WISCONSIN HOSPITAL ASSOCIATION, INC.

SUMMARY OF THE 2004 MEDICARE PROPOSED RULE FOR OUTPATIENT PROSPECTIVE PAYMENT

SEPTEMBER 2003

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SUMMARY OF THE 2004 MEDICARE PROPOSED RULE FOR OUTPATIENT PROSPECTIVE PAYMENT

The Centers for Medicare and Medicaid Services (CMS) published proposed regulations for the Medicare Outpatient Prospective Payment System (OPPS) in the August 12, 2003 *Federal Register*. Changes are scheduled to be effective for services on or after January 1, 2004. The proposed rule provides for a 60-day comment period. Comments must be received no later than 5 p.m. on October 6. One original and two copies may be delivered to:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1471-P
P.O. Box 8018
Baltimore, MD 21244-8018

Alternatively, comments (an original and two copies) may be hand-delivered to CMS at:

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

This summary also discusses the proposed regulations for the Medicare Payment Reform for Part B Drugs published in the August 12, 2003 *Federal Register*. This proposal would effect payment for pass-through drugs under outpatient PPS. Comments on this proposal must be received no later than 5 p.m. on October 14. One original and two copies may be delivered to:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1229-P
P.O. Box 8013
Baltimore, MD 21244-8013

Alternatively, comments (an original and two copies) may be hand-delivered to CMS at the same addresses as listed above for the outpatient PPS proposed rule.

I. AMBULATORY PAYMENT CLASSIFICATION (APC) PAYMENTS

CONVERSION FACTOR - Federal Register page 48007

The proposed rule increases the conversion factor from $52.151 to $54.289 based on the inpatient marketbasket factor of 3.5%, with an adjustment for budget neutrality and an increase due to a reduction in the carve-out for pass-through payments from 2.3% in 2003 to 2.0% in 2004.

WAGE INDEX ADJUSTMENT

The wage indexes published in this proposed rule, and used to calculate budget neutrality adjustments are from the 2004 Inpatient PPS *Proposed* Rule. The wage indexes included in the final rule will be updated to the final inpatient PPS wage index. Consistent with prior years, the labor-related portion of OPPS payment rates is 60%.

OUTLIER PAYMENTS - Federal Register page 48007

In 2003, the outlier payment target was 2.0% and CMS proposes to maintain the 2.0% target in 2004. Under the 2004 proposal, the outlier methodology would pay 50% of costs over the threshold; with the threshold set at 2.75 times the payment for the individual APC. This is an increase from the 45% payment percentage that applied in 2003.

Program Memorandum A-03-004, issued on January 17, 2003, instructed intermediaries to update the cost-to-charge ratios (CCR) used in the outpatient outlier and pass-through calculations. Revised CCRs based on data from the most recent tentative settled cost report were to be implemented by April 30. CMS did not use the new CCRs in the calculation of the proposed outlier thresholds. The updated calculations in the final rule should result in revisions to the 2004 outlier payment policy that will either lower the thresholds or increase the payment percentages.

TRANSITIONAL CORRIDOR PAYMENTS - Federal Register page 48007

Background: Transitional corridor payments provide partial relief to hospitals that are receiving less in payments under the outpatient PPS methodology than they received under the prior payment system. Rural hospitals with 100 or fewer beds, cancer hospitals, and children hospitals are held harmless and are paid the full amount of the decrease compared to the prior payment system. Transitional corridor and hold harmless payments expire on December 31, 2003 except for cancer hospitals and children's hospitals, which are permanently held harmless.

CMS Proposal: In the proposed rule, CMS expresses concern over the effect this change will have on small rural hospitals. **CMS is considering an adjustment to the clinic and emergency room rates for small rural hospitals as a means to help sustain outpatient services in rural areas. However, CMS states that any adjustment made under its administrative authority would be required to be budget neutral** and would be offset by reductions elsewhere in the outpatient system. CMS is requesting comments on this issue.

Both the House and the Senate bills that are currently in conference have provisions that would extend hold harmless payments for small rural hospitals. WHA strongly supports these provisions. While the CMS proposal would require offsetting reductions to payments, the legislative solutions would add new funds to the payment system.

RECALIBRATION OF APC WEIGHTS - Federal Register page 47982

Weights for 2003 were calculated using claims for services furnished between April 2001 and March 2002. The proposed APC weights for 2004 were calculated using costs calculated from claims for services furnished from April 1, 2002 through December 31, 2002. The calculation also reflections the APC group changes described in Section III of this summary.

LIMIT ON REDUCTIONS IN APC WEIGHTS

Background: CMS implemented a policy last year to limit the amount that the payment for an APC could decrease compared to the prior year. Under this policy, reductions in APC prices of more than 15% were "dampened." For any APC where the median cost fell by 15 percent or more from 2002 to 2003, CMS limited the reduction to 15 percent plus one-half of the difference between the value derived from claims data and the 15 percent reduction. For example, an APC that decreased by 20% in 2003 compared to 2002 would be modified to lessen the reduction as follows:

15 percent + (½ * 20 percent – 15 percent) = allowable reduction of 17.5 percent

In addition, price reductions for APCs related to blood, blood products, and hemophilia clotting factors were limited to about 15% in 2003 and external data were used for selected APCs containing procedures and devices where the device represented 80% or more of the costs.

