(7) of the Act to provide that hold harmless transitional corridor payments will continue through December 31, 2005 for rural hospitals having 100 or fewer beds.

Section 411 of the DIMA further amends section 1833(t)(7) of the Act to provide that hold harmless transitional corridor payments shall apply to sole community hospitals, as defined in section 1886(d)(5)(D)(iii) of the Act, which are located in rural areas, with respect to services furnished during cost reporting periods beginning on or after January 1, 2004, and

continuing through December 31, 2005. For purposes of this provision, a sole community hospital's location in a rural area will be determined as it is under the inpatient PPS, in 42 CFR 412.63(b).

## **II. Provisions of the Interim Final Rule with Comment Period**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA), enacted December 8, 2003 makes changes to the Social Security Act (the Act) relating to calendar year 2004 payments under the Hospital Outpatient Prospective Payment System. This interim final rule with comment period implements changes resulting from enactment of the DIMA that are effective January 1, 2004, as follows:

### Transitional Corridor Payments Extended

Hold harmless transitional corridor payments are continued through December 31, 2005 for small rural hospitals having 100 or fewer beds. In addition, hold-harmless transitional corridor provisions shall apply to sole community hospitals as defined in section 1886(d)(5)(D)(iii) of the Act with respect to cost reporting periods beginning on or after January 1, 2004 and will continue through December 31, 2005.

### Payment for "specified covered outpatient drugs"

Separately paid radiopharmaceutical agents and drugs or biologicals that had transitional pass-through status on or

before December 31, 2002, are classified into 3 categories: innovator multiple source drugs; noninnovator multiple source drugs; and sole source drugs. Payment levels based on the reference average wholesale price as of May 1, 2003 are specified for each category.

Payment for pass-through drugs

Drugs and biologicals furnished during 2004 for which pass-through payment was first made on or after January 1, 2003 (which removes them from application of section 621 of the DIMA) and were approved by the FDA for marketing as of April 1, 2003, will be paid 85 percent of AWP pursuant to section 1842(o)(1)(B) and 1842(o)(4)(A), unless sections 1842(o)(4)(B), (C) or (D) apply.

Certain drugs, biologicals and radiopharmaceutical agents that are pass-through drugs in 2004 and that also meet the definition of "specified covered outpatient drugs", except as otherwise specified, are paid 88 percent of the reference AWP. Those drugs, biologicals, and radiopharmaceutical agents remain pass-through drugs and all policies that apply to them as pass-through drugs continue to apply.

Exclude separately payable drugs and biologicals from outlier payments

Separately paid drugs and biologicals are excluded from outlier payments.

Brachytherapy sources are to be paid separately

All devices of brachytherapy consisting of a seed or seeds (or radioactive source) are paid based on the hospital's charge for the device adjusted to cost. All such brachytherapy sources are excluded from outlier payments.

**III. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

**IV. Waiver of Notice of Proposed Rulemaking and the 30-Day Delay in the Effective Date**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule in accordance with 5 U.S.C. section 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues

involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In this case, we believe that it is in the public interest to comply with the statutory requirement to implement these changes effective January 1, 2004. Failure to meet this deadline would cause a delay in payment increases for many drugs and biologicals and brachytherapy sources.

Section 1871 of the Act also provides for publication of a notice of proposed rulemaking and opportunity for public comment before CMS issues a final rule. However, section 1871(b)(2)(B) provides an exception when a law establishes a specific deadline for implementation of a provision and the deadline is less than 150 days after the law's date of enactment. The DIMA was enacted by the Congress on November 25, 2003 and signed into law by the President on December 8, 2003. The provisions of this rule that amend the Medicare hospital outpatient prospective payment system are required to be implemented January 1, 2004. Therefore, these provisions are subject to waiver of proposed rulemaking in accordance with section 1871(b)(2)(B) of the Act.

