as ''pseudo'' singles because they were submitted by providers as multiple procedure claims.

2. Use of Single Procedure Claims

We use single procedure claims to set the median costs for APCs because we are, so far, unable to ensure that packaged costs can be correctly allocated across multiple procedures performed on the same date of service. However, bypassing specified codes that we believe do not have significant packaged costs enables use of more data from multiple procedure claims. For CY 2003, we created ''pseudo'' single claims by bypassing HCPCS codes 93005 (Electrocardiogram, tracing), 71010 (Chest x-ray), and 71020 (Chest x-ray) on a submitted claim. However, we did not use claims data for the bypassed codes in the creation of the median costs for the APCs to which these three codes were assigned because the level of packaging that would have remained on the claim after we selected the bypass code was not apparent and, therefore, it was difficult to determine if the medians for these codes would be correct.

For CY 2004, we created ''pseudo'' single claims by bypassing these three codes and also by bypassing an additional 269 HCPCS codes in APCs. We selected these codes based on a clinical review of the services and because it was presumed that these codes had only very limited packaging and could appropriately be bypassed for the purpose of creating ''pseudo'' single claims. The APCs to which these codes were assigned were varied and included mammography, cardiac rehabilitation, and level I plain film x-rays. To derive more ''pseudo'' single claims, we also broke claims apart where there were dates of service for revenue code charges on that claim that could be matched to a single procedure code on the claim on the same date.

As in CY 2003, we did not include the claims data for the bypassed codes in the creation of the APCs to which the 269 codes were assigned because, again, we had not established that such an approach was appropriate and would aid in accurately estimating the median cost for that APC. For CY 2004, from about 16.3 million otherwise unusable claims, we used about 9.5 million multiple procedure claims to create about 27 million ''pseudo'' single claims. For the CY 2005 OPPS rates in this final rule with comment period, from about 24 million otherwise unusable claims, we used about 18 million multiple procedure claims to create about 52 million ''pseudo'' single claims.

For CY 2005, we proposed to continue using date of service matching as a tool for creation of ''pseudo'' single claims and take a more empirical approach to creating the list of codes that we would bypass to create ''pseudo'' single claims. The process we proposed for CY 2005 OPPS resulted in our being able to use some part of 89 percent of the total claims eligible for use in OPPS ratesetting and modeling in developing this final rule with comment period. In CY 2004, we used some part of the data from 82 percent of eligible claims. This process enabled us to use, for CY 2005, 84 million single bills for ratesetting: 52 million ''pseudo'' singles and 33 million ''natural'' single bills.

We proposed to bypass the 383 codes, which we published in Table 17 of the proposed rule (69 FR 50476 through 50486), to create new single claims and to use the line-item costs associated with the bypass codes on these claims in the creation of the median costs for the APCs into which they are assigned (69 FR 50474 through 50486). Of the codes on this list, only 123 (32 percent) were used for bypass in CY 2004.

We developed the proposed bypass list using four criteria:

a. We developed the following empirical standards by reviewing the frequency and magnitude of packaging in the single claims for payable codes other than drugs and biologicals. We proposed to use these standards to determine codes that could be bypassed to create ''pseudo'' single claims for median setting. (More explanation regarding the use of these standards is provided in our August 16, 2004 OPPS proposed rule (69 FR 50475).)

- There were 100 or more single claims for the code.
- Five percent or fewer of the single claims for the code had packaged costs on that single claim for the code.
- The median cost of packaging observed in the single claim was equal to or less than $50.
- The code is not a code for an unlisted service.

b. We examined APCs relying on a low volume of single claims, and it became apparent that several radiological supervision and interpretation codes were commonly billed with the procedural codes in the APCs. We then reviewed all radiological supervision and interpretation codes to assess their viability as bypass codes. For the codes included on the proposed list published in Table 17, we determined that, generally, the packaging on claims, including these radiological supervision and interpretation codes, should be associated with the procedure performed.

c. We examined radiation planning and related codes provided by a professional organization. In the organization's opinion, the codes could safely be bypassed and used without packaging to set medians for the APCs into which these codes are assigned. Many of the codes the organization recommended met our criteria under item a., and the remaining codes were close. Therefore, after reviewing such codes, we proposed to adopt as bypass codes all radiation planning and related codes as provided by the organization.

d. We included HCPCS codes 93005 and 71010. These codes have been bypassed for the past 3 years and generate a significant amount of new single claims because they are very commonly done on the same date of surgery. They have low median packaged costs and a low percentage of single claims with any packaged costs, 6 percent and 18 percent, respectively.

In the August 16, 2004 proposed rule, we invited public comment on the ''pseudo'' single process, including the bypass list and the criteria. We received a number of public comments on our proposals.

Comment: Some commenters stated that CMS should provide an impact analysis by medical specialty and APC for the bypass list. Commenters indicated that 26 radiation oncology codes, which represent over 40 percent of the radiation oncology codes, are on the proposed list and that it is not clear what impact the inclusion of these codes will have on payment for radiation oncology procedures.

Response: The OPPS pays hospitals for the hospital services they furnish and, therefore, we focus our impact analysis on the providers who provide services and to whom the payment is made. It is impractical to do an impact analysis by hospital category, much less medical specialty and APC, for each and every step of the process we use to establish medians on which we base our payment rates.

However, to facilitate the public's ability to do specialized detailed analyses beyond what is practical for us to do, we make available the claims we use to set median costs. Specifically, the claims we used to set the payment rates for CY 2004 OPPS and CY 2005 OPPS are available to the public for public use in extended and focused analysis at any level of interest. Moreover, exhaustive discussion of our process is contained in both the CY 2004 and CY 2005 OPPS final rule with comment period claims accounting documents that are available on *www.cms.hhs.gov/providers/*

hopps.asp, to facilitate the use of such claims for further analysis. Therefore, we provide to the public the data needed for a focused exhaustive analysis of impact by medical specialty or on any basis on which any party with a special interest has a particular concern.

The 383 bypass codes presented in Table 17 of the proposed rule represent the result of an empirical and clinical analysis that identified HCPCS codes for which we could not observe significant packaged costs in the CY 2003 claims data and for which there was no clinical reason that a procedure or service should have significant packaged costs. These criteria are detailed in the proposed rule and were carefully chosen to avoid the inaccurate redistribution of packaged costs (69 FR 50474 through 50475). Inclusion of a HCPCS code on the bypass list is not predicated on the median impact, but rather empirical evidence or clinical arguments that these procedures do not contain significant packaged costs that would call into question their appropriateness for inclusion on the bypass list.

Comment: Most commenters supported the use of a bypass list and date of service matching as a way to use more data from multiple claims. One commenter was concerned that the bypass list may inappropriately break multiple claims into single procedure claims by assuming that the amount and frequency of packaging on procedures found on single bills was the same as would exist on multiple procedure claims. The commenter stated that claims involving multiple APCs are by their nature the most complex combinations of services requiring many more resources than if they were performed singly and that, therefore, CMS may be incorrect to generalize that the packaging found on single bills would also be present for the same procedure done as a multiple procedure. Another commenter opposed the use of the bypass list, citing it as a ''bandaid'' and as not a satisfactory way to deal with the presence of multiple procedure claims over the long run. The commenter indicated that, given the OPPS experience gained over the past years, CMS should be able to perform a study of multiple procedure claims that provides a mechanism for using them.

Response: We have retained and used the proposed bypass methodology in creating the median costs used to set the CY 2005 OPPS relative payment weights in this final rule with comment period. We believe that the use of the bypass list gives us considerably more single claims for ratesetting than had we not used it and that it is a valid representation of codes for which there is seldom any packaging and for which the packaging that exist, is minimal. Given the inability of any concrete processes that provide a way to attribute packaging on multiple bill claims, we believe that the best and only alternative available is for us to use the packaging on single bill claims to determine whether a code can be safely bypassed in the creation of ''pseudo single'' claims for median setting. We continue to examine the means by which we could use all multiple procedure claims and to invite additional recommendations from the public on how we might do so.

Comment: One commenter strongly objected to any method of using multiple procedure claims that would rely in any way on payment weights because the commenter believed that any such method would compound problems in the data by carrying them forward into future years.

Response: We expect to examine a number of different ways of using the data from multiple procedure claims and will evaluate each carefully before we discard any particular process. As we have in the past for updating the OPPS, if we decide to pursue any particular process change, we will discuss our findings and any proposed changes to the OPPS median development process in the proposed rule and consider public comments on the proposal before we change the process.

Comment: Some commenters indicated that the use of single procedure claims means that the most typical correctly coded claims are not used for many services. They added that many of the procedures that implant a device are actually replacing an existing device, which means that the removal of the device is billed with one code while the implant is billed with another code on the same claim on the same date of service, thereby creating a multiple procedure claim that will become two ''pseudo'' single claims under the CMS process. The commenters also stated that services that are provided only in addition to other services, such as noncoronary intravascular ultrasound, can never be correctly coded as a single procedure claim. They contended that such correctly coded claims will be multiple major procedure claims and thus will not be used for median cost setting. The commenters stated that the nature of some services being routinely performed in combination with other services means that, under the current CMS methodology, only small percentages of the claims will be used to set the medians and that those claims are likely to be the incorrectly coded claims.

Response: We recognize that there are categories of service that are typically done in combination with other services at such frequency that acquiring valid single procedure claims is very difficult, if not impossible. We are planning to explore these services for which the medians are set based on a small percentage of the claims that are submitted with the APC Panel in the future to determine what methods may be available to deal effectively with these situations.

In the August 16, 2004 proposed rule, we also discussed suggestions that we had received for creating ''pseudo'' single claims, which included recommendations that the costs in packaged revenue codes and packaged HCPCS codes be allocated separately to paid HCPCS codes based on the prior year's payment weights or payment rates for the single procedures. Still other suggestions recommended that we allocate the packaged costs in proportion to the charges or to the costs for the major procedures based on the current year's claims. We are concerned that using a prior year's median costs, relative weights or payment rates as the basis to allocate current year's packaged costs to current year costs for payable HCPCS codes may not be appropriate. For example, if two procedures are performed and one uses an expensive device, this methodology would split the costs of the device between the service that uses the device and a service that does not use the device, thus resulting in an incorrect allocation of the packaged costs. For this reason, we did not propose to incorporate these suggestions in our ratesetting methodology. However, we stated in our proposed rule that we intended to examine them more thoroughly.

We did not propose a methodology beyond use of dates of service and the expanded bypass list. However, we solicited specific proposals that would be provided as comments on how multiple procedure claims can be better used in calculating the relative payment weights.

Comment: One commenter asked that CMS clarify whether the ''pseudo'' single claims data for CPT codes 93307 (Echo exam of heart), 93303 (Echo transthoracic), and 93320 (Doppler echo exam, heart) were used in setting APC relative weights and, if so, the impact of this proposal. Another commenter asked that CMS clarify whether HCPCS codes for drugs, radiopharmaceuticals, and blood products were bypassed to create ''pseudo'' singles. The commenter

believed that packaged costs are never associated with these items; therefore, they should always be bypassed.

Response: The claims data for the three referenced CPT codes were used in setting the APC relative weights for these services. They were included in the list of bypass codes because they met the criteria for inclusion, which focused on selecting only claims that often did not include packaged services and for which packaging on the single bills was very modest.

We agree with the commenter that drugs, radiopharmaceuticals, and blood products would rarely be expected to have associated packaged costs. Presence of codes for these items on a claim does not result in a multiple claim, as we do not consider the items to be major procedures.

Comment: One commenter asked that CMS add CPT codes 76362 (Computed tomography guidance for, and monitoring of, visceral tissue ablation), 76394 (Magnetic resonance guidance for, and monitoring of, visceral tissue ablation), and 76940 (Us guide, tissue ablation) to the bypass list because they are often billed with CPT code 47382 (Radiofrequency ablation procedures of the liver) and CPT code 20982 (Radiofrequency ablation procedures of the bone). The commenter believed that this approach would create more single claims for those codes.

Response: The three CPT codes that the commenter requested we add to the bypass list did not have sufficient claims volume at the time the bypass list was created to meet the criteria for inclusion. When we next review the bypass list, we will examine these codes for inclusion on any future bypass list.

Comment: One commenter objected to use of data-based criteria as the only determinant of whether services are included on the bypass list. Specifically, the commenter objected to the inclusion of CPT evaluation and management codes 99213 and 99214 on the bypass list even though CPT codes 99211, 99212, and 99215 are not included on the list. The commenter believed that CMS should not assume that these codes do not typically have packaged costs associated with them because less than 5 percent of the claims with the code appeared on a claim with packaged charges. The commenter believed that all codes that ''meet the 5 percent data test'' should be qualitatively reviewed to determine whether clinical practice and charging methods support the assertion that packaged dollars are not related to the service proposed for the bypass list. The commenter also recommended that CMS include on the bypass list ''add-on'' CPT codes that have a status indicator of ''N'' so that the remaining packaged services on the claim would be packaged to the main procedure if that were the only other APC reported on the claim. The commenter recommended that ''add-on'' CPT codes with APC payment should be accepted as bypass codes if the only other CPT code on the claim is the main procedure.