Proposal: CMS proposes that APCs related to blood, blood products, and hemophilia clotting factors would be limited to approximately a 10% rate reduction in 2004 compared to 2003 (Federal Register page 48005). Rates for these products were limited to a 15% decrease in 2003 but CMS believes that this would not sufficiently limit the reduction if applied again in 2004. CMS has asked for comments on this proposal.

CMS also proposes to limit decreases to APC rates for drugs and radiopharmaceuticals that will be separately payable in 2004 (Federal Register page 47998). For separately payable drugs and radiopharmaceuticals whose 2004 median costs decreased by more than 15 percent from the 2003 median cost, CMS is proposing to limit the reduction in median costs to 15 percent plus one-fourth of the difference between the value derived from claims data and a 15 percent reduction. For example, a drug APC that decreased by 20% in 2004 compared to 2003 would be modified as follows:

15 percent + (¼ * 20 percent – 15 percent) = allowable reduction of 16.25 percent

Dampening was applied to all APCs in 2003 but would only cover blood product and drug APCs under the 2004 proposal. The following table shows the APCs with more than a 10% reduction in median costs between the costs used to calculate 2003 weights and the costs used to calculate 2004 weights. A majority of these APCs will experience substantial payment decreases because they were "dampened" in 2003 but will not be protected from weight decreases in 2004.

APCs with Decreases Over 10% from 2003 to Proposed 2004

Final APC	Description	SI	Final 2003 Dampened Median Cost	2004 Proposed Rule APC Median Cost	Percent Difference APC Median Cost (2003 Dampened vs. 2004 Proposed Rule)
0312	Radioelement Applications	S	$3,141.77	$216.18	-93.12%
0330	Dental Procedures	S	$284.02	$32.87	-88.43%
0692	Electronic Analysis of Neurostimulator Pulse Generators	S	$371.55	$56.40	-84.82%
0651	Complex Interstitial Radiation Source Application	S	$3,250.63	$588.67	-81.89%
0225	Implantation of Neurostimulator Electrodes	S	$8,277.07	$3,283.68	-60.33%
0352	Level I Injections	X	$13.10	$6.31	-51.83%
0068	CPAP Initiation	S	$123.29	$65.83	-46.61%
0124	Revision of Implanted Infusion Pump	T	$2,975.12	$1,608.78	-45.93%
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	T	$4,429.71	$2,495.57	-43.66%
1719	Brachytx seed,Non-HDR Ir-192	K	$31.04	$17.89	-42.36%
0699	Level IV Eye Tests & Treatments	T	$223.07	$130.15	-41.65%
0199	Obstetrical Care Service	T	$232.46	$142.74	-38.59%
0313	Brachytherapy	S	$1,249.57	$769.14	-38.45%
0236	Level II Posterior Segment Eye Procedures	T	$1,873.66	$1,153.59	-38.43%
0123	Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant	S	$380.54	$234.84	-38.29%
0223	Implantation or Revision of Pain Management Catheter	T	$2,437.21	$1,525.61	-37.40%
0385	Level I Prosthetic Urological Procedures	T	$6,199.09	$3,895.76	-37.16%
0681	Knee Arthroplasty	T	$8,780.47	$5,669.25	-35.43%
0302	Level III Radiation Therapy	S	$548.35	$363.26	-33.75%
0301	Level II Radiation Therapy	S	$187.53	$125.03	-33.33%
0094	Level I Resuscitation and Cardioversion	S	$228.18	$154.77	-32.17%
0671	Level II Echocardiogram Except Transesophageal	S	$140.57	$96.05	-31.67%
0098	Injection of Sclerosing Solution	T	$99.06	$68.15	-31.20%
0346	Level II Transfusion Laboratory Procedures	X	$30.59	$22.72	-25.73%
0043	Closed Treatment Fracture Finger/Toe/Trunk	T	$148.63	$112.70	-24.17%
0687	Revision/Removal of Neurostimulator Electrodes	T	$1,535.37	$1,171.45	-23.70%
0359	Level II Injections	X	$67.50	$51.53	-23.66%
0122	Level II Tube changes and Repositioning	T	$638.40	$494.56	-22.53%
0363	Level I Otorhinolaryngologic Function Tests	X	$64.56	$50.02	-22.52%
0081	Non-Coronary Angioplasty or Atherectomy	T	$2,584.47	$2,041.29	-21.02%
0191	Level I Female Reproductive Proc	T	$12.27	$9.84	-19.80%
0685	Level III Needle Biopsy/Aspiration Except Bone Marrow	T	$355.90	$286.61	-19.47%
0371	Level I Allergy Injections	X	$29.69	$23.93	-19.39%
0152	Percutaneous Abdominal and Biliary Procedures	T	$595.64	$486.01	-18.41%
0222	Implantation of Neurological Device	T	$13,528.13	$11,061.74	-18.23%
0118	Chemotherapy Administration by Both Infusion and Other Technique	S	$325.75	$267.63	-17.84%
0086	Ablate Heart Dysrhythm Focus	T	$3,138.30	$2,611.43	-16.79%
0202	Level VIII Female Reproductive Proc	T	$2,706.38	$2,273.91	-15.98%
0228	Creation of Lumbar Subarachnoid Shunt	T	$3,541.71	$2,996.28	-15.40%
0347	Level III Transfusion Laboratory Procedures	X	$66.49	$56.52	-14.99%
0245	Level I Cataract Procedures without IOL Insert	T	$863.71	$736.87	-14.69%
0189	Level III Female Reproductive Proc	T	$90.69	$77.39	-14.67%
0085	Level II Electrophysiologic Evaluation	T	$2,478.31	$2,128.77	-14.10%
0665	Bone Density:AppendicularSkeleton	S	$49.02	$42.34	-13.63%
0670	Intravenous and Intracardiac Ultrasound	S	$1,796.55	$1,555.61	-13.41%
0368	Level II Pulmonary Tests	X	$62.61	$54.62	-12.76%
0107	Insertion of Cardioverter-Defibrillator	T	$19,378.60	$17,025.21	-12.14%
0362	Level III Otorhinolaryngologic Function Tests	X	$168.41	$148.74	-11.68%
0287	Complex Venography	S	$415.06	$368.16	-11.30%
0120	Infusion Therapy Except Chemotherapy	T	$129.56	$115.11	-11.15%
0212	Nervous System Injections	T	$196.63	$175.73	-10.63%
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow	T	$103.36	$92.43	-10.57%
0676	Level II Transcatheter Thrombolysis	T	$245.24	$219.77	-10.39%
0268	Ultrasound Guidance Procedures	S	$82.47	$74.07	-10.19%