In addition, we ordinarily provide a 30-day delay in the effective date of the provisions of an interim final rule. Section 553(d) of the APA (5 U.S.C. section 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication in the **Federal Register**. 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 finding and its reasons in the rule issued.

In this case, we believe that it is in the public interest to comply with the statutory requirement to implement these changes effective January 1, 2004 without the 30-day delay in effective date. Failure to meet this deadline would cause a delay in payment increases for many drugs and biologicals and brachytherapy sources.

In addition to the APA requirements, section 1871(e)(1), as amended by section 903(b)(1) of DIMA also requires that a substantive change in a regulation shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published the substantive change. Section 903(b)(1) provides an exception to the requirement of a 30-day

delay in the effective date if the Secretary finds that the waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest.

For purposes of DIMA, we believe that it is in the public interest to comply with the statutory requirement to implement these changes effective January 1, 2004 without the 30-day delay in effective date for the same reasons stated above—failure to meet this deadline would cause a delay in payment increases for many drugs and biologicals and brachytherapy sources. In addition, we find it is necessary to waive the 30-day delay period in order to timely comply with the statutory requirement that new payment rates be effective on January 1, 2004. We are providing a 60-day public comment period.

## **V. Regulatory Impact Analysis**

### **A. Overall Impact**

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258,

which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

We estimate the effects of the provisions that will be implemented by this final rule will result in expenditures exceeding \$100 million in any 1 year. Our Office of the Actuary estimates that the total change in expenditures under the OPSS for CY 2004 as a result of the changes made by DIMA to be approximately \$150 million. Therefore, this final rule with comment is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S. C. 804(2). Therefore the discussion below, in combination with the rest of this final rule constitutes a regulatory impact analysis. The RFA requires agencies to analyze options for regulatory relief of small businesses. However a regulatory flexibility analysis is not required for an interim final rule because no proposed rule is being issued.

Therefore the discussion below constitutes a regulatory impact analysis but no regulatory flexibility analysis is provided.

#### Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This interim final rule will not mandate any requirements for State, local or tribal governments. This interim final rule will not impose unfunded mandates on the private sector of more than \$110 million dollars.

#### Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this interim final rule in accordance with Executive order 13132, Federalism, and have determined that it will not have an impact on the rights, roles, and responsibilities of State, local or tribal governments.

#### B. Anticipated Effects of Changes in this Interim Final Rule and Alternatives Considered for each Change

All of the changes made in this interim final rule with comment are required by DIMA. We are required under section 621 of the DIMA to revise payments for certain drugs and biologicals and for radiopharmaceuticals. We are also required under section 621 of the DIMA to pay for brachytherapy sources on the basis of application of a cost to charge ratio to the charges for the

sources. In addition, we are required under section 621 of the DIMA to continue transitional outpatient payment for certain hospitals.

Impact on drugs and biologicals that will be paid under pass-through provisions in 2004.

Four of the drugs and biologicals that will be paid under pass-through provisions in 2004 will be paid at 95 percent of AWP. Nine of the drugs and biologicals that will be paid under pass-through provisions in 2004 will be paid at 85 percent of AWP in 2004. This is a reduction of 10 percent of AWP compared to the payment that would have been made for these drugs and biologicals before passage of the DIMA.

As discussed previously in this rule, some pass-through drugs and biologicals also meet the criteria for "specified covered outpatient drugs" under 1833(t)(14) and, except as specified in this rule, will be paid 88 percent of the reference AWP. Notwithstanding the payment amount, however, they remain pass-through drugs.

Hospitals that provide drugs paid at 85 percent of AWP will be paid less than they would have been paid absent passage of the new law.