Response: The commenter is incorrect in believing that the only criterion used to determine if a code were suitable for inclusion on the bypass list was whether 5 percent of the claims for the code appeared with packaged charges. As we discussed above, there were a number of criteria that had to be met which were focused on ensuring that packaging did not occur often or in significant amounts when it did occur. We reviewed the clinical appropriateness of the codes that were derived from applying the criteria, and did not remove any as a result of the review. Given the large volume of evaluation and management services, we believe that the evaluation and management codes we included on the bypass list were appropriate for inclusion. As we discussed with regard to the radiological supervision and evaluation codes and the simple EKG and chest x-ray codes, clinical practice and charging methods were also factors in determining inclusion on the bypass list.

With respect to the add-on codes, those that have a status indicator of ''N'' would not cause a claim to be a multiple procedure claim (because they are not separately paid). Thus it would not be useful to add them to the bypass list (which is intended to break multiple procedure claims into two single claims). Those add-on codes that are paid separately may or may not have packaging associated with them. Thus, it would be incorrect to assume that all packaging on the claim would be associated with the core procedure to which the add-on code is an appendage. For example, insertion of a left ventricular pacing lead as an add-on procedure to the insertion of a cardioverter-defibrillator carries considerable packaged costs with the add-on service, such as the device, significant additional operating room time, and extra drugs and medical supplies, and, therefore, it would not be suitable for inclusion on the bypass list.

After carefully reviewing all public comments received, we are adopting as final the bypass codes listed in Table 16 below.

BILLING CODE 4120–01–P

Table 16.—HCPCS Bypass Codes for Creating "Pseudo" Single Claims for Calculating Median Costs

HCPCS Code	Short Description
11719	Trim nail(s)
11720	Debride nail, 1-5
11721	Debride nail, 6 or more
31579	Diagnostic laryngoscopy
54240	Penis study
70100	X-ray exam of jaw
70110	X-ray exam of jaw
70130	X-ray exam of mastoids
70140	X-ray exam of facial bones
70150	X-ray exam of facial bones
70160	X-ray exam of nasal bones
70200	X-ray exam of eye sockets
70210	X-ray exam of sinuses
70220	X-ray exam of sinuses
70250	X-ray exam of skull
70260	X-ray exam of skull
70328	X-ray exam of jaw joint
70330	X-ray exam of jaw joints
70355	Panoramic x-ray of jaws
70360	X-ray exam of neck
70371	Speech evaluation, complex
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70544	Mr angiography head w/o dye
71010	Chest x-ray
71015	Chest x-ray
71020	Chest x-ray
71021	Chest x-ray
71022	Chest x-ray
71030	Chest x-ray
71034	Chest x-ray and fluoroscopy
71090	X-ray & pacemaker insertion
71100	X-ray exam of ribs
71101	X-ray exam of ribs/chest
71110	X-ray exam of ribs
71111	X-ray exam of ribs/ chest
71120	X-ray exam of breastbone
71130	X-ray exam of breastbone
71250	Ct thorax w/o dye
72040	X-ray exam of neck spine
72050	X-ray exam of neck spine
72052	X-ray exam of neck spine
72070	X-ray exam of thoracic spine
72072	X-ray exam of thoracic spine
72074	X-ray exam of thoracic spine

HCPCS Code	Short Description
72080	X-ray exam of trunk spine
72090	X-ray exam of trunk spine
72100	X-ray exam of lower spine
72110	X-ray exam of lower spine
72114	X-ray exam of lower spine
72120	X-ray exam of lower spine
72125	Ct neck spine w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72170	X-ray exam of pelvis
72190	X-ray exam of pelvis
72192	Ct pelvis w/o dye
72220	X-ray exam of tailbone
73000	X-ray exam of collar bone
73010	X-ray exam of shoulder blade
73020	X-ray exam of shoulder
73030	X-ray exam of shoulder
73050	X-ray exam of shoulders
73060	X-ray exam of humerus
73070	X-ray exam of elbow
73080	X-ray exam of elbow
73090	X-ray exam of forearm
73100	X-ray exam of wrist
73110	X-ray exam of wrist
73120	X-ray exam of hand
73130	X-ray exam of hand
73140	X-ray exam of finger(s)
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73510	X-ray exam of hip
73520	X-ray exam of hips
73540	X-ray exam of pelvis & hips
73550	X-ray exam of thigh
73560	X-ray exam of knee, 1 or 2
73562	X-ray exam of knee, 3
73564	X-ray exam, knee, 4 or more
73565	X-ray exam of knees

HCPCS Code	Short Description
73590	X-ray exam of lower leg
73600	X-ray exam of ankle
73610	X-ray exam of ankle
73620	X-ray exam of foot
73630	X-ray exam of foot
73650	X-ray exam of heel
73660	X-ray exam of toe(s)
73700	Ct lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74000	X-ray exam of abdomen
74210	Contrst x-ray exam of throat
74220	Contrast x-ray, esophagus
74230	Cine/vid x-ray, throat/esoph
74235	Remove esophagus obstruction
74240	X-ray exam, upper gi tract
74245	X-ray exam, upper gi tract
74246	Contrst x-ray uppr gi tract
74247	Contrst x-ray uppr gi tract
74249	Contrst x-ray uppr gi tract
74250	X-ray exam of small bowel
74235	Remove esophagus obstruction
74300	X-ray bile ducts/pancreas
74301	X-rays at surgery add-on
74305	X-ray bile ducts/pancreas
74327	X-ray bile stone removal
74328	X-ray bile duct endoscopy
74329	X-ray for pancreas endoscopy
74330	X-ray bile/panc endoscopy
74340	X-ray guide for GI tube
74350	X-ray guide, stomach tube
74355	X-ray guide, intestinal tube
74360	X-ray guide, GI dilation
74363	X-ray, bile duct dilation
74475	X-ray control, cath insert
74480	X-ray control, cath insert
74485	X-ray guide, GU dilation
74742	X-ray, fallopian tube
75894	X-rays, transcath therapy

HCPCS Code	Short Description
75898	Followup angiography
75900	Arterial catheter exchange
75901	Remove cva device obstruct
75902	Remove cva lumen obstruct
75945	Intravascular us
75946	Intravascular us add-on
75952	Endovasc repair abdom aorta
75953	Abdom aneurysm endovas rpr
75954	Iliac aneurysm endovas rpr
75960	Transcatheter intro, stent
75961	Retrieval, broken catheter
75962	Repair arterial blockage
75964	Repair artery blockage, each
75966	Repair arterial blockage
75968	Repair artery blockage, each
75970	Vascular biopsy
75978	Repair venous blockage
75980	Contrast x-ray exam bile duct
75982	Contrast x-ray exam bile duct
75984	X-ray control catheter change
75992	Atherectomy, x-ray exam
75993	Atherectomy, x-ray exam
75994	Atherectomy, x-ray exam
75995	Atherectomy, x-ray exam
75996	Atherectomy, x-ray exam
75998	Fluoroguide for vein device
76012	Percut vertebroplasty, fluor
76013	Percut vertebroplasty, ct
76040	X-rays, bone evaluation
76061	X-rays, bone survey
76062	X-rays, bone survey
76066	Joint survey, single view
76075	Dexa, axial skeleton study
76076	Dexa, peripheral study
76078	Radiographic absorptiometry
76090	Mammogram, one breast
76091	Mammogram, both breasts
76095	Stereotactic breast biopsy

HCPCS Code	Short Description
76096	X-ray of needle wire, breast
76100	X-ray exam of body section
76101	Complex body section x-ray
76360	Ct scan for needle biopsy
76380	CAT scan follow-up study
76393	Mr guidance for needle place
76511	Echo exam of eye
76512	Echo exam of eye
76516	Echo exam of eye
76519	Echo exam of eye
76536	Us exam of head and neck
76645	Us exam, breast(s)
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76830	Transvaginal us, non-ob
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76870	Us exam, scrotum
76880	Us exam, extremity
76941	Echo guide for transfusion
76945	Echo guide, villus sampling
76946	Echo guide for amniocentesis
76948	Echo guide, ova aspiration
76977	Us bone density measure
77280	Set radiation therapy field
77285	Set radiation therapy field
77300	Radiation therapy dose plan
77301	Radiotherapy dose plan, imrt
77315	Teletx isodose plan complex
77326	Brachytx isodose calc simp
77327	Brachytx isodose calc interm
77328	Brachytx isodose plan compl
77331	Special radiation dosimetry
77332	Radiation treatment aid(s)
77333	Radiation treatment aid(s)
77334	Radiation treatment aid(s)

HCPCS Code	Short Description
77336	Radiation physics consult
77370	Radiation physics consult
77399	External radiation dosimetry
77403	Radiation treatment delivery
77409	Radiation treatment delivery
77411	Radiation treatment delivery
77412	Radiation treatment delivery
77413	Radiation treatment delivery
77414	Radiation treatment delivery
77416	Radiation treatment delivery
77417	Radiology port film(s)
77418	Radiation tx delivery, imrt
77470	Special radiation treatment
78350	Bone mineral, single photon
78351	Bone mineral, dual photon
80502	Lab pathology consultation
85060	Blood smear interpretation
86585	TB tine test
86850	RBC antibody screen
86870	RBC antibody identification
86880	Coombs test, direct
86885	Coombs test, indirect, qual
86886	Coombs test, indirect, titer
86890	Autologous blood process
86900	Blood typing, ABO
86901	Blood typing, Rh (D)
86905	Blood typing, RBC antigens
86906	Blood typing, Rh phenotype
86930	Frozen blood prep
86970	RBC pretreatment
88104	Cytopathology, fluids
88106	Cytopathology, fluids
88107	Cytopathology, fluids
88108	Cytopath, concentrate tech
88160	Cytopath smear, other source
88161	Cytopath smear, other source
88172	Cytopathology eval of fna
88180	Cell marker study

HCPCS Code	Short Description
88182	Cell marker study
88300	Surgical path, gross
88304	Tissue exam by pathologist
88305	Tissue exam by pathologist
88311	Decalcify tissue
88312	Special stains
88313	Special stains
88321	Microslide consultation
88323	Microslide consultation
88325	Comprehensive review of data
88331	Path consult intraop, 1 bloc
88342	Immunohistochemistry
88346	Immunofluorescent study
88347	Immunofluorescent study
90801	Psy dx interview
90805	Psytx, off, 20-30 min w/e&m
90806	Psytx, off, 45-50 min
90807	Psytx, off, 45-50 min w/e&m
90808	Psytx, office, 75-80 min
90809	Psytx, off, 75-80, w/e&m
90810	Intac psytx, off, 20-30 min
90818	Psytx, hosp, 45-50 min
90826	Intac psytx, hosp, 45-50 min
90845	Psychoanalysis
90846	Family psytx w/o patient
90847	Family psytx w/patient
90853	Group psychotherapy
90857	Intac group psytx
90862	Medication management
92002	Eye exam, new patient
92004	Eye exam, new patient
92012	Eye exam established pat
92014	Eye exam & treatment
92082	Visual field examination(s)
92083	Visual field examination(s)
92135	Opthalmic dx imaging
92136	Ophthalmic biometry
92225	Special eye exam, initial

HCPCS Code	Short Description
92226	Special eye exam, subsequent
92230	Eye exam with photos
92250	Eye exam with photos
92275	Electroretinography
92285	Eye photography
92286	Internal eye photography
92520	Laryngeal function studies
92546	Sinusoidal rotational test
92548	Posturography
92552	Pure tone audiometry, air
92553	Audiometry, air & bone
92555	Speech threshold audiometry
92556	Speech audiometry, complete
92567	Tympanometry
92582	Conditioning play audiometry
92585	Auditor evoke potent, compre
93005	Electrocardiogram, tracing
93225	ECG monitor/record, 24 hrs
93226	ECG monitor/report, 24 hrs
93231	ECG monitor/record, 24 hrs
93232	ECG monitor/report, 24 hrs
93236	ECG monitor/report, 24 hrs
93270	ECG recording
93278	ECG/signal-averaged
93303	Echo transthoracic
93307	Echo exam of heart
93320	Doppler echo exam, heart
93731	Analyze pacemaker system
93733	Telephone analy, pacemaker
93734	Analyze pacemaker system
93736	Telephonic analy, pacemaker
93743	Analyze ht pace device dual
93797	Cardiac rehab
93798	Cardiac rehab/monitor
93875	Extracranial study
93880	Extracranial study
93882	Extracranial study
93886	Intracranial study