BUDGET NEUTRALITY - Federal Register page 47991

To ensure that aggregate payments do not increase or decrease due to recalibration or changes in the APC groups, the proposed 2004 rule applies a budget neutrality factor of 1.0031 to all APC weights. This is a significant change from 2003, when all APC weights were adjusted by 0.969 to ensure budget neutrality. The large downward adjustment was required to offset the fact that the "dampening" limit on weight reductions was applied to a large number of APCs. In 2004, "dampening" covers a much smaller group of APCs. As a result, many APCs for routine services such as clinic plain film radiology and other routine services will experience a substantial rate increase compared to 2003. For Example, APC 0601 Mid Level Clinic Visits would receive an increase in weight from 0.9690 in 2003 to 1.0031 in 2004. As a result, payment for this APC would increase by 7.8% from $50.53 to $54.46.

GENERIC DRUGS AND RADIOPHARMACEUTICALS - Federal Register page 48003

Background: In general, the costs for generic drugs, biologicals, and radiopharmaceuticals are lower than the acquisition costs for sole source drugs. CMS believes there is approximately a 12-month lag between the time generic items are made available and the time when the claims data will accurately reflect the lower costs associated with the generic alternative. CMS believes that the program is overpaying providers for drugs that have recently dropped in price due to generic competitors.

Proposal: **CMS is proposing to adjust payments for certain non-pass-through drugs to account for the assumed cost decrease caused by the entry of generic alternatives into the market**. CMS intends to identify generic drugs approved by the Food and Drug Administration (FDA) during a six-month time period before the first day of the claims period used as the basis for the annual OPPS update. If CMS determines that claims data do not reflect the cost of the generic alternative, the payment rate for the drug would be set based on 43% of the average wholesale price rather than calculated based on median costs.

CMS reviewed FDA approvals for generic drugs, biologicals, and radiopharmaceuticals issued between October 2001 and December 2002. CMS found six drugs that fit the criteria and would receive reduced payments under the proposal. When CMS determines that claims data accurately reflects the cost of the generic alternatives, CMS will use that data to set payment rates. CMS has requested comments on the proposed methodology and on the drugs that were selected for adjustment. The following drugs would be paid under the proposed methodology:

APC	Description	Date of Generic Approval by the FDA	43 Percent of AWP	2004 Median Cost (with dampening if applicable)
832	Idarubicin hcl injection	May 2002	$190.08	$188.25
831	Ifosfomide injection	May 2002	$68.07	$115.46
863	Paclitaxel injection	May 2002	$74.27	$116.61
730	Pamidronate disodium	May 2002	$120.34	$184.40
857	Bleomycin sulfate	October 2001	$130.98	$169.28
820	Daunorubicin hcl	November 2001	$35.46	$89.65

ORPHAN DRUGS - Federal Register page 48004

Background: Orphan drugs are generally expensive drugs that by definition are rarely used. CMS has recognized that packaging these drugs would result in insufficient payment to cover the cost of the drug. Therefore, CMS makes a separate payment for these drugs. CMS defines an orphan drug as: a drug designated as an orphan drug by the FDA and approved by the FDA for treatment of only the orphan condition, and that the current United States Pharmacopoeia Drug Information (USPDI) shows have neither an approved use nor an off-label use for other than the orphan condition. CMS designated four orphan drugs in 2003 and agreed to pay for them based reasonable costs. Commentators argued that CMS had missed several drugs that meet the criteria for orphan designation and after review; CMS has identified seven additional drugs that will be designated as orphan drugs in 2004.