It is unclear whether the reduction in payments for these drugs will have any effect on beneficiary access to them. Hospitals consider many factors when they determine whether they choose to provide the drugs and it is unclear whether the

reduction in payment for Medicare will result in impaired access. However, reduction in the payment amounts for some drugs means that beneficiaries will have lower copayments for those drugs and that they, and complementary insurers who pay beneficiary cost sharing, will have reduced expenses. Hospitals, however, will clearly be paid reduced amounts by Medicare for these drugs compared to the amounts that would be paid had the statute not imposed these changes. Manufacturers and distributors of the pass-through drugs that will be paid at 85 percent of AWP will be under increased pressure to reduce the price of the drugs since the hospitals to which they sell the items will be paid lower amounts by Medicare for them when used in hospital outpatient departments.

We considered setting payment at 85 percent for pass-through drugs that also meet the definition of "specified covered outpatient drugs" as allowed in the cross reference from 1833(t)(6) to 1842(o). However, given that the drugs are eligible for payment under both sets of criteria, we chose to increase their payment to 88 percent of reference AWP, except as otherwise specified. We believe that this choice will result in the least possible disruption to beneficiary access to these drugs.

We considered no alternatives with regard to payment for pass-through drugs that did not meet the definition of

"specified covered outpatient drugs" because the law provides only one payment methodology for these drugs.

Impact of changes for "specified covered outpatient drugs".

Radiopharmaceutical agents and drugs or biologicals for which payment was made on a pass-through basis on or before December 31, 2002, are now to be paid under section 1833(t)(14) of the Act as added by DIMA. Under these provisions, radiopharmaceuticals and drugs and biologicals that meet the criteria, are paid amounts that must be limited as specified in the law. Specifically, items that meet the definition of sole source drugs must be paid no less than 88 percent of reference AWP nor more than 95 percent of reference AWP. Items that meet the definition of innovator multiple source drugs must be paid no more than 68 percent of AWP and items that meet the definition of noninnovator multiple source drugs must be paid no more than 46 percent of AWP.

As described previously, these categories are defined in section 1927(k)(7) of the Act. That section classifies drugs, biologicals and radiopharmaceuticals for purposes of the Medicaid drug rebate program. CMS has a database in which these items are categorized to which we looked to seek the classification of each drug, biological and radiopharmaceutical paid under pass-through provisions before December 31, 2002. Table 1 shows those items that we believe meet the definition of sole source drug. Table 2 shows those items for which it is not clear to us whether the

item should be classified as a sole source drug or as both an innovator multiple source and a noninnovator multiple source drug and which we will pay as noninnovator multiple source drugs until we receive comments and determine the classification into which the drug falls. Paying for those drugs with questionable classification as noninnovator multiple source drugs allows payment to be made to hospitals for these drugs when they are furnished and also protects hospitals from incurring overpayments. Once we review the public comments and establish the correct classification and codes for the billing of innovator multiple source drugs, hospitals may subject adjustment bills to be paid the additional amounts due.

We will pay the 121 drugs in Table 1 at the amounts shown, as previously discussed. Six of these drugs will have no payment change from the payment announced in the November 7, 2003 final rule. Six of these drugs will receive decreases in payment compared to the final rule because the payment established in the November 7, 2003 final rule exceeded 95 percent of the reference AWP. The payment amounts for these drugs are now set at 95 percent of the reference AWP in accordance with the law. One hundred nine of these drugs will receive increases in payment compared to the final rule because the payment established in the November 7, 2003 final rule was less than 88 percent of reference AWP. The payment amounts for these drugs, biologicals and radiopharmaceuticals is now set at 88 percent of the reference AWP.

We will temporarily pay the 52 drugs in Table 2 at the amounts shown, as previously discussed. Thirteen of these items will be paid the amount that was published in the November 7, 2003 final rule. Thirty-eight of these items will receive payment decreases. One of these items did not have a reference AWP under the SDP and will require further research to determine the correct payment amount. Until we determine a reference AWP for this item it will be paid at the amount that was published in the November 7, 2003 final rule.