HCPCS Code	Short Description
93888	Intracranial study
93922	Extremity study
93923	Extremity study
93924	Extremity study
93925	Lower extremity study
93926	Lower extremity study
93931	Upper extremity study
93965	Extremity study
93970	Extremity study
93971	Extremity study
93975	Vascular study
93976	Vascular study
93978	Vascular study
93979	Vascular study
93990	Doppler flow testing
94015	Patient recorded spirometry
95115	Immunotherapy, one injection
95165	Antigen therapy services
95805	Multiple sleep latency test
95807	Sleep study, attended
95812	EEG, 41-60 minutes
95813	EEG, over 1 hour
95816	EEG, awake and drowsy
95819	EEG, awake and asleep
95822	EEG, coma or sleep only
95864	Muscle test, 4 limbs
95872	Muscle test, one fiber
95900	Motor nerve conduction test
95921	Autonomic nerv function test
95926	Somatosensory testing
95930	Visual evoked potential test
95937	Neuromuscular junction test
95950	Ambulatory EEG monitoring
95953	EEG monitoring/computer
96000	Motion analysis, video/3d
96100	Psychological testing
96105	Assessment of aphasia
96115	Neurobehavior status exam

HCPCS Code	Short Description
96900	Ultraviolet light therapy
96910	Photochemotherapy with UV-B
96912	Photochemotherapy with UV-A
96913	Photochemotherapy, UV-A or B
98940	Chiropractic manipulation
99213	Office/outpatient visit, est
99214	Office/outpatient visit, est
99241	Office consultation
99243	Office consultation
99244	Office consultation
99245	Office consultation
99273	Confirmatory consultation
99274	Confirmatory consultation
99275	Confirmatory consultation
C9708	Preview Tx Planning Software
D0473	Micro exam, prep & report
G0005	ECG 24 hour recording
G0006	ECG transmission & analysis
G0015	Post symptom ECG tracing
G0101	CA screen;pelvic/breast exam
G0127	Trim nail(s)
G0131	CT scan, bone density study
G0132	CT scan, bone density study
G0166	Extrnl counterpulse, per tx
G0175	OPPS Service,sched team conf
G0195	Clinicalevalswallowingfunct
G0196	Evalofswallowingwithradioopa
G0198	Patientadapation&trainforspe
G0202	Screeningmammographydigital
G0204	Diagnosticmammographydigital
G0206	Diagnosticmammographydigital
G0236	Digital film convert diag ma
Q0091	Obtaining screen pap smear

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B. Calculation of Median Costs for CY 2005

In this section of the preamble, we discuss the use of claims to calculate the OPPS payment rates for CY 2005. (The hospital outpatient prospective payment page on the CMS Web site on which this final rule with comment period is posted provides an accounting of claims used in the development of the final rates: *http://www.cms.hhs.gov/hopps.)* The accounting of claims used in the development of the final rule with comment period is included under supplemental materials for this final rule with comment period. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, we note that below we discuss the files of claims that comprise the data sets that are available for purchase under a CMS data user contract. Our CMS Web site, *http://www.cms.hhs.gov/providers/hopps* includes information about purchasing the following two OPPS data files: ''OPPS limited data set'' and ''OPPS identifiable data set.''

In this final rule with comment period, we are using the same methodology as proposed in the August 16, 2004 proposed rule to establish the relative weights that we used in calculating the OPPS payment rates for CY 2005 shown in Addenda A and B to this final rule with comment period. This methodology is as follows:

We used outpatient claims for full CY 2003 to set the relative weights for CY 2005. To begin the calculation of the relative weights for CY 2005, we pulled all claims for outpatient services furnished in CY 2003 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (for example, critical access hospital (CAH) claims, and hospital claims for clinical laboratory services for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition codes 04, 20, 21, and 77. These are claims that providers submitted to Medicare knowing that no payment will be made. For example, providers submit claims with a condition code 21 to elicit an official denial notice from Medicare and document that a service is not covered. We then excluded claims for services furnished in Maryland, Guam, and the U.S. Virgin Islands because hospitals in those geographic areas are not paid under the OPPS.

We divided the remaining claims into the three groups shown below. Groups

2 and 3 comprise the 106 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X, 13X, 14X (hospital bill types), or 76X (CMHC bill types). Other bill types, such as ASCs, bill type 83, are not paid under the OPPS and, therefore, these claims were not used to set OPPS payment.

2. Bill types 12X, 13X, or 14X (hospital bill types). These claims are hospital outpatient claims.

3. Bill type 76X (CMHC). (These claims are later combined with any claims in item 2 above with a condition code 41 to set the per diem partial hospitalization rate determined through a separate process.)

In previous years, we have begun the CCR calculation process using the most recent available cost reports for all hospitals, irrespective of whether any or all of the hospitals included actually filed hospital outpatient claims for the data period. However, in developing the proposed rule and this final rule with comment period, we first limited the population of cost reports to only those for hospitals that filed outpatient claims in CY 2003 before determining whether the CCRs for such hospitals were valid. This initial limitation changed the distribution of CCRs used during the trimming process discussed below.

We then calculated the CCRs at a departmental level and overall for each hospital for which we had claims data. We did this using hospital specific data from the Hospital Cost Report Information System (HCRIS). As indicated in the proposed rule, we used the same CCRs as those used in calculating the relative weights that we used in developing the proposed rule. We did not recalculate CCRs to reflect updated cost report data.

We then flagged CAHs, which are not paid under the OPPS, and hospitals with invalid CCRs. These included claims from hospitals without a CCR; those from hospitals paid an all-inclusive rate; those from hospitals with obviously erroneous CCRs (greater than 90 or less than .0001); and those from hospitals with CCRs that were identified as outliers (3 standard deviations from the geometric mean after removing error CCRs). In addition, we trimmed the CCRs at the departmental level by removing the CCRs for each cost center as outliers if they exceeded +/− 3 standard deviations of the geometric mean. In prior years, we did not trim CCRs at the departmental level. However, for CY 2005, as proposed, we trimmed at the departmental CCR level to eliminate aberrant CCRs that, if found in high volume hospitals, could skew the medians. We used a four-tiered hierarchy of cost center CCRs to match a cost center to a revenue code with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's departmental CCR was deleted by trimming, we set the departmental CCR for that cost center to ''missing,'' so that another departmental CCR in the revenue center hierarchy could apply. If no other departmental CCR could apply to the revenue code on the claim, we used the hospital's overall CCR for the revenue code in question.

We then converted the charges on the claim by applying the CCR that we believed was best suited to the revenue code indicated on the line with the charge. (We discussed in greater detail the allowed revenue codes in the proposed rule (69 FR 50487).) If a hospital did not have a CCR that was appropriate to the revenue code reported for a line-item charge (for example, a visit reported under the clinic revenue code but the hospital did not have a clinic cost center), we applied the hospital-specific overall CCR, except as discussed in section V.H. of this final rule with comment period, for calculation of costs for blood.

Thus, we applied CCRs as described above to claims with bill types 12X, 13X, or 14X, excluding all claims from CAHs and hospitals in Maryland, Guam, or the U.S. Virgin Islands, and flagged hospitals with invalid CCRs. We excluded claims from all hospitals for which CCRs were flagged as invalid.

We identified claims with condition code 41 as partial hospitalization services of CMHCs and removed them to another file. These claims were combined with the 76X claims identified previously to calculate the partial hospitalization per diem rate.

We then excluded claims without a HCPCS code. We also removed claims for observation services to another file. We removed to another file claims that contained nothing but flu and pneumococcal pneumonia (''PPV'') vaccine. Influenza and PPV vaccines are paid at reasonable cost and, therefore, these claims are not used to set OPPS rates. We note that the two above mentioned separate files containing partial hospitalization claims and the observation services claims are included in the files that are available for purchase as discussed above.

We next copied line-item costs for drugs, blood, and devices (the lines stay on the claim but are copied off onto another file) to a separate file. No claims were deleted when we copied these lines onto another file. These line-items are used to calculate the per unit median for drugs, radiopharmaceuticals, and blood and blood products. The line-item costs were also used to calculate the per administration cost of drugs, radiopharmaceuticals, and biologicals (other than blood and blood products) for purposes of determining whether the cost of the item would be packaged or paid separately. Section 1833(t)(16)(B) of the Act, as added by section 621(a)(2) of Pub. L. 108–173, requires the Secretary to lower to $50 the threshold for separate payment of drugs and biologicals and the per administration cost derived using these line-item cost data would be used to make that decision for CY 2005. As discussed in the November 7, 2003 OPPS final rule with comment period (68 FR 63398), we had also applied a $50 threshold to these items for the CY 2004 update to the OPPS.

We then divided the remaining claims into five groups.

1. *Single Major Claims:* Claims with a single separately payable procedure, all of which would be used in median setting.

2. *Multiple Major Claims:* Claims with more than one separately payable procedure or multiple units for one payable procedure. As discussed below, some of these can be used in median setting.

3. *Single Minor Claims:* Claims with a single HCPCS code that is not separately payable. These claims may have a single packaged procedure or a drug code.

4. *Multiple Minor Claims:* Claims with multiple HCPCS codes that are not separately payable without examining dates of service. (For example, pathology codes are packaged unless they appear on a single bill by themselves.) The multiple minor file has claims with multiple occurrences of pathology codes, with packaged costs that cannot be appropriately allocated across the multiple pathology codes. However, by matching dates of service for the code and the reported costs through the ''pseudo'' single creation process discussed earlier, a claim with multiple pathology codes may become several ''pseudo'' single claims with a unique pathology code and its associated costs on each day. These ''pseudo'' singles for the pathology codes would then be considered a separately payable code and would be used like claims in the single major claim file.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS are excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, durable medical equipment or clinical laboratory.

We note that the claims listed in numbers 1, 2, and 4 above are included in the data files that can be purchased as described above.

We set aside the single minor claims and the non-OPPS claims (numbers 3 and 5 above) because we did not use either in calculating median cost.

We then examined the multiple major and multiple minor claims (numbers 2 and 4 above) to determine if we could convert any of them to single major claims using the process described previously. We first grouped items on the claims by date of service. If each major procedure on the claim had a different date of service and if the line-items for packaged HCPCS and packaged revenue codes had dates of service, we broke the claim into multiple ''pseudo'' single claims based on the date of service.

After those single claims were created, we used the list of ''bypass codes'' in Table 16 of this final rule with comment period to remove separately payable procedures that we determined contain limited costs or no packaged costs from a multiple procedure bill. A discussion of the creation of the list of bypass codes used for the creation of ''pseudo'' single claims is contained in section III.A.2. of this preamble.

When one of the two separately payable procedures on a multiple procedure claim were on the bypass code list, the claim was split into two single procedure claims records. The single procedure claim record that contained the bypass code did not retain packaged services. The single procedure claim record that contained the other separately payable procedure retained the packaged revenue code charges and the packaged HCPCS charges.

We excluded those claims that we were not able to convert to singles even after applying both of the techniques for creation of ''pseudo'' singles. We then packaged the costs of packaged HCPCS (codes with status indicator ''N'' listed in Addendum B to this final rule with comment period) and packaged revenue codes into the cost of the single major procedure remaining on the claim. The list of packaged revenue codes is shown in Table 17 below.

After removing claims for hospitals with error CCRs, claims without HCPCS codes, claims for immunizations not covered under the OPPS, and claims for services not paid under the OPPS, 56 million claims were left. This subset of claims is roughly one-half of the 106 million claims for bill types paid under the OPPS. Of these 56 million claims, we were able to use some portion of 52 million (91 percent) whole claims to create the 84 million single and ''pseudo'' single claims for use in the CY 2005 median payment ratesetting.

We also excluded claims that either had zero costs after summing all costs on the claim or for which CMS lacked an appropriate provider wage index. For the remaining claims, we then wage adjusted 60 percent of the cost of the claim (which we determined to be the labor-related portion), as has been our policy since initial implementation of the OPPS, to adjust for geographic variation in labor-related costs. We made this adjustment by determining the wage index that applied to the hospital that furnished the service and dividing the cost for the separately paid HCPCS code furnished by the hospital by that wage index. As proposed, we used the final pre-reclassified wage indices for IPPS and any subsequent corrections. We used the pre-reclassified wage indices for standardization because we believe that they better reflect the true costs of items and services in the area in which the hospital is located than the post-reclassification wage indices, and would result in the most accurate adjusted median costs.