Original Four Identified as Orphan Drugs for 2003

CPT/HCPCS	Status Indicator	Description	APC	Payment Rate
J0205	K	Alglucerase injection	0900	$ 29.71
J0256	K	Alpha 1 proteinase inhibitor	0901	$ 1.16
J9300	K	Gemtuzumab ozogamicin	9004	$ 950.17
J1785	K	Injection imiglucerase /unit	0916	$ 2.88

Additional Seven Identified as Orphan Drugs for 2004

CPT/HCPCS	Status Indicator	Description	APC	Payment Rate
J2355	K	Oprelvekin injection	7011	$ 147.92
J3240	K	Thyrotropin injection	9108	$ 358.63
J7513	K	Daclizumab, parenteral	1612	$ 202.52
J9015	K	Aldesleukin/single use vial	0807	$ 385.10
J9160	K	Denileukin diftitox, 300 mcg	1084	$ 819.29
J9216	K	Interferon gamma 1-b inj	0838	$ 134.32
Q2019	K	Basiliximab	1615	$ 608.07

Proposal: CMS indicates that because the number of orphan drugs will increase, the number of Medicare beneficiaries who will receive orphan drug will increase as well. **CMS believes that "payments made outside of the Outpatient Prospective Payment System (OPPS) should remain relatively small," and therefore is proposing to discontinue reasonable cost payments for orphan drugs**. Instead, CMS is proposing to base payments for orphan drugs on the methodology used to pay for other non-pass-through drugs by placing them in APCs and calculating rates based on median costs. CMS is soliciting comments on this proposal.

MULTIPLE PROCEDURE REDUCTION - Federal Register page 47981

Background: When more than one surgical procedure with payment status indicator "T" is performed during a single operative session, facilities receive full APC payment for the procedure having the highest payment rate. For all other procedures with a status indicator of "T" performed during the same operative session, both the APC payment and the beneficiary coinsurance are reduced by 50%.

During the last two years, many devices have been removed from pass-through status and the costs have been packaged and included in the rates for the associated surgical procedures. Reducing the entire payment by 50% assumes that the cost of any medical devices that are packaged and included as part of the payment for the procedure are also reduced by 50%. While many costs of a procedure are reduced when performing multiples, **WHA and others have objected that the cost of expensive medical devices that are packaged into the procedure payment are not reduced. In the proposed rule, CMS discusses this issue but argues that the resulting discounted payment is still adequate. Therefore, CMS proposes no changes to the discounting of payments for multiple procedures in 2004**.

Proposal: While CMS proposes no change in the discount policy, two options were presented for comment and future consideration. One option is to change the status indicators of certain APCs requiring the use of high cost devices from "T" to ''S''. This would put them in the category of "significant procedures" which are NOT discounted for multiple procedures. The second option is to create ''combination APCs'' in order to make a single payment when two APCs with high medical device costs are billed together. Under this option, hospitals would not change their coding or billing procedures. Instead, the outpatient payment logic would be modified so that when hospitals bill the two APCs together, it would be paid a single rate for both services. The payment rate for the new ''combination'' APC would be based upon the weight calculated from the combined median cost for the two services.

DRUG AND DEVICE CODING

Background: In 2003, the pass-through status of many drugs and devices expired. These drugs and devices were packaged into the payment for the primary procedure or service with which they are associated. At that time, CMS deleted the HCPCS codes that were used to code these drugs and devices. Hospitals no longer received separate payment for these items and were no longer required to report codes for the individual items and services included in the package.

Proposal: CMS proposes to require that hospitals report individual codes for all drugs and devices used during the episode, including those that are packaged. CMS now believes that by deleting the codes for packaged drugs and devices it has lost coding information that are needed for accurate rate setting. Even though payment is not directly related to that information, CMS believes that reporting the codes may be in hospitals' best interest because it may result in more accurate payments. CMS requests comments on this proposal.

II. TRANSITIONAL PASS-THROUGH PAYMENTS Federal Register page 47991

The BBRA provided transitional pass-through payments for certain drugs, pharmaceuticals, biologicals, and medical devices. Pass-through payments for a specific item are limited to a period of at least two years, but not more than three years. The number of drugs and devices paid as pass-throughs has decreased significantly subsequent to 2002 as shown below.

APC Category	Status Code	2002	2003	2004
New Drugs and Biologicals	G	247	19	14
Medical Devices	H	97	5	8
Total		334	24	22

The aggregate amount of pass-through payments cannot exceed 2.5% of total OPPS payments through 2003 and is limited to 2.0% in 2004. Limiting pass-through payments to 2.0% of total outpatient PPS payments results in a $456 million pool according to the CMS estimate. CMS has designated the following items for pass-through payment in 2004. These 22 drugs and devices account for $212 million in anticipated pass-through payments according to CMS' estimate.

Drugs and Devices Designated for Pass-through Payment in 2004.