It is unclear what the final overall impact of these changes will be because we are, as yet, unable to determine into which categories 52 items in dispute will fall. Moreover, once they are categorized, we do not anticipate that we will know the frequency with which hospitals will use the innovator multiple source drug versus the noninnovator multiple source drug in the outpatient department. Moreover, it is not clear to what extent hospitals may change their behavior with regard to which type of a drug they choose to purchase and whether their purchasing decisions will be affected by whether they furnish the item to hospital outpatient departments or inpatient departments.

We considered whether to classify the 52 items with questionable category assignment as both innovator multiple source and noninnovator multiple source drugs and to create HCPCS codes to be used when innovator multiple source drugs are administered. However, we believe that public comment is

necessary to determine the correct classification of these items. Similarly, we believe that, given the burden the law imposes on hospitals for reporting drugs by the category into which they fall, it was important to receive public comment regarding whether new codes should be created and regarding ways we can reduce the reporting burden on hospitals. Hence, until we receive and review the comments, we will not be able to assess the impact of these requirements of the law.

We do acknowledge, however, that for the 52 drugs that are not sole source drugs, the temporary payments to hospitals at the noninnovator multiple source drug rate will be less than the payment that would have been made under the November 7, 2003 final rule. For those drugs that are sole source drugs, the payment will increase in most cases.

Hospitals that provide sole source drugs will be paid more for these drugs under these provisions than they would have been paid before enactment of the DIMA. Hospitals that provide innovator multiple source drugs and noninnovator multiple source drugs will be paid less for these items than they would have been before enactment of the DIMA. This may encourage use of sole source drugs and discourage use of multiple source drugs. As a result beneficiaries may have greater access to sole source drugs but will also incur greater copayments because those payment rates are higher than they would have been before enactment of DIMA. In turn, there may be increased payment by complementary

insurers for these items. Manufacturers of sole source drugs may realize increased sales and manufacturers of generic drugs may see reduced sales.

We considered whether to permit a drug that is classified by AMP as a sole source drug, an innovator multiple source drug and a noninnovator multiple source drug to be paid under all three classifications. We decided not to pay a drug as a sole source drug if it is also a multiple source drug for reasons described previously in this interim final rule. We considered no alternatives because the law is quite specific with regard to the classification of drugs and the payment rules that apply to each class of drug.

Impact of cost-based payment for sources of brachytherapy.

The law provides that sources of brachytherapy will be paid an amount equal to the hospital's charge for the source adjusted by the applicable cost to charge ratio. It is unclear whether this will result in an increase or decrease in payment for brachytherapy sources. However, removing the brachytherapy source from packaged payment for the services with which it is furnished removes incentives for using the least number of sources needed for the therapeutic purpose. There is no evidence that packaged payment for brachytherapy sources resulted in inappropriately low utilization of brachytherapy, nor that separate payment will result in any change in availability of the service. We are unable to estimate the impact of this change on utilization and program payment.

We considered no alternatives to this policy because the statute was specific with regard to how payment for brachytherapy sources must be made.

Impact of continuation of transitional outpatient payments for certain hospitals.

The law provides that transitional outpatient payments must continue for rural hospitals with 100 or fewer beds and be provided for sole community hospitals in rural areas through December 31, 2005. There are approximately 600 sole community hospitals and approximately 1150 rural hospitals with 100 beds or fewer that may be affected by this provision. These hospitals will continue to receive transitional corridor payments in addition to the payments they will receive under OPSS. These payments should continue to strengthen the ability of these hospitals to furnish services to beneficiaries who reside in the areas served by these hospitals. Beneficiaries should be better assured of access to services in these hospitals. These hospitals will be assured of payment for the reasonable costs of providing outpatient services.

We considered no alternatives because the statute is quite directive with regard to the extension of hold harmless protection to these hospitals.

B. Conclusion

We have prepared the analysis above because we have determined that this interim final rule will have a significant

economic impact. In accordance with the provisions of Executive Order 12866, this interim final rule was reviewed by the Office of Management and Budget.

#### Publication of Addenda

The addenda included in this interim final rule, Addenda A and D1 replace the addenda in the November 7, 2003 **Federal Register** (68 FR 63478). The revised addenda reflect changes required by the DIMA as well as corrections to minor errors contained in the addenda published November 7, 2003.