We then excluded claims that were outside 3 standard deviations from the geometric mean cost for each HCPCS code. We used the remaining claims to calculate median costs for each separately payable HCPCS code; first, to determine the applicability of the ''2 times'' rule, and second, to determine APC medians as based on the claims containing the HCPCS codes assigned to each APC. As stated previously, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (''the 2 times rule''). Finally, we reviewed the medians and reassigned HCPCS codes to different APCs as deemed appropriate. Section III.B. of this preamble includes a discussion of the HCPCS code assignment changes that resulted from examination of the medians and for other reasons. The APC medians were recalculated after we reassigned the affected HCPCS codes.

A detailed discussion of the medians for blood and blood products is provided at section V.I. of this preamble. We provide a discussion of the medians for APC 0315 (Level II Implantation of Neurostimulator), and APC 0651 (Complex Interstitial Radiation Application), at sections III.C.2.a. and III.C.2.b., respectively, of this preamble.

A discussion of the medians for APCs that require one or more devices when the service is performed is provided at section III.C. of this preamble. A discussion of the median for observation services is provided at section VII.D. of this preamble and a discussion of the median for partial hospitalization is provided at section X.C. of this preamble.

We received a number of public comments concerning our proposed data processes for calculating the CY 2005 OPPS relative weights and median costs.

Comment: Some commenters requested that CMS provide specialty-specific and APC-specific impact tables that provide additional information and analysis of its proposal to trim CCRs on a departmental basis. The commenters stated that CMS should justify why it trimmed departmental CCRs at ±3 standard deviations from the geometric mean and explain the impact of the change.

Response: We chose to trim at ±3 standard deviations from the geometric mean because cost and charge data are traditionally log normal distributed and because the 3 standard deviations threshold is standard policy for identifying outliers in CMS' payment systems. We do not believe that an impact analysis for the departmental-level CCR trim is necessary because the overall number of cost-centers trimmed were minimal relative to the number of hospitals and because this trim only removed extreme department CCRs, both low and high. We fully expect that, had we chosen not to trim at the department-level, extreme cost estimates would have been removed during our trim at the HCPCS-level performed later in the data development process.

For example, we trimmed the most department CCRs, 68, from cost center 5500, Medical Supplies Charged to Patients. The low CCRs that were trimmed ranged from 0.00008 to 0.0281. The high CCRs that were trimmed ranged from 0.39530 to 6069.17. Even after the department-level trim, only 7 percent of the hospitals in our data set defaulted to the overall CCR for services mapped to this cost center.

Comment: One commenter stated that the CCRs fell between 1996 and 2002 because charges were increasing faster than costs and that this change resulted in a significant payment decrease for hospitals for which we used the default CCR. The commenter urged CMS to instruct fiscal intermediaries to work with these hospitals in determining

CCRs that will provide accurate cost estimates.

Response: The commenter misunderstood the source of the CCRs used to adjust hospital costs to charges for OPPS median setting. We do not use the CCRs that fiscal intermediaries calculate for purposes of outlier payments, and cost reimbursement. Instead, we use hospital specific data from the health care cost reporting information system and independently calculate CCRs for each standard and nonstandard cost center in which the costs of outpatient services are to be found as well as an overall CCRs for the costs of outpatient care. Hence, intermediaries have no role in the calculation of the CCRs used to reduce charges to approximate costs for OPPS median cost setting.

Comment: One commenter asked that CMS justify why did it not use cost-to-charge data from all hospitals for CY 2005 OPPS calculations when, in the past, CMS used cost report data from all hospitals without regard to whether the hospital had filed data during a specified period.

Response: In the past, we first calculated CCRs for all providers, trimmed the overall hospital CCRs, and then compared the providers for which we had valid CCRs to the providers for which we had claims data. For CY 2005 OPPS, we first determined the providers for which we had claims data and we then calculated the CCRs for those hospitals so that the trimming would occur only across the hospitals for which we had claims data because a CCR is of value only if there are claims to which to apply it.

Comment: One commenter urged CMS to greatly expand the outpatient code editor (OCE) edits to return to providers claims that fail edits that are appropriate to the type of service being billed. The commenter cited as examples, the creation of edits that return claims for chemotherapy administration procedures if anti-neoplastics (cancer chemotherapy) are not also billed on the same day and edits that return claims for services that require the use of contrast agents if no contrast agent were billed. The commenter believed that this would greatly improve the data on which median costs are set.

Response: We do not intend, at this time, to greatly expand the OCE edits to force correct coding as the commenter recommends beyond the edits for correct coding of device procedures that are discussed in section III.C.4 of this final rule with comment period. While we recognize that these kinds of edits would likely result in better coding, they would also impose a significant burden on hospitals. We do, however, encourage hospitals to review their claims completion processes carefully and to edit their claims before they are submitted to maximize the likelihood that the claims are correct and complete. Such a practice would both assist us in developing better OPPS rates, but more importantly, ensure that hospitals are being correctly paid for all of the services they furnish to our beneficiaries.

Comment: One commenter noted the prevalence of drug billing and charging errors and recommended that CMS revise its median trimming methodology for drugs from ±3 standard deviations from the geometric mean to a trim by provider by drug based on the correlation of units and charges. This approach assumes that hospitals engaged in accurate and consistent unit coding and billing will demonstrate a strong correlation between units and per unit charges. The commenter noted that CMS' current trim is very conservative, especially for low costs per unit because it will only eliminate negative cost values, which do not exist in the data. The commenter further suggested that CMS' trim of department-level CCR's and the use of C-code only claims to set device medians are comparable to this proposal.

Response: We agree that billing accurate units has proven challenging for some hospitals in light of various differences in packaged versus delivered units, changing drug pricing, and unit changes in HCPCS codes. Clearly, our goal in conducting the current trim at ±3 standard deviations from the geometric mean is to remove aberrant per unit costs, or costs that are so far removed from the geometric mean that the probability of their occurrence is less than 1 percent. However, even after this trim is conducted, we remain concerned about the per unit cost estimates for some drug codes.

We believe, however, that the current trim of drug costs, while conservative, is not as limiting as suggested in the comment. The natural logarithm of costs per unit less than $1 will be negative. The trim compares the natural logarithm of the cost to the geometric mean, ±3 standard deviations and removes low and high cost observations. The low trim threshold may also be negative if costs are less than $1. In addition to using a trim, we also rely on a median cost rather than an average cost. Averages are subject to the influence of extreme outliers. Using a median instead of a mean eliminates this concern. Assuming most line-items for any given drug are coded correctly, using a trim and the median should provide a robust per unit cost estimate. Nonetheless, we do recognize that for selected low-volume or complex products, this approach is still not sufficient to remove all errors.

We are concerned, however, about implementing systematic trimming at the provider-level as suggested by the commenter for several reasons. First, this approach would remove the data for multiple providers from any given median calculation, making the assumption that their data were inaccurate, when, in fact, a few instances of poor coding may adversely impact the provider's correlation coefficient. Thus, a provider may actually be coding and charging accurately in many cases. In rare instances, we have removed a specific provider when it is more than obvious that the data are erroneous, but we only do this after a careful review of the provider's claims data. It is our preference to remove aberrant line-items rather than a provider's entire data for any given drug. Second, correlation coefficients for a provider may fluctuate if they are based on very low-volume, even if the majority of line-items appear accurate. Third, the commenter's proposed correlation coefficient approach lacks a generally accepted threshold when a providers' data should be removed, unlike the widely accepted trim of 3 standard deviations from the mean. Finally, this approach assumes that a negative correlation coefficient implies that a provider erred in setting its charging practices.

While we agree that the proposed trim seeks to improve the accuracy of the claims data, which is the goal of all trimming, we disagree that the commenter's proposed trim is necessarily comparable to the use of a department-level CCR trim and the limitation of claims to those with C-codes for estimating medians for device-dependent APCs. The department-level trim does not eliminate a provider entirely, it eliminates the department-level CCR for a specific hospital and replaces this CCR with the overall CCR for that hospital. Relying on C-coded claims to calculate device-dependent medians assures us that the device was used with the device-dependent procedure. The specific cost associated with the device code is not considered in subsetting claims and the subsetting is done by claim, not by provider. While the commenter's proposed methodology is not appropriate for use at this time, we nonetheless believe that the commenter's suggested approach can serve as a useful tool in helping us begin the process of identifying providers

Comment: One commenter indicated that using the overall CCR where the

departmental CCR cannot be used may skew the costs derived from application of CCRs to charges. The commenter suggested that CMS develop a method for replacing departmental CCRs similar to that used for blood and blood products whereby the CCR that would apply would not be the overall CCR but a national CCR calculated based on the departmental CCRs of hospitals that do report the more pertinent specific cost centers on their cost reports.

Response: We will consider whether doing so is practical and whether it would yield more accurate cost estimates. However, there were very specific characteristics of the reporting of blood such as a very specific cost center and very specific revenue codes that may not exist for other services.

Comment: One commenter asked that CMS undertake a study to improve the reporting of costs in conjunction with the CCR development. The commenter stated that a more timely process should be implemented so that currently accurate CCRs are used to translate hospital charges to costs and that consideration should be given to attaining greater detail from the hospitals to calculate the CCRs to better reflect the full line of services being offered by hospitals.

Response: We study means by which we could improve the development of cost-to-charge ratios annually. We also use the most current cost report data from the HCRIS system to calculate the cost to-charge-ratios and we use charges from the most current claims data. However, hospitals have great latitude in the way they organize their costs and complete their cost reports. We have no plans to alter the existing instructions to require cost report detail that is not currently provided. We will, instead, continue to examine how the data currently submitted by hospitals can be used to secure the most accurate estimates of cost for the full range of services furnished by hospitals.

After carefully reviewing all comments, we are adopting as final, for OPPS services furnished on or after January 1, 2005, the process for calculating median costs that we described in this section and the list of packaged services shown in Table 17 below. This table contains the list of packaged services by revenue code that we used in developing the APC weights and medians listed in Addenda A and B of this final rule with comment period.

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Table 17.--Packaged Services by Revenue Code

Revenue Code	Description
250	PHARMACY
251	GENERIC
252	NONGENERIC
254	PHARMACY INCIDENT TO OTHER DIAGNOSTIC
255	PHARMACY INCIDENT TO RADIOLOGY
257	NONPRESCRIPTION DRUGS
258	IV SOLUTIONS
259	OTHER PHARMACY
260	IV THERAPY, GENERAL CLASS
262	IV THERAPY/PHARMACY SERVICES
263	SUPPLY/DELIVERY
264	IV THERAPY/SUPPLIES
269	OTHER IV THERAPY
270	M&S SUPPLIES
271	NONSTERILE SUPPLIES
272	STERILE SUPPLIES
274	PROSTHETIC/ORTHOTIC DEVICES
275	PACEMAKER DRUG
276	INTRAOCULAR LENS SOURCE DRUG
278	OTHER IMPLANTS
279	OTHER M&S SUPPLIES
280	ONCOLOGY
289	OTHER ONCOLOGY
290	DURABLE MEDICAL EQUIPMENT
343	DIAGNOSTIC RADIOPHARMS
344	THERAPEUTIC RADIOPHARMS
370	ANESTHESIA
371	ANESTHESIA INCIDENT TO RADIOLOGY
372	ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC
379	OTHER ANESTHESIA
390	BLOOD STORAGE AND PROCESSING
399	OTHER BLOOD STORAGE AND PROCESSING
560	MEDICAL SOCIAL SERVICES
569	OTHER MEDICAL SOCIAL SERVICES
621	SUPPLIES INCIDENT TO RADIOLOGY
622	SUPPLIES INCIDENT TO OTHER DIAGNOSTIC
624	INVESTIGATIONAL DEVICE (IDE)
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631	SINGLE SOURCE
632	MULTIPLE
633	RESTRICTIVE PRESCRIPTION
637	SELF-ADMINISTERED DRUG (INSULIN ADMIN. IN EMERGENCY DIABETIC COMA)
681	TRAUMA RESPONSE, LEVEL I
682	TRAUMA RESPONSE, LEVEL II
683	TRAUMA RESPONSE, LEVEL III

Revenue Code	Description
684	TRAUMA RESPONSE, LEVEL IV
689	TRAUMA RESPONSE , OTHER
700	CAST ROOM
709	OTHER CAST ROOM
710	RECOVERY ROOM
719	OTHER RECOVERY ROOM
720	LABOR ROOM
721	LABOR
762	OBSERVATION ROOM
810	ORGAN ACQUISITION
819	OTHER ORGAN ACQUISITION
942	EDUCATION/TRAINING

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C. Adjustment of Median Costs for CY 2005

1. Device-Dependent APCs

Table 19, which we published in the proposed rule (69 FR 50492), contains a list of APCs consisting of HCPCS codes that cannot be provided without one or more devices. For CY 2002 OPPS, we used external data in part to establish the medians used for weight setting. At that time, many devices were eligible for pass-through payment. For that year, we estimated that the total amount of pass-through payments would far exceed the limit imposed by statute. To reduce the amount of a pro rata adjustment to all pass-through items, we packaged 75 percent of the cost of the devices (using external data furnished by commenters on the August 24, 2001 proposed rule) into the median cost for the APCs associated with these pass-through devices. The remaining 25 percent of the cost was considered to be pass-through payment. (Section VI. of this preamble includes a discussion of the pro rata adjustment.)