CPT	Description	APC	Status Indicator	2004 APC Rate
C9111	Inj, bivalirudin, 250mg vial	9111	G	$ 397.81
C9112	Perflutren lipid micro, 2ml	9112	G	$ 148.20
C9113	Inj pantoprazole sodium, via	9113	G	$ 22.80
C9116	Ertapenem sodium, per 1 gm	9116	G	$ 45.31
Q4053	Pegfilgrastim, per 1 mg	9119	G	$ 467.09
C9120	Injection, fulvestrant	9120	G	$ 175.16
C9121	Injection, argatroban	9121	G	$ 14.25
C9200	Orcel, per 36 cm2	9200	G	$ 1,135.25
C9203	Perflexane lipid micro	9203	G	$ 142.50
J2324	Nesiritide, per 0.5 mg vial	9114	G	$ 144.40
J3315	Triptorelin pamoate	9122	G	$ 415.24
J3487	Zoledronic acid	9115	G	$ 203.40
C9204	Ziprasidone mesylate	9204	G	$ 41.56
C9205	Oxaliplatin	9205	G	$ 94.46
C1783	Ocular imp, aqueous drain dev	1783	H	Cost Based
C1814	Retinal tamp, silicone oil	1814	H	
C1884	Embolization protective system	1884	H	
C1888	Endovas non-cardiac ablation catheter	1888	H	
C1900	Lead coronary venous	1900	H	
C2614	Probe, perc lumb disc	2614	H	
C2632	Brachytx sol, I-125, per mCi	2632	H	
C1818	Integrated keratoprosthesis	1818	H	

PRO RATA ADJUSTMENT TO PASS-THROUGH PAYMENTS – Federal Register page 47992

CMS must apply a pro rata reduction if it determines, prospectively, that pass-through payments otherwise will exceed the 2.0% cap. CMS indicates that it is uncertain whether the cap will be exceeded because it has not completed estimates of pass-through payments for certain drugs and devices for 2004. Furthermore, CMS indicates that new device categories and new drugs and biologicals could be

announced after the publication of the proposed rule, or even after the publication of the final rule. CMS made the same statements last year and it appears that the 2003 pass-through payments after including any pass-through items designated after publication of the rule were significantly below the limit. CMS does not include an estimate of how much was actually spent on pass-through items in 2003. **WHA is concerned that pass-through payments are less than the amount that was carved out of the rate for this purpose in both 2003 and 2004. We will address this issue in our comments**.

PASS-THROUGH DRUGS AND BIOLOGICALS - Federal Register page 47995

Background: The law requires that pass-through payments for new drugs be established at 95% of the average wholesale price (AWP) of the drug. Currently, AWPs are determined based on the prices published in the Red Book. However, CMS is concerned that this does not accurately reflect the prices for drugs and that Medicare is paying more for drugs than other purchasers. Therefore, CMS intends to develop a new methodology for establishing the AWP.

Proposal: In the August 20, 2003 *Federal Register,* CMS released a proposed rule detailing four options to establish a replacement methodology to set Part B drug payments. The outpatient proposed rule states that when the new methodology is final, it will be applied to outpatient PPS pass-through drug payments.

The new methodology would effect all Part B payments that are determined using the AWP including some payments for physicians, pharmacies, durable medical equipment suppliers, and certain drugs separately billed by end stage renal disease (ESRD) facilities. It would also apply to hospital outpatient PPS pass-through payments. It would NOT effect drugs paid on a cost or prospective basis including drugs furnished during a hospital inpatient stay, outpatient PPS non-pass-through drugs, drugs covered by the ESRD composite rate, and drugs furnished by critical access hospitals and skilled nursing facilities.

CMS discussed the following options in the August 20 Federal Register:

- Use the existing “comparability” provision of the law to adjust drug prices. Section 1842(b)(3) of the Social Security Act provides that each carrier “will take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to policyholders and subscribers of the carrier.’’ Under this option, carriers would be instructed to use their own private payments for drugs to establish limits for Medicare drug payments within their locality. CMS does not address the fact that this law covers carriers only while hospital outpatient payments are made through intermediaries.

- Apply a discount to the AWPs published in commercial compendia such as the Red Book. General Accounting Office (GAO) and Office of Inspector General (OIG) studies report that the AWP is significantly higher than the prices actually charged to physicians and suppliers. CMS indicates that a majority of the prices examined had a discount of 10% to 20% off the list AWP. Under this option, the Medicare payment would be established at 80% to 90% of the published AWP as of April 1, 2003. The price would be “locked-in” and updated annually using the consumer price index (CPI) for medical care.

- Define the AWP to be the widely available market price. Instead of the list price, Medicare payments would be the price that “a prudent physician or prudent supplier would pay when purchasing the drug from common sources.” CMS defines this as the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers. This option would require the development of a means of obtaining market price information.

- Expand competitive bidding programs. Under this proposal, Medicare would establish competitive acquisition areas and entities would bid to supply drugs within that area. Providers could choose to acquire drugs from that entity and the entity would bill Medicare. If a provider did not choose to acquire drugs through that entity, the provider would purchase the drugs elsewhere and bill Medicare directly. Medicare would pay the provider based on the average sales price (ASP). The ASP for a drug would be calculated based on the manufacturer's total sales of the drug in the last quarter divided by the total units sold. Medicare payments would be made at a markup over the ASP that CMS estimates would be from 101% to 112%.