In addition to the addenda included here, we will post the updated Addenda B and C on our web site at [www.cms.hhs.gov/regulations/hopps/](http://www.cms.hhs.gov/regulations/hopps/).

**List of Subjects in 42 CFR Part 419**

Hospitals, Medicare, Reporting and recordkeeping  
requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

**PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES**

1. The authority citation for part 419 continues to read as follows:

**Authority:** Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

**Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services**

2. Section 419.32 is amended by revising paragraph (d).

**§419.32 Calculation of prospective payment rates for hospital outpatient services.**

\* \* \* \* \*

(d) Budget neutrality. (1) CMS adjusts the conversion factor as needed to ensure that updates and adjustments under §419.50(a) are budget neutral.

(2) In determining adjustments for 2004 and 2005, CMS will not take into account any additional expenditures per 1833(t)(14) that would not have been made but for enactment of

section 621 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

**Subpart D—Payments to Hospitals**

3. Section §419.43 is amended as follows:

A. Paragraph (d)(1) introductory text is revised.

B. Paragraph (e) is revised.

C. New paragraph (f) is added.

The revisions and additions read as follows:

**§419.43 Adjustments to national program payments and beneficiary copayment amounts.**

\* \* \* \* \*

(d) Outlier adjustment—(1) General rule. Subject to paragraph (d)(4) of this section, CMS provides for an additional payment for a hospital outpatient service (or group of services) not excluded under paragraph (f) of this section for which a hospital's charges, adjusted to cost, exceed the following:

\* \* \* \* \*

(e) Budget neutrality. CMS establishes payment under paragraph (d) of this section in a budget-neutral manner excluding services and groups specified in paragraph (f) of this section.

(f) Excluded services and groups. Drugs and biologicals that are paid under a separate APC and devices of brachytherapy, consisting of a seed or seeds (including a radioactive source) are excluded from qualification for outlier payments.

**Subpart G—Transitional Pass-Through Payments**

4. Section 419.64 is amended by revising paragraph (d).

**§419.64 Transitional pass-through payments: Drugs and biologicals.**

\* \* \* \* \*

(d) Amount of pass-through payment. (1) Subject to any reduction determined under §419.62(b), the pass-through payment for a drug or biological as specified in section 1842(o)(1)(A) and (D)(i) is 95 percent of the average wholesale price of the drug or biological minus the portion of the APC payment CMS determines is associated with the drug or biological.

(2) Subject to any reduction determined under 419.62(b), the pass-through payment for a drug or biological as specified in 1842(o)(1)(B) and (E)(i) is 85 percent of the average wholesale price, determined as of April 1, 2003, of the drug or biological minus the portion of the APC payment CMS determines is associated with the drug or biological.

**Subpart H—Transitional Corridors**

5. Section 419.70 is amended as follows:

A. Paragraph (d) (1) is amended by removing "2004" and adding "2006" in its place.

B. A new paragraph (d) (3) is added to read as follows:

**§419.70 Transitional adjustment to limit decline and payment.**

\* \* \* \* \*

(d) \* \* \*

(3) Temporary treatment for sole community hospitals located in rural areas. For covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004, and continuing through December 31, 2005, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by the amount of that difference if the hospital—

(i) Is a sole community hospital, under §412.92 of this chapter; and

(ii) Is located in a rural area as defined in §412.63(b) of this chapter or is treated as being located in a rural area under section 1886(d) (8) (E) of the Act.

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

**Dated:** \_\_\_\_\_

\_\_\_\_\_  
**Dennis G. Smith,**  
Acting Administrator,  
Centers for Medicare & Medicaid  
Services.

**Approved:** \_\_\_\_\_



\_\_\_\_\_  
**Tommy G. Thompson,**  
Secretary.

**BILLING CODE 4120-01-P**