For CY 2003 OPPS, which was based on CY 2001 claims data, we found that the median costs for certain device-dependent APCs when all claims were used were substantially less than the median costs used for CY 2002. We were concerned that using the medians calculated from all claims would result in payments for some APCs that would not compensate the hospital even for the cost of the device. Therefore, we calculated a median cost using only claims from hospitals that had separately billed the pass-through device in CY 2001 (that is, hospitals whose claims contained the C-code for the pass-through device). Furthermore, for any APC (whether device-dependent or not) where the median cost would have decreased by 15 percent or more from CY 2002 to CY 2003, we limited decreases in median costs to 15 percent plus half of the amount of any reduction beyond 15 percent (68 FR 47984). For a few particular device-dependent APCs for which we believed that access to the service was in jeopardy, we blended external data furnished by commenters on the August 9, 2002 proposed rule (67 FR 57092) with claims data to establish the median cost used to set the payment rate. For CY 2003, we also eliminated the HCPCS C-codes for the devices and returned to providers those claims on which the deleted device codes were used. (The November 1, 2002 OPPS final rule (67 FR 66750) and section III.C.4 of this preamble contain a discussion regarding the required use of C-codes for specific categories of devices.)

For CY 2004 OPPS, which was based on CY 2002 claims data, we used only claims on which hospitals had reported devices to establish the median cost for the device-dependent APCs in Table 18. We did this because we found that the median costs calculated when we used all claims for these services were inadequate to cover the cost of the device if the device was not separately coded on the claim. Using only claims containing the code for the device (a C-code) provided costs that were closer to those used for CY 2002 and CY 2003 for these services. For a few particular APCs in which we believed that access to the service was in jeopardy, we used external data provided by commenters on the August 12, 2003 proposed rule in a 50 percent blend with claims data to establish the device portion of the median cost used to set the payment rate (68 FR 63423). We also reinstated for CY 2004, but on a voluntary basis, the reporting of C-codes for devices.

Thus, in developing the median costs for device-dependent APCs for CYs 2002, 2003, and 2004, we applied certain adjustments to our claims data as provided under the authority of section 1833(t)(9)(A) of the Act to ensure equitable payments to the hospitals for the provision of such services. As stated in the August 16, 2004 proposed rule, we have continued to receive comments from interested parties as part of the APC Panel process urging us to determine whether the claims data that would be used in calculating the median costs for device-dependent APCs for payment in CY 2005 would represent valid relative costs for these services (69 FR 50490). Careful analysis of the CY 2003 data that we used in calculating the median costs for the CY 2005 OPPS payment rates revealed problems similar to those discussed above in calculating device-dependent APC median costs based solely on claims data. Calculation of the CY 2005 median costs for the device-dependent APCs indicated that some of the medians appeared to appropriately reflect the costs of the services, including the cost of the device, and others did not. Of the 41 device-dependent APCs analyzed, 27 have median costs that are lower than the medians on which the OPPS payments were based in CY 2004. In contrast, 14 device-dependent APCs have median costs that are higher than the medians on which OPPS payments were based in CY 2004.

The differences between the CY 2004 payment medians and the proposed CY 2005 median costs using CY 2003 claims data are attributable to several factors. As discussed above, the CY 2004 payment medians were based on a subset of claims that contained the codes for the devices without which the procedures could not be performed, and several APCs were adjusted using external data. The CY 2005 OPPS median costs on which the proposed payment rates in the August 16, 2004 proposed rule were based, were calculated based on all single bills, including ''pseudo'' single bills, for the services in the APCs and (not a subset

of claims containing device codes) and were not adjusted using external data. In fact, as stated previously, we eliminated device coding requirements for hospitals in CY 2003. Consequently, there were no device codes reported for almost all devices in the CY 2003 claims data. Thus, it was not possible to use only the CY 2003 claims data containing device codes to calculate APC device-dependent medians as was done in CY 2004. Similarly, it was not possible to calculate a percentage of the APC cost attributed to device codes based on CY 2003 claims data.

In light of these data issues for CY 2005, we examined several alternatives to using CY 2003 claims data to calculate the proposed median costs for device-dependent APCs. As discussed in the August 16, 2004 proposed rule, we considered using CY 2004 OPPS medians with an inflation factor, as recommended by the APC Panel and by several outside organizations. We rejected this option because it would not recognize any changes in relative costs for these APCs and would not direct us towards our goal of using all single claims data as the basis for payment weights for all OPPS services.

We also considered using the medians we calculated from all single bills with no adjustments. However, the results of using this approach without increasing the payments for some important high cost services for CY 2005 could result in the closing of hospital programs that provide these services thus, jeopardizing access to needed care. Therefore, we did not adopt this approach.

In addition, we considered subsetting claims based on the presence of charges in certain revenue codes. These revenue codes include: 272, sterile supplies; 275, pacemakers; 278, other implants; 279, other supplies/devices; 280, oncology; 289, other oncology; and 624, investigational devices. We determined that the medians increased for some device-dependent APCs when we used only claims with a charge in at least one of these revenue codes, but our analysis provided no reliable evidence that the charges that would be found in these revenue codes were necessarily for the cost of the device.

Further, we considered using CY 2002 claims to calculate a ratio between the median calculated using all single bills and the median calculated using only claims with HCPCS codes for devices on them, and applying that ratio to the median calculated using all single bills from CY 2003 claims data. We rejected this option because it assumes that the relationship between the costs of the claims with and without codes for devices is a valid relationship not only for CY 2002 but CY 2003 as well. It also assumes no changes in billing behavior. We have no reason to believe either of these assumptions is true and, therefore, we did not choose this option.

In summary, we considered and rejected all of the above options. We have given special treatment to the device-dependent APCs for the past 3 years, recognizing that, in a new payment system, hospitals need time to establish correct coding processes and, considering the need to ensure continued access to these important services. After 3 years of such consideration, we believe that it is time to begin a transition to the use of pure claims data for these services (reflected in these APCs) to ensure the appropriate relativity of the median costs for all payable OPPS services. Our goal is to establish payment rates that provide appropriate relative payment for all services paid under the OPPS without creating payment disincentives that may reduce access to care.

Therefore, we proposed to base median costs for device-dependent APCs in CY 2005 on the greater of (1) median costs calculated using CY 2003 claims data, or (2) 90 percent of the APC payment median for CY 2004 for such services. We proposed this adjustment because we believe that some variation in median costs is to be expected from year to year, and we believe that recognizing up to a 10 percent variation in our payment approach is a reasonable limit. In the August 16, 2004 proposed rule, we solicited comments on all aspects of theses issues and particularly on steps that can be taken in the future to transition from the historic payment medians to claims based median costs for OPPS ratesetting for these important services. In addition, we discussed this issue with the APC Panel at its September 1 through 2, 2004 meeting. The Panel recommended that we base median costs for these APCs on no less than 95 percent of the CY 2004 median not to exceed 105 percent of the CY 2004 payment median.

We received numerous public comments on our proposals.

Comment: A number of commenters objected to the proposal to set the payment medians for device APCs at 90 percent of the CY 2004 payment median for the APC. They indicated that many of these APCs had already been reduced substantially over the past few years and that permitting them to be reduced another 10 percent would mean that some hospitals may close their programs and send patients to other hospitals for these services. Some commenters recommended that the median costs for these APCs be set at 100 percent of the CY 2004 payment median. Some commenters recommended that CMS use the CY 2004 payment median plus an update amount as the median cost for the CY 2005 OPPS. Commenters also recommended that instead of using median costs from claims data with any adjustment, that we collect actual hospital acquisition data or use cost data provided by manufacturers and other stakeholders and substitute that data for the device portion of the median costs. They indicated that we used external data in the past and that we should do so this year also. They cited APCs 0081, 0107, 0108, 0225, 0229, 0259, 0385, and 0386 as cases in which the proposed APC payment rates were less than the cost of the devices and as those for which CMS should use external data in setting the payment rates for CY 2005. A commenter supported the proposal to pay the greater of the CY 2005 claims based median or 90 percent of the CY 2004 payment median.

Response: For the reasons discussed below, we set the adjusted CY 2005 OPPS device-dependent median at the greater of the CY 2005 OPPS unadjusted median or 95 percent of the CY 2004 OPPS adjusted final payment median rather than the greater of the CY 2005 unadjusted median or 90 percent of the CY 2004 OPPS adjusted final median as we proposed in the August 16, 2004 proposed rule. We view this as a transition to the full use of claims data to set the medians for these services. The integrity of a prospective payment system lies heavily in its reliance on a standardized process applied to a standardized data source. The use of external data can, as some commenters point out, unfairly unbalance the payments and result in inequities in payment. (Section III.C.5. of this preamble includes a discussion on the use of external data.)

We considered setting the medians at the CY 2004 adjusted final payment medians with and without further inflation, but we think a certain amount of fluctuation in costs from year to year is to be expected as the costs of services decline after they have been on the market for some time. Moreover, we considered our proposal to pay the greater of the CY 2005 unadjusted median or 90 percent of the CY 2004 OPPS adjusted final payment median, but acknowledged the concerns of the commenters who believe that setting the comparison at 95 percent of the CY 2004 OPPS final adjusted payment median was more appropriate and less likely to impede access to these important services. We recognize that adjustments

to median costs derived from claims data may be necessary yet again in the CY 2006 OPPS due to the voluntary nature of the reporting of device codes in CY 2004. However, as discussed further below at section III.C.4. of this preamble in our discussion of mandatory coding for devices, we expect that reporting of device codes in the CY 2005 claims will enable us to rely upon the claims data for setting the median costs without adjustment in CY 2007.

Comment: Some commenters opposed the APC Panel's recommendation to limit increases in median costs for device APCs to 5 percent over the CY 2004 payment median because the commenters believe such a limit would be arbitrary and would be a hindrance to the improvement of cost data.

Response: We agree and we have not limited the extent to which the median costs for device-dependent APCs may increase for the CY 2005 OPPS. We believe that in a number of cases, providers are reporting the charges for the devices and have otherwise greatly improved coding of their services, resulting in increases in median costs that appear to appropriately reflect the costs of the services furnished. We have no indication that the increases do not otherwise properly reflect the costs of services and, therefore, see no reason to constrain the increases that have resulted.

Comment: Some commenters stated that CMS should look long term to determining a factor through regression analysis that enables CMS to adjust the charges for high cost devices so that the methodology will result in more accurate costs for high cost devices.

Response: We will review and consider the results of credible studies of the possible compression of all charges, both for high cost services and low cost services. Studies that focus only on part of the spectrum of hospital charges, for example, those which look at low markup of high cost items but not at high markup of low cost items, would not be useful in a relative weight system.

Comment: Some commenters indicated that hospitals typically markup high cost items and services less than they markup low cost items and services and that CMS' cost finding methodology does not recognize this because it applies a uniform cost-to-charge ratio (for the department or hospital overall) to the charges, which then yields distorted costs. They recommended that CMS resolve this problem using external data from manufacturers and other stakeholders until such time that CMS can comply with the GAO study that recommended that CMS ''analyze variation in hospital charge setting to determine if the OPPS payment rates uniformly reflect hospitals' costs of provided outpatient services and if they do not, to make appropriate changes to the methodology.'' The commenters asked that CMS provide explicit instructions to hospitals regarding how to adequately capture and charge for high cost devices.

Response: As we discussed previously, we have decided not to use external data to adjust the APC payment rates for CY 2005 OPPS. We do, however, reassess our existing methodology each year to determine how we can best create rates that uniformly reflect hospitals' cost of providing outpatient services. We will not provide instructions to hospitals regarding how to capture and charge for high cost devices. As a matter of policy, we do not tell hospitals how to set their charges for their services. However, we will continue to inform hospitals of the importance of their charge data in future ratesetting and encourage them to include all appropriate charges on their Medicare claims.

Comment: One commenter objected to us applying the wage index adjustment to the cost of a device in a device-dependent APC because, as the commenter stated, the wage index is intended to address the identified differential in wages across localities. The commenter contends that there is no demonstration of a similar differential in the costs of devices across localities.