The implementation date for the new methodology is unclear. In the outpatient PPS proposed rule, CMS states that it is possible that a mid-year 2004 change to drug pass-through payments could be made if the final Part B drug payment rule is published in time. Until a new methodology is determined, CMS proposes to continue to pay pass-through drugs based on 95% of the AWP.

TIME LIMITS FOR PASS-THROUGH PAYMENT

The law limits payment for pass-through items to between two and three years. It has been CMS policy to remove drugs and devices from pass-through status as quickly as possible and most are incorporated into the APC rates after two years. It is also CMS' policy is to pay all drugs, devices, and other items inherent in performing a procedure through packaging unless there is a compelling reason to pay separately. Therefore, as former pass-through items are incorporated into the APC rates, many are redefine as packaged services with no separate payment. Instead, the costs of these drugs and devices are included in the calculation of the rates for the procedures that are billed with the drug or device. CMS has made exceptions to continue separate payment for orphan drugs, blood and blood products, and certain vaccines.

Expiring Pass-through Drugs (Federal Register page 47996): In 2004, CMS proposes to continue the policy that was established in 2003 to incorporate lower cost expiring pass-through drugs into the procedure APCs. Separate APCs and payments are provided for the more expensive drugs. CMS proposes to remove eight drugs from pass-through status after December 31, 2003. Those drugs with an average cost less than $150 per line will be packaged into their associated APCs. Drugs with a median line cost of greater than $150 will be assigned to individual APCs. Drugs that move to K status typically experience a significant payment decrease because the new rates based on median costs are lower than the prior average wholesale price-(AWP) based payments. CMS proposes to make an exception to the $150 threshold and continue separate payment for drugs that received separate payment in 2003 but whose costs have now dropped below the limit.

Proposed 2004 Status for Drugs No Longer Paid as Pass-throughs

Status	Description	Count
E	Non-Covered	x
N	Packaged Services	x
K	Non-Pass-through Drugs and Biologicals	x

Expiring Pass-through Devices (Federal Register page 47993)**:** CMS proposes to retire two devices from pass-through status after December 31, 2003: C1765 Adhesion Barrier and C2618 Probe, cryoblation. In 2004, these items will be treated as packaged items with no separate payment will be provided. Instead, the cost for these devices will be incorporated into the rates of associated procedure APCs.

III. APC GROUPS

APCs for Services Other than Pass-Throughs
Number of APC Groups by Category

APC Category	Status Code	2003	2004 Proposed
Medical Visits	V	6	6
Surgical Procedures	T	200	204
Significant Procedures	S	102	126
Ancillary Services	X	42	43
Drugs/Biologicals	K	160	185
Partial Hospitalization	P	1	1
New Technology	S/T	34	74
Total		**545**	**639**

The 2004 proposed rule revises the APC groups to take into account drugs and devices that no longer qualify for pass-through status, new and deleted Healthcare Common Procedure Coding System (HCPCS) Current Procedural Terminology (CPT) codes, changes in technologies, new services, and new cost data. APCs are also modified to comply with the "two times" rule as required by the Balanced Budget Refinement Act (BBRA). This rule limits the variation within APCs so that the most costly procedure in a group does not have a median cost more than twice that of the lowest cost procedure in the group. In addition**,** the rule includes input from the Advisory Panel on APC Groups, an outside panel of experts established as required by the Balanced Budget Act (BBA). The more significant revisions to the APC groups are described below.

NEW TECHNOLOGY APCS - Federal Register page 47979

Background: In 2002, CMS added 32 "new device technology" APCs to cover devices which are not represented in the 1996 base year data, but did not meet the transitional payment pass-through criteria. Procedures are assigned to new technology APCs until enough data is collected to allow assignment to clinically appropriate APCs. New technology APCs are defined on the basis of "cost bands," not the clinical characteristics of a service. Each APC covers technologies within a defined range of costs and the payment rate for each new technology APC is based on the midpoint of the range. For example, in 2003, APC 0975 covers all new technologies with a median cost between $500 and $750 and provides a payment rate of $625.

Proposal: CMS believes that the current cost intervals for the current new technology APCs are too broad. Therefore, **CMS proposes to replace the current 32 new technology APCs with 74 APCs**. The proposed APCs would be defined by cost bands from $0 to $100 in increments of $50, from $100 through $2,000 in intervals of $100, and from $2,000 through $6,000 in intervals of $500. For example, proposed APC 1507 would cover new technologies with a median cost between $500 and $600 and would provide for a payment rate of $550.

CMS is proposing to delete four HCPCS codes, defining items of medical equipment that are currently paid in new technology APCs. CMS believes that these codes do not conform to current policy to not create HCPCS codes for equipment used to provide a service. Instead, CMS holds that most equipment should be packaged like other resources that are required to furnish a service such as cost of a room, cost of staff, and cost of supplies. The deleted codes are:

C1088: Laser Optic Treatment system, Indigo Laseroptic Treatment System,
C9701: Stretta System,
C9703: Bard Endoscopic Suturing System, and
C9711: H.E.L.P. Apheresis System.