Response: Previous studies have shown that across the entirety of all services paid under OPPS, approximately 60 percent of total cost is labor related. Therefore we believe it is appropriate to apply the wage index to 60 percent of the payment for each service. The application of the wage index to the payment for the device-dependent APC can either inflate the total payment for the device-dependent APC or reduce it depending on whether the hospital is in a high cost or low cost area. In many cases, if we ceased to apply the wage index adjustment to 60 percent of the APC payment, the payment to the hospital for the APC would be significantly reduced. We will, however, consider whether it is appropriate to continue to apply the wage index adjustment as we currently do.

Comment: One commenter asked that we add CPT codes 47382, (Radiofrequency ablation procedures of the liver) and CPT code 20982, (Radiofrequency ablation procedures of the bone) to the list of device-dependent APCs because they require the use of devices.

Response: We will consider whether these services should be added to the list of device-dependent APCs in the future. However, it is unclear to us what proportion of total cost of each of these procedures is the cost of the device because codes are not reported for the devices. We do not agree that the cost of the devices could be derived from charges reported in particular revenue codes because there is no identification of the items charged under any revenue code.

Comment: Some commenters indicated that the reductions in APC payments following termination of pass-through status for devices have resulted in the elimination of programs at hospitals that have chosen to no longer implant prosthetic devices.

Response: We share the concern that beneficiaries should have access to services covered under Medicare and believe that our payment policies under OPPS have consistently taken this concern into account.

Comment: Some commenters indicated that the proposed payment rates for APCs 0081, 0107, 0108, 0222, 0229, 0385, and 0386 are inadequate and do not cover the cost of the device; therefore, they do not provide payment for the facility services. The commenters stated that hospitals have taken a loss on these services for several years and cannot continue to provide the services at a loss. The commenters developed alternative cost estimates using external data and urged CMS to use these data rather than its claims data as the basis for developing median costs.

Response: As stated, for device-dependent APC in general, we have not used external data to adjust any median costs for CY 2005 OPPS. Instead, we set the medians for these APCs at the greater of the median cost for CY 2005 derived using claims data or 95 percent of the CY 2004 OPPS adjusted payment median. Beginning in CY 2005, we will also require that the claims containing codes assigned to these APCs also contain a code for an appropriate device for the claim to be paid, so that in CY 2007 we will have correctly coded claims to help us in setting the payment weights.

Comment: Some commenters stated that the proposed payment for cryoablation of the prostate (CPT code 55873) is insufficient to cover the cost for the procedure. They further stated that CMS should factor in external data that shows hospital costs to exceed $9,000, eliminate or adjust claims for APC 0674 in which the charges for

cryoablation probes are less than $7500, or discard all claims containing CPT code 55873 in the Medicare database for which the total hospital costs are less than $6500. The commenters indicated that access to this care would be impeded if the APC payment is not sufficient to pay the full cost of the service. The commenters believed that APC payment at less than full costs for the service will give rise to the use of alternative means of treating prostate cancer. These commenters indicated that the charges hospitals report on their claims are seldom sufficient to result in the full cost of all of the supplies and equipment needed to furnish the service. The commenters also indicated that when the only claims used to set the median are those for which the code for cryoablation probes is found, the median increases significantly.

Response: The codes for the cryoablation probes used in providing cryoablation of the prostate were billed in CY 2003 because they were paid as pass-through payments in CY 2003. Therefore, they exist in the claims data and we used them to screen for correctly coded claims in setting the median cost for APC 0674. The median derived using the subset of claims is $6,562.69, a decrease of 5.10 percent from the CY 2004 final payment median for APC 0674. Therefore, based on the device-dependent APC policy that we are finalizing for CY 2005, we set the median for APC 0674 at 95 percent of the CY 2004 final payment median, or $6,569.33.

Comment: Some commenters supported the increased payment for cochlear implant services (CPT code 69930 in APC 0259) even though they indicated that they believe that the Medicare payment continues to be insufficient to fully pay for the costs of both the device and the procedure. One commenter provided an independent statistical analysis of the Medicare claims data and invoice data that the commenter indicated revealed hospital costs of $27,954 based on a screen of claims that contained HCPCS code L8614 and asked that CMS set the payment at that amount. Some commenters stated that they believe that some hospitals are using the cochlear implant codes to code implantation of less expensive implantable hearing aid devices. The commenter also asked that CMS provide education and develop a guidance document for hospitals specific to coding and billing for cochlear implant surgery.

Response: The device code for cochlear implants remained active in CY 2003 because Medicare uses it for purposes other than the OPPS. In developing the CY 2005 OPPS medians, we created a subset of claims for implantation of cochlear implants that contained the device code and calculated the median for the CY 2005 OPPS using only those correctly coded claims. This yielded a median cost of $26,006.74, which we used as the basis for the APC 0259 payment weight for the CY 2005 OPPS. While it is certainly possible that some hospitals are misusing the code for cochlear implantation to bill for less costly implanted hearing aid devices, we have no way to make that determination using the claims data. However, we note that hospitals billing in such a manner do so at their own risk of being found to have filed a false claim. We will consider what general education activities we need to undertake with regard to all devices but we are disinclined to focus on specific devices to the exclusion of others.

Comment: One commenter indicated that the proposed decrease in payment rates for APC 0039 (Level I Implantation of Neurostimulator) is not acceptable as it would not enable hospitals to cover the cost of the service. Moreover, the commenter stated that hospitals have failed to code and bill correctly for this service and that there are no disincentives for incorrect coding and billing. The commenter further stated that the only diagnosis on the claims for APC 0039 should be that for epilepsy because that is the fundamental reason for implanting the device. However, according to the commenter, examination of the claims for APC 0039 revealed that only 12 percent of those claims contained an epilespsy diagnosis; therefore, the remaining claims caused the median to incorrectly represent the implantation of the device for treatment of epilepsy. The commenter recommended that CMS use external data to ensure that the costs of the device and procedure are adequate to avoid discouraging hospitals from providing the care.

Response: As with other device-dependent APCs, the absence of device codes on the claims for CY 2003 means that we were unable to screen the claims to positively identify which claims include the neurostimulator device costs and we are not confident that screening only for the diagnosis of epilepsy will resolve the coding problem. Therefore, we have set the median for APC 0039 at 95 percent of the CY 2004 final adjusted payment median.

Comment: Some commenters objected to the assignment of status indicator ''T'' to APC 0229 (Transcatheter Placement of Intravascular Stent) because they believe it should not be subject to the multiple procedure reduction due to its dependence on a device. They believed that the payment for the services is undervalued because it is typically done with other procedures and that it is further underpaid by the application of the multiple procedure reduction.

Response: We have not changed the status indicator for APC 0229 because the cost of the device for services in this APC is less than 50 percent of the total cost of the service. Therefore, the multiple procedure reduction of 50 percent does not result in the APC payment being less than the device cost. Moreover, there are efficiencies when multiple services are performed on the same day that we believe justify applying the multiple procedure reduction to the services in this APC.

Comment: One commenter asked that CMS require hospitals to show the actual acquisition cost for devices on the bill using a UB92 value code and the amount. The commenter recommended that where 50 percent or more of the APC is attributable to packaged device cost, CMS should obtain actual device information and use it to determine if APC cost calculations are reasonable.

Response: We do not believe the imposition of an additional reporting requirement would be effective. Such a requirement would be both burdensome and unlikely to provide the actual hospital acquisition cost because hospitals have the ability to reflect general rebates and discounts on a per device basis.

Comment: One commenter asked that we make separate payments for CRT–Ds (pacemaker-defibrillators) for which there was a new technology add-on payment under the IPPS for FY 2005, so that payment for this service under the IPPS and the OPPS would be better aligned.

Response: CRT–Ds were paid on a pass-through basis under the OPPS in CYs 2001 and 2002. Their OPPS pass-through status expired in CY 2003 and their component services were packaged into clinical APC 0107 (Insertion of Cardioverter-Defibrillator) and APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) and. Accordingly, no separate additional payment is appropriate for these devices.

After carefully reviewing the comments, considering the APC Panel recommendations and examining the claims data, we are adjusting the medians for device-dependent APCs based on comparison of the CY 2005 median costs and the CY 2004 final payment median costs. Specifically, we decided to set the median costs for these

APCs at the higher of the CY 2005 median cost from our claims data or 95 percent of the CY 2004 final adjusted median cost used to set the payment in CY 2004 rather than 90 percent of the CY final adjustment median cost as we proposed.

We believe that this adjustment methodology provides an appropriate transition to eventual use of all single bill claims data without adjustment, and that the methodology moves us towards the goal of using all single bill data without adjustment by CY 2007. It is a simple and easily understood methodology for adjusting median costs. Where reductions occur compared to CY 2004 OPPS, we believe that, under this methodology, the reductions will be sufficiently modest that providers will be able to accommodate them without ceasing to furnish services that Medicare beneficiaries need.

In addition, beginning in CY 2005, as proposed, we are requiring hospitals to bill all device-dependent procedures using the appropriate C-codes for the devices. We believe that this approach mitigates against the reduction of access to care while encouraging hospitals to bill correctly for the services they furnish. We intend this requirement to be the first step towards use of all available single bill claims data to establish medians for device-dependent APCs. Our goal is to use all single bills for device-dependent APCs in developing the CY 2007 OPPS, which we expect to base on data from claims for services furnished in CY 2005. We further discuss our coding requirement in section III.C.4. of this preamble.

Table 18 below, which is sorted by APC, contains the CY 2004 OPPS payment medians, the CY 2005 OPPS final adjusted medians using single bill claims from January 1, 2003, through December 31, 2003), and the medians derived from the adjustment processes discussed further below.

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Table 18.-- Median Costs for Device-Dependent APCs

APC	Description	SI	Final CY 2004 OPPS APC Median	Unadjusted CY 2005 OPPS APC Median Cost	Percentage Change from CY 2004 to CY 2005	Adjusted Final CY 2005 OPPS Median	CY 2005 Total Frequency
0032	Insertion of Central Venous/Arterial Catheter	T	$662.31	$475.76	-28.17%	$629.19	79,381
0039	Implantation of Neurostimulator (new for 2004 OPPS; breakout of APC 222)	S	$13,555.80	$10,015.34	-26.12%	$12,878.01	1,833
0040	Level II Implantation of Neurostimulator Electrodes (new for 2004 OPPS; breakout of APC 225)	S	$3,002.98	$2,885.37	-3.92%	$2,885.37	10,657
0080	Diagnostic Cardiac Catheterization	T	$2,075.91	$2,123.65	2.30%	$2,123.65	396,154
0081	Non-Coronary Angioplasty or Atherectomy	T	$2,018.99	$1,782.44	-11.72%	$1,918.04	127,156
0082	Coronary Atherectomy	T	$6,352.89	$4,546.84	-28.43%	$6,035.25	632
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	T	$3,412.47	$2,920.81	-14.41%	$3,241.85	8,364
0085	Level II Electrophysiologic Evaluation	T	$2,041.13	$2,034.82	-0.31%	$2,034.82	19,113
0086	Ablate Heart Dysrhythm Focus	T	$2,590.21	$2,637.96	1.84%	$2,637.96	8,792
0087	Cardiac Electrophysiologic Recording/Mapping	T	$2,294.94	$559.11	-75.64%	$2,180.19	11,859
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	T	$6,754.63	$6,279.62	-7.03%	$6,416.90	5,016
0090	Insertion/Replacement of Pacemaker Pulse Generator	T	$5,581.04	$4,996.52	-10.47%	$5,301.99	8,148
0104	Transcatheter Placement of Intracoronary Stents	T	$4,765.05	$4,750.06	-0.31%	$4,750.06	21,614
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T	$3,399.05	$1,649.73	-51.46%	$3,229.10	4,355
0107	Insertion of Cardioverter-Defibrillator	T	$19,431.68	$12,119.59	-37.63%	$18,460.10	7,224
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T	$26,092.91	$18,077.80	-30.72%	$24,788.26	5,281
0115	Cannula/Access Device Procedures	T	$1,478.06	$1,502.71	1.67%	$1,502.71	106,398
0119	Implantation of Infusion Pump (we proposed to remove 49419 from APC 119 and place it in 115); the 2005 median was calculated from 25 claims after examination of all single bills and removal of erroneously coded claims	T	$7,765.02	$5,320.82	-31.48%	$7,376.77	385
0122	Level II Tube changes and Repositioning	T	$510.80	$473.64	-7.27%	$485.26	18,775

APC	Description	SI	Final CY 2004 OPPS APC Median	Unadjusted CY 2005 OPPS APC Median Cost	Percentage Change from CY 2004 to CY 2005	Adjusted Final CY 2005 OPPS Median	CY 2005 Total Frequency
0167	Level III Urethral Procedures	T	$1,730.23	$1,664.80	-3.78%	$1,664.80	10,194
0202	Level X Female Reproductive Proc	T	$2,246.87	$2,322.83	3.38%	$2,322.83	13,526
0222	Implantation of Neurological Device (APC 39 was part of 222 in 2003)	T	$13,383.79	$9,056.69	-32.33%	$12,714.60	5,224
0225	Level I Implementation of Neurostimulator Electrodes	S	$11,873.72	$12,327.52	3.82%	$12,327.52	1,482
0227	Implantation of Drug Infusion Device	T	$9,270.36	$8,542.64	-7.85%	$8,806.84	3,408
0229	Transcatherter Placement of Intravascular Shunts	T	$3,572.98	$3,638.52	1.83%	$3,638.52	41,858
0259	Level VI ENT Procedures (Cochlear implants; median uses device code only single bills)	T	$22,643.98	$26,006.74	14.85%	$26,006.74	945
0313	Brachytherapy	S	$795.83	$812.60	2.11%	$812.60	15,859
0384	GI Procedures with Stents	T	$1,669.39	$1,232.28	-26.18%	$1,585.92	20,108
0385	Level I Prosthetic Urological Procedures	S	$3,870.60	$4,080.56	5.42%	$4,080.56	843
0386	Level II Prosthetic Urological Procedures	S	$6,699.79	$6,674.53	-0.38%	$6,674.53	4,817
0418	Left ventricular lead In new tech 1547 at $850 for 2004; device coming off pass through for 2005	T		$4,363.37		$4,363.37	530
0425	Level II Arthroplasty with prosthesis (new for 2005; broken out of APC 48; data 2004 is from APC 48)	T	$2,966.13	$5,715.97	92.71%	$5,715.97	795
0648	Breast Reconstruction with Prosthesis	T	$3,113.43	$2,875.96	-7.63%	$2,957.76	1,329
0652	Insertion of Intraperitoneal Catheters	T	$1,558.34	$1,626.29	4.36%	$1,626.29	5,473
0653	Vascular Reconstruction/Fistula Repair with Device	T	$1,731.08	$1,638.33	-5.36%	$1,644.53	29,776
0654	Insertion/Replacement of a permanent dual chamber pacemaker	T	$6,495.61	$6,060.94	-6.69%	$6,170.83	21,197
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	T	$8,225.23	$7,913.85	-3.79%	$7,913.85	15,152
0656	Transcatheter Placement of Intracoronary Drug Eluting Stents	T	$5,965.05	$6,156.14	3.20%	$6,156.14	5,759
0670	Intravenous and Intracardiac Ultrasound	S	$1,582.08	$1,779.08	12.45%	$1,779.08	4,335
0674	Prostate Cryoablation (device was on pass through in 2003; 2003 claims median for 2005 is based on C-code claims)	T	$6,915.08	$6,562.69	-5.10%	$6,569.33	1,516
0680	Insertion of Patient Activated Event Recorders	S	$3,621.15	$3,744.69	3.41%	$3,744.69	2,067
0681	Knee Arthroplasty	T	$5,657.87	$5,353.66	-5.38%	$5,374.98	788

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We also note that as a result of our initial data analysis for device-dependent APCs, we proposed to make the following additional adjustments to specific device-dependent APCs for the reasons specified:

a. APC 0226: Implantation of Drug Infusion Reservoir

We proposed to remove APC 0226 (Implantation of Drug Infusion Reservoir) from the list of device-dependent APCs and to use its unadjusted single bill median of $2,793.30 as the basis for the payment weight. CPT code 62360 (Implantation or replacement of device for intrathecal or epidural drug infusion, subcutaneous reservoir) is assigned to APC 0226. In CY 2002, when we packaged 75 percent of the cost of the device into the payment for the procedure with which the device was billed to reduce the pro rata adjustment, we inadvertently packaged the cost of an implantable infusion pump (C1336 and C1337) rather than that of a drug reservoir. Our data indicated that the reservoir used in performing CPT code 62360 costs considerably less than an implantable infusion pump, and we believe that the median cost for APC 0226 appropriately reflects the relative cost of the service and the required device.

We did not receive any public comments on this proposal. Accordingly, we have removed APC 0226 from the device-dependent APC list and used its unadjusted single bill median of $2,541.43 as the basis for its CY 2005 relative payment weight.

b. APC 0048: Arthroscopy With Prosthesis

In addition, we proposed to delete APC 0048 (Arthroplasty with Prosthesis) from the list of device-dependent APCs for CY 2005 and to not adjust the median costs for this APC because we believe that the CY 2005 median cost for this APC as restructured is reasonable and appropriate. Based on our careful analysis of the CY 2003 claims data for this APC, we believe the difference between the CY 2004 and CY 2005 median cost is attributable to the migration of certain high cost CPT codes (23470, 24361, 24363, 24366, 25441, 25442, 25446) from APC 0048 to new APC 0425 (Level II Arthroplasty with Prosthesis) and, as such, this change would not adversely limit beneficiary access to this important service. Therefore, we did not propose to apply a device-dependent adjustment to the median cost for APC 0048.

We did not receive any public comments on this proposal. Accordingly, for CY 2005 we are removing APC 0048 from the device-dependent list and are not adjusting the median cost for this APC.

c. APC 0385: Level I Prosthetic Urological Procedures

We proposed to move CPT code 52282 (Cystourethroscopy, insert urethral stent), from APC 0385 (Level I Prosthetic Urological Procedure) and assign it to APC 0163 (Level IV Cystourethoscopy and other Genitourinary Procedures), for clinical homogeneity. As titled, APC 0385 was intended for the assignment of certain urological procedures that require the use of prosthetics. However, CPT code 52282 requires the use of a stent rather than a urological prosthetic. Therefore, we proposed to reassign CPT code 52282 to APC 0163. Recalculation of the median cost for APC 0385 after reassigning CPT code 52282 yielded a median cost for that APC that is consistent with its CY 2004 median payment. Thus, we did not propose a device-dependent adjustment for the median cost for APC 0385.

Comment: Some commenters asked that we keep CPT code 52282 in APC 0385 and not move it to APC 0163. These commenters believed that placement of CPT code 52282 in APC 0385 would maintain clinical coherence and resource similarity. They also supported the APC Panel's recommendation that all three codes, which we proposed to move from APC 0385 to 0386 (CPT codes 53440, 53444, and 54416) should be retained in APC 0385 for CY 2005 OPPS because they are dissimilar in terms of the nature of the surgical procedure and the sophistication of the prosthetic urology device that is implanted.

Response: We have moved CPT code 52282 from APC 0385 to APC 0163 because we believe that this service is more compatible from a clinical and resource perspective with the other cystourethroscopy services assigned to APC 0163 than with services assigned to APC 0385. We have retained CPT codes 53440 and 53444 to APC 0385 because the median costs for these procedures in the CY 2003 data that were used to develop this final rule with comment period indicate that the resources required for them are similar to those for CPT code 54400, which is also assigned to APC 0385. However, we have placed CPT code 54416 in APC 0386 because the median cost shows that the resources are much more like those for services assigned to APC 0386 than the median costs for services in APC 0385. CPT code 54416 requires removal and replacement of a non-inflatable or inflatable prosthesis and our resource data demonstrate relatively high costs for the service, most typically associated with replacement of an inflatable prosthesis. Thus, the nature of the services are sufficiently similar such that CPT code 54416 is clinically coherent with the services in APC 0386.

d. APC 0119: Implantation of Infusion Device and APC 0115: Cannula/Access Device Procedures

We proposed to remove CPT code 49419 (Insert abdom cath for chemo tx), from APC 0119 (Implantation of Infusion Pump) and assign it to APC 0115 (Cannula/Access Device Procedures) to achieve clinical homogeneity within APC 0115. Unlike all the other codes assigned to APC 0115, HCPCS code 49419 does not require the use of an infusion pump. Rather, this code is used when inserting an intraperitoneal cannula or catheter with a subcutaneous reservoir. Thus, we believed it would be more appropriate clinically to reassign HCPCS code 49419 to APC 0115 that includes procedures that require the use of devices similar to that required for CPT code 49419.

Comment: One commenter recommended that we move the CPT code 36260 (Insertion of infusion pump) and CPT code 36563 (Insert tunneled cv catheter) from APC 0119 to APC 0227 (Implantation of Drug Infusion Device), which is also for implantation of infusion pumps. The commenter indicated that all of these services are for implantation of infusion pumps and that the external cost data on the pumps are not dissimilar.

Response: We have not combined the codes in these APCs because they are not clinically homogeneous. Specifically, the services in APC 0227 are for the insertion of spinal infusion pumps and those in APC 0119 are for insertion of vascular infusion pumps. We see no clinical reason to move these codes as suggested by the commenter.

2. Treatment of Specified APCs

a. APC 0315: Level II Implantation of Neurostimulator

As stated in the August 16, 2004 proposed rule, CPT code 61866 (Implant neurostim arrays) was brought to our attention by means of an application for a new device category for transitional pass-through payment for the Kinetra® neurostimulator, a dual channel neurostimulator currently approved and used for Parkinson's disease. We denied approval for a new device category for the Kinetra® neurostimulator because the device is described by a previously

existing category, C1767 (Generator, neurostimulator (implantable)).

The manufacturer of Kinetra® stated that the AMA created CPT 61886 to accommodate implantation of the Kinetra® neurostimulator and that no services other than implantation of the Kinetra® are currently described by that CPT code. Even though the Kinetra® did not receive full FDA pre-market approval until December 2003, hospital outpatient claims were reported in CYs 2002 and 2003 (289 total claims in CY 2003) for this device. The manufacturer asserted that these claims must have been miscoded because the Kinetra® could not have been used in performing CPT code 61886 before obtaining FDA approval in December 2003. Therefore, the manufacturer did not believe that the device cost could be included in the median for CPT code 61886, which has been assigned to APC 0222.

In examining the CY 2003 claims for CPT code 61866, we noted that many of the claims also contained codes for procedures related to treatment with cranial nerve stimulators, including the placement of electrodes for cranial nerve stimulation. The placement of the cranial neurostimulator electrodes used with the Kinetra® is currently an inpatient rather than outpatient procedure. Therefore, we would not expect patients being prepared for cranial nerve stimulation to also have a Kinetra® neurostimulator for deep brain stimulation for Parkinson's disease placed at the same time. Thus, it seems possible that the CY 2003 claims for CPT code 61886, generally, are incorrectly coded and do not include the dual chamber neurostimulator in the reported charges.

Prior to the availability of the dual channel neurostimulator Kinetra® for bilateral deep brain stimulation, it is our understanding that patients diagnosed with Parkinson's disease had two single channel neurostimulator generators implanted in the same operative session. According to the Kinetra® manufacturer, this device will now replace the insertion of two single channel neurostimulators and the cost of the Kinetra® is equivalent to the cost of two single channel neurostimulators. Given this information, we examined our CY 2003 claims data and found that 69 single claims were reported for patients with a diagnosis of Parkinson's disease and that 2 single channel neurostimulator pulse generators (CPT code 61885) were implanted on the same day. The median cost for these claims was $20,631. Other than the device costs, we believe the procedural costs for the insertion of two single channel devices or one dual channel device should be roughly comparable. Therefore, we proposed to establish a new APC 0315, Level II Implantation of Neurostimulator, for CPT code 61886, and assign it a median cost of $20,631. Because of our concern that hospitals correctly code OPPS claims for CPT code 61886, we also proposed to require device coding (C-code) for APC 0315 to improve the coding on all claims for placement of a dual channel cranial neurostimulator pulse generator or receiver, as we proposed for APC 0039, Implantation of Neurostimulator, for placement of a single channel cranial neurostimulator, discussed in section III. C. of this preamble.

Comment: We received one comment in support of our proposed median cost for APC 0315.

Response: We appreciate the commenter's support. Accordingly, we are finalizing our CY 2005 proposal to assign CPT code 61886 to APC 0315 with an assigned median cost of $20,633.70.

b. APC 0651: Complex Interstitial Radiation Application

For CY 2003, APC 0651 included CPT code 77778 (Complex interstitial radiation source application). This code was not to be used for prostate brachytherapy because we created HCPCS codes G0256 (Prostate brachytherapy with palladium sources) and G0261 (Prostate brachytherapy with iodine sources) in which we packaged the cost for placement of needles or catheters and sources into a single APC payment for each G code (67 FR 66779). When we calculated the median from all single bills for CPT code 77778 from CY 2003 data for CY 2005 OPPS, we found that 73 percent of the single bills for this APC were for prostate brachytherapy and, therefore, were miscoded. The median for APC 0651, using all single bills, including those miscoded for prostate brachytherapy, was $2,641.67. When we removed the incorrectly coded claims for prostate brachytherapy, which we believed to contain brachytherapy sources and which are paid separately for CY 2004 and will be paid separately for CY 2005, the median was $1,491.39. This is the amount that we proposed for payment for CY 2005 OPPS for APC 0651. The proposed median was considerably higher than the median cost of $589.72 for CY 2004 OPPS (from CY 2002 claims data).