NUCLEAR MEDICINE APCS - Federal Register page 47974

Background: Subsequent to 2002, a number of radiopharmaceuticals that were paid as pass-through drugs were "retired." These drugs were no longer paid as pass-throughs and the costs for these items were incorporated into the APC rates. Due to the packaging of radiopharmaceuticals into the APC payments for nuclear medicine procedures, commentators have expressed concern that the current nuclear medicine APC structure is no longer homogeneous in terms of resource consumption.

Proposal: After review of the use and cost of various radiopharmaceuticals CMS proposes to restructure the APCs for nuclear medicine. Under this proposal, CMS would eliminate the six existing nuclear medicine APCs and replace them with 20 new APCs based on the organ being examined or treated, and the complexity of the procedure.

2003 APC	2003 Desciption	2003 Rate	New 2004 APC	Description	2004 Rate
0286	Myocardial Scans	$ 340.59	0389	Non-imaging Nuclear Medicine	$ 89.44
0290	Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans	$ 105.61	0390	Level I Thyroid Imaging	$ 154.37
0291	Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans	$ 207.69	0391	Level II Thyroid Imaging	$ 201.81
0292	Level III Diagnostic Nuclear Medicine Excluding Myocardial Scans	$ 223.86	0392	Adrenal Imaging	$ 364.18
0294	Level II Therapeutic Nuclear Medicine	$ 212.74	0393	Red Cell/Plasma Studies	$ 221.06
0666	Myocardial Add-on Scans	$ 154.63	0394	Hepatobiliary Imaging	$ 240.88
			0395	GI Tract and B12 Studies	$ 213.75
			0396	Bone Imaging	$ 230.43
			0397	Vascular Imaging	$ 134.29
			0398	Cardiac Imaging	$ 361.14
			0399	Cardiac Add-on Imaging	$ 87.04
			0400	Hematopoietic Imaging	$ 210.05
			0401	Pulmonary Imaging	$ 266.72
			0402	Brain Imaging	$ 297.60
			0403	CSF Imaging	$ 213.17
			0404	Renal Imaging	$ 279.79
			0405	Non-renal GU Studies	$ 42.01
			0406	Tumor/Infection Imaging	$ 258.10
			0407	Thyroid Radionucliide treatment	$ 232.34
			0408	Non-thyroid Radionucliide treatment	$ 217.16

PAYMENT FOR DRUG ADMINISTRATION AND CHEMOTHERAPY – Federal Register page 47974

Background: Currently, the following eight HCPCS codes are used for drug administration payments:

90782 Injection, SC/IM
90783 Injection, IA
90784 Injection, IV
90788 Injection of antibiotic
Q0081 Infusion therapy other than chemotherapy
Q0083 Chemotherapy by other than infusion
Q0084 Chemotherapy by infusion
Q0085 Chemotherapy by both infusion and other

The payment for these procedures includes the cost of certain drugs that are packaged into the rate. When a hospital administers a packaged drug, CMS believes that the hospital receives the appropriate reimbursement. However, these procedure codes are also billed when a hospital administers a separately payable drug. CMS believes that this results in an overpayment, because the hospital is paid for the drug that is separately billed as well as the procedure which includes some cost for packaged drugs.

Proposal: CMS is proposing four options to revise the APCs for infusion therapy and chemotherapy (Q0081, Q0083, Q0084, and Q0085). CMS does not propose to revise the other drug administration codes at this time but is requesting comments regarding payments for them. The following options are provided:

- Option 1: no change.

- Option 2: Eliminate the current codes for administration (Q0081, Q0083, Q0084, and Q0085) and create eight new codes to enable hospitals to report that they administered a packaged drug or a separately payable drug. New APC rates would be established for each of the new codes. CMS would also require that hospitals report HCPCS codes for both packaged and separately payable drugs to insure that the new APC rates are correct. Only one chemotherapy administration and one non-chemotherapy administration code could be billed per day. This would result in complicated and detailed billing procedures that would be a burden for hospitals. CMS did not endorse any option, but did provide the most detail on this option and used it to calculate the APC rates. The rates under this proposal are shown on the following table.

Deleted 2003 APCs for Chemotherapy

2003 APC	2003 Description	2003 APC Rate
0120	Infusion Therapy Except Chemotherapy	$ 113.70
0116	Chemotherapy Administration by Other Technique Except Infusion	$ 40.43
0117	Chemotherapy Administration by Infusion Only	$ 187.98
0118	Chemotherapy Administration by Both Infusion and Other Technique	$ 286.02

New 2004 APCs for Chemotherapy

2004 APC	2004 Description	2004 APC Rate
0376	Admin of packaged cancer chemotherapy drug(s) by other than infusion, per day.	$ 116.61
0377	Admin of separately payable cancer chemotherapy drug(s) by other than infusion, per day.	$ 36.23
0378	Admin of packaged cancer chemotherapy drug(s) by in-fusion, per day.	$ 238.63
0379	Admin of separately payable cancer chemotherapy drug(s) by infusion, per day.	$ 131.91
0380	Admin of packaged cancer chemotherapy drugs by both infusion and other than infusion, per d	$ 281.53
0381	Admin of separately payable cancer chemotherapy drugs by both infusion and other than infusion	$ 117.24
0382	Infusion of packaged non-cancer chemotherapy drug(s), per day.	$ 254.28
0383	Infusion of separately payable non-cancer chemo drug(s) or non-drug infusion therapy, per day.	$ 99.99

- Option 3: Eliminate the four existing codes for administration and create six new codes to enable hospitals to report that they administered a packaged drug or separately paid drug and pay a different APC amount for each of the six new codes. This option would be the same as Option 2,

but would eliminate codes for chemotherapy by both infusion and other techniques. Instead, up to three chemotherapy administration codes could be billed per day. CMS believes that this will allow for more accurate recognition of the cost of administering multiple drugs. As with the prior option, hospitals would be required to report HCPCS codes for both packaged and separately payable drugs.

- Option 4: Payment would be similar to Option 3 except the current codes Q0081, Q0083, and Q0084 would be retained. Instead of replacing these codes, the outpatient grouper logic would be modified to use the drugs billed on the claim to assign an APC for packaged drugs or an APC for separately paid drugs. Again, hospitals would be required to report HCPCS codes for both packaged and separately payable drugs. Lists of packaged and separately payable drugs would be created and the program would pay the appropriate APC for administration based on the designation of the drugs on the bill. This option would not require that hospitals change their coding of drug administration. However, it relies on accurate coding of the drugs to ensure correct payment.

CMS is requesting comments on these four options.

IV. GUIDELINES FOR EVALUATION AND MANAGEMENT CODES – Federal Register page 48008

Background: Prior to OPPS, hospitals were paid based on "charges reduced to costs," therefore, because it did not affect payment, there were inaccuracies in the level of service reported. Under OPPS, it is necessary to properly report the level of service to receive payment. Emergency and clinic visits are paid based on three levels of service: low, mid, and high. The level is determined by the reported emergency and management (E/M) CPT code.

There is currently no uniform policy on which E/M code should be used, leaving it up to the individual hospital to set up guidelines for proper coding. These codes were defined to reflect the activities of physicians and do not translate well to the activities performed in the hospital setting (including ongoing nursing care, preparation for diagnostic testing, and patient education). To facilitate proper coding, the initial implementation of OPPS included the requirement that each hospital create a set of internal guidelines for determining the proper level of service. Developing and following these guidelines is considered to put a hospital in compliance with OPPS coding requirements. CMS, concerned with statutory requirements and inaccuracies, has proposed the implementation of uniform coding guidelines for the OPPS system.

Proposal: In April, 2001 CMS released a proposed rule and asked for public comments on this issue. After reviewing all the public comments received, the APC panel recommendations and the recommendations made by a joint American Hospital Association (AHA) / American Health Information Management Association (AHIMA) panel, CMS has proposed tentative guidelines. The proposal calls for the creation of new E/M codes to reflect hospital outpatient department resource use rather. Eight new HCPCs codes, to be defined later, would be created to be used for coding clinics and emergency room visits. A crosswalk would be developed mapping current cost data from coded using the current HCPCS codes to the new codes. CMS is still considering AHA/AHIMA expert panels recommendations and will accept recommendations from the public. CMS states that the new guidelines would be implemented no earlier than January 2004 and sufficient time will be provided to transition to the new policies.

V. PARTIAL HOSPITALIZATION - Federal Register page 48011

Background: Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a freestanding Community Mental Health Center (CMHC). Payment to providers for partial hospitalization services is based on a per diem payment for the PHP APC. The PHP per diem amount was initially based solely on hospital data resulting in a per diem rate of $212 in 2002. In 2003, CMS used both hospital PHP and freestanding CMHC data to calculate the rate. The rate increased substantially to $240, even after a 0.583 adjustment was applied to the CMHC data to account for the difference between costs calculated using CMHC "as submitted" cost reports compared to settled cost reports.

Proposal: **In the 2004 proposed rule, CMS calculated the rate using only hospital PHP data resulting in a $208 per diem payment**. According to CMS, they found that the median cost per day for free-standing CMHCs was $605 after adjusting for the difference between "as submitted" and settled cost reports. The median cost per day for hospital PHPs was $225. CMS believes that this difference is due to large increases in CMHC charges. CMS theorizes that costs are overstated due to the use of outdated cost-to-charge ratios (CCR). Based on this analysis, CMS decided not to use CMHC data in the rate calculation. CMS intends to revisit this issue in the final rule when updated CCRs will be available.

CMS proposes to establish a distinct outlier policy for CMHC programs. An analysis of 2001 claims found that 155 CMHCs received $48 million in outlier payments compared to only $9,000 for the 660 hospital PHPs. Partial 2002 data showed that 125 CMHCs received $37 million in outlier payments compared to only $13,000 for hospital PHPs. The $37 million in outlier payments almost equals the total regular APC payments received by CMHCs. As noted above, CMS believes that CMHC charges have increased at a rate that overstates costs given the lag between the CCRs and the actual year charges. Therefore, CMS proposes to establish a separate outlier pool for CMHCs. CMS would allocate 0.36% of the 2.0% outlier pool to CMHCs based on their proportion of total outpatient payments. A separate CMHC outlier threshold would be established at 11.75 times the partial hospitalization APC rate and payment would be provided for 50% of the cost over the threshold.