We believed that this adjusted median was appropriate for APC 0651 when used for prostate brachytherapy because the service described by CPT code 77778 is only one of several components of the payment for the service in its entirety. When it is used for prostate brachytherapy, hospitals should also bill for the placement of the needles and catheters using CPT code 55859 and should also bill the brachytherapy sources separately. Hospitals will be paid for both APCs and for the cost of sources.

Section 621(b)(1) of Pub. L. 108–173 specifically provides separate payment in CY 2005 ''* * * for a device of brachytherapy, consisting of a seed or seeds (or radioactive source) * * *'' at the hospital's charge adjusted to cost. We proposed to package the cost of other services such as the needles or catheters into the payment for the brachytherapy APCs and not to pay on the same basis as the brachytherapy sources because the law does not include needles and catheters in its definition of brachytherapy sources to be paid on charges adjusted to cost.

We also recognized that APC 0651 is used for brachytherapy services other than prostate brachytherapy and that, in some of those cases, there are no other separate procedure codes for placement of the needles or catheters. In those cases, which are represented in the claims we used to calculate the proposed median (once the miscoded claims for prostate brachytherapy were excluded), we believed that the charges for CPT code 77778 may have included the placement of the needles or catheters and, therefore, the median may be somewhat overstated when used as the basis for payment for prostate brachytherapy and the other forms of brachytherapy that have procedure codes for placement of needles and catheters. Similarly, we believed that the median may be understated when used to pay for brachytherapy services for which there are no separate HCPCS codes for needle or catheter placement. We considered whether to create new G codes for the placement of catheters and needles for the brachytherapy services for which such codes do not exist, but we were concerned that doing so might create unneeded complexity and that the existing data may not support establishing medians for the new codes. We requested comments on how to address those services for which there are currently no HCPCS codes for placement of needles and catheters for brachytherapy applications.

Comment: Commenters indicated that the absence of codes for brachytherapy needle/catheter placement is problematic because hospitals are forced to use existing ''not otherwise classified'' codes that makes claims analysis difficult for ratesetting. They asked that we create three ''not otherwise classified'' HCPCS codes for the placement of needles and catheters

for application of brachytherapy sources other than prostate brachytherapy so that they can be billed and paid appropriately. Specifically, they asked (1) that CMS create a code for 1–4 needles/catheters and place it in APC 1507; (2) that CMS create a code for placment of 5–10 catheters and place it in New Technology APC 1513; and (3) that CMS create a new code for more than 10 needles/catheters and place it in New Technology APC 1522.

Response: We have not created HCPCS codes for needle/catheter placement for CY 2005 as suggested by the commenters. We do not believe that the requested new, ''not otherwise classified'' codes would be any more meaningful for OPPS ratesetting than the existing ''not otherwise classified'' codes.

As explained in the November 30, 2001 final rule (66 FR 59897), new Technology APCs are for complete procedures, not devices or drugs or biologicals, but such items may be part of the cost of the complete service. To qualify for OPPS payment under the new technology APCs, a service must meet the following criteria:

- Service must be a complete service.
- Service must not be described by an existing HCPCS code or combination of codes.
- Service could not have been adequately represented in the claims data used for the most current annual OPPS payment update.
- Service does not qualify for additional payment under pass-through payment provisions.
- Service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.
- Service is medically reasonable and necessary.
- Service falls within scope of Medicare benefits.

Processes and requirements for pass-through and new technology service APC applications are provided in more detail on the OPPS Web site: *http://www.cms.hhs.gov/poviders/hopps/.*

Implicit in the criteria is that there exists a meaningful description of the services for which new technology status is being requested. We do not believe the ''not otherwise classified'' codes proposed by the commenters are sufficiently specific that they could satisfy the criteria. We believe that CPT already contains sufficient ''not otherwise classified'' codes for the coding of placement of brachytherapy needles and catheters in locations of the body for which specific codes do not now exist. We are unable to specify the ''not otherwise classified'' codes that should be used because the ''not otherwise classified'' codes are generally categorized by body part or function, and, therefore, the code that would apply depends on the location in the body in which the needles and catheters are being placed. For example, placement of needles or catheters in a shoulder muscle would be coded differently from placement of needles or catheters in the pancreas.

Comment: Some commenters supported the proposed payment for APC 0651 (Complex Interstitial Radiation Source Application). They indicated that, together with separate payment for the brachytherapy sources and the placement of needles and catheters, the proposed payment would provide adequate payment for these important services.

Response: We appreciate the commenters' support. Further discussion regarding the payment for APC 0651 is provided at III.C.2.b.

Comment: One commenter indicated that there are many supplies and devices other than needles and catheters that are used in providing brachytherapy and asked that CMS develop codes for them so that they could be billed as coded items because such coding would facilitate capture of all the costs associated with performing the services.

Response: We have not created new device codes for the supplies and equipment that the commenter requested because such items are incidental to the service. We do not believe that such incidental items justify development of new device codes.

In this final rule with comment period, the median cost for APC 0651 is $1,283.44, resulting in a national unadjusted payment rate of $1,248.93. There were fewer CY 2003 final action claims for this service in the database that was constructed from the most current claims data and used to develop the weights and median costs for this final rule with comment period. Twelve hospitals whose claims had appeared in the CY 2003 claims data used to calculate the proposed weights and median costs withdrew their claims before we pulled the data for this final rule with comment period. This may have been because they realized that they had billed incorrectly and withdrew the claims to bill correctly.

Our examination of the claims data set for this final rule with comment period reveals that the claims largely appear to not include charges for brachytherapy sources. The unadjusted median cost that resulted from use of these claims is $1,283.44, a 117 percent increase over the median cost for CY 2004 for this APC. As we noted previously, the median should reflect accurately the appropriate claims for the APC. We have no reason to believe that this median is flawed. Therefore, we have used it as the basis for the CY 2005 OPPS unadjusted payment rate of $1,248.93.

c. APC 0659: Hyperbaric Oxygen Therapy

In the August 16, 2004 proposed rule, we stated that over the past year, we have received a number of questions about billing and payment for HCPCS code C1300 (Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval). In light of these issues, we carefully examined the CY 2003 single procedure claims data that we proposed to use to calculate the CY 2005 median for APC services. Based on our examination of single procedure claims filed for HCPCS code C1300 in CY 2003, we believe that the claims for these services were either miscoded or the therapy was aborted before its completion. The claims that we examined reflected a pattern that is inconsistent with the clinical delivery of this service. Hyperbaric oxygen therapy (HBOT) is prescribed for clinical conditions such as promoting the healing of chronic wounds. It is typically prescribed on average for 90 minutes and, therefore, you would expect hospitals to bill multiple units of HBOT to achieve full body hyperbaric oxygen therapy. In addition to the therapeutic time spent at full hyperbaric oxygen pressure, treatment involves additional time for achieving full pressure (descent), providing air breaks to prevent neurological and other complications from occurring during the course of treatment, and returning the patient to atmospheric pressure (ascent). Our examination of the claims data revealed that providers who billed multiple units of C1300 reported a consistent charge for each ''30 minute'' unit. Conversely, providers who billed only a single unit of C1300, suggesting either a miscoded or aborted service, reported a charge that was 3 to 4 times greater than the per ''30 minute'' unit reported by providers billing multiple units of HCPCS code C1300. While it appears that many of the single procedure HBOT claims that we examined represented billing for a full 90 to 120 minutes of HBOT (including ascent, descent, and air break time), they were improperly billed as 1 unit rather than as 3 or 4 units of HBOT. Consequently, this type of incorrect coding would result in an inappropriately high per 30 minute median cost for HBOT or a median cost

for HBOT of $177.96 derived using single service claims and ''pseudo'' single service claims. This is a significant issue because HBOT is the only procedure assigned to APC 0659.

Our initial analysis of the HBOT claims data further revealed that about 40 percent of all HBOT claims included packaged costs. To confirm our belief that these packaged costs were not associated with HBOT, we examined the other major payable procedures billed in conjunction with HBOT. As a result, we identified billed services such as drug administration and wound debridement that we would typically expect to have associated packaged services. We also looked at the magnitude of packaged costs in our single bills and found the majority of these costs were small, less than $30, and concentrated in revenue codes 25X, Pharmacy, and 27X, Medical/Surgical Supplies.

As a result of these coding anomalies, we proposed to calculate a ''30 minute'' median cost for APC 0659, using a total of 30,736 claims containing multiple units or multiple occurrences of HBOT, about 97 percent of all HBOT claims. Based on our finding, we proposed to exclude claims with only one unit of HBOT. We estimated costs on these claims using the respiratory therapy cost center CCR when one was available. Otherwise we used the hospital's overall CCR. Using this proposed methodology, the proposed median cost per unit of C1300 was $82.91. Based on hospitals' charges on correctly coded claims, we believe this estimate is much more accurate for 30 minutes of HBOT. Thus, we proposed a median cost for APC 0659 of $82.91 for CY 2005.

We received many public comments on this proposal.

Comment: Overall, commenters expressed concern about the proposed reduction in payment for HBOT. There also was great consistency in the comments. Almost all the commenters cited a recent research report by The Lewin Group (Lewin) that examined our methodology for calculating a payment rate for APC 0659 and offered us several alternatives for identifying a median for HBOT. In their evaluation of our proposed change for calculating a median for HBOT, The Lewin Group ultimately concluded that, while our proposed use of claims with multiple units of C1300 in lieu of the clams with a single unit of C1300 was appropriate for calculating the median cost, we used an inappropriate cost-to-charge ratio to estimate costs from charges on those multiple unit claims.

Lewin surveyed the majority of hospitals billing Medicare for HBOT, requesting specific pages from each hospital's cost report to determine where HBOT services are reported and the associated CCR. Lewin received completed responses from 120 hospitals, a 30 percent response rate. The majority of responding hospitals, 63 percent, frequently broke out the costs of hyperbaric/wound care in a subscripted cost center on their cost report. In addition, 24 percent included their costs in the respiratory therapy cost center, and the remainder included their costs in disparate cost centers including emergency room and physical therapy. For those hospitals reporting separate line-items for hyperbaric/wound care, Lewin used CMS claims data to estimate a median CCR of 0.400 as compared with the median CCR for respiratory therapy of 0.248. Lewin also sought to establish the generalizability of their sample findings by demonstrating that responding hospitals were geographically diverse and that the respiratory therapy CCR for the responding hospitals was comparable to that observed in the claims data. Finally, Lewin used their survey findings to estimate a proportional difference in CCRs between respiratory therapy and the observed, hyperbaric-related CCRs of 1.411 and, applying this adjustment to the CMS claims data, they calculated a payment rate of $118.21.

Practically all commenters offered four possible alternatives to our proposed methodology. First, commenters suggested that CMS leave HBOT reimbursement at its CY 2004 level until CMS can accurately estimate costs and charges for HBOT. Second, commenters suggested that CMS apply The Lewin Group methodology in estimating median cost. Third, commenters suggested that CMS adopt The Lewin Group's estimated median of $118.21 per 30 minutes. With regard to this specific recommendation, several commenters stated that they thought that the $118 rate was appropriate, and one commenter believed a rate of $120 or greater would be acceptable. Finally, commenters suggested that CMS default to the overall CCR of 0.47 in lieu of using the respiratory therapy CCR.

Response: We agree with the commenters that The Lewin Group analysis provides sufficient evidence that the CCR for HBOT is not reflected solely in the respiratory therapy cost center. With regard to the first recommended alternative, we do not believe it is appropriate to maintain the CY 2004 HBOT payment rate for CY 2005. We have clearly demonstrated that the single procedure claims are inappropriate for calculating a median cost, and the submitted research did not dispute our median calculation methodology. We cannot undertake the recommended second alternative and replicate The Lewin Group's methodology because the hyperbaric/wound care cost report cost center line-items are neither standard nor non-standard cost centers. We presume that these line-items for hyperbaric/wound care are subscripted cost centers that are ultimately rolled-up in to a standard cost center on the electronic cost report data. Without the specific subscripted information, we cannot calculate a cost-to-charge ratio specific to HBOT.

We also do not believe it is appropriate to adopt the $118.21 estimate made by Lewin using its survey results and our data, the third recommended alternative. The Lewin survey indicates diversity among hospitals in the subscripted location of reported hyperbaric oxygen costs on the cost report. In addition, the $118.21 is based on an adjustment to the CCR that assumes all nonresponding hospitals report their costs in the hospital-specific hyperbaric oxygen-related cost centers, even though roughly one-fourth of hospitals in the Lewin sample were demonstrated to report costs in the respiratory therapy cost center and 13 percent reported costs in other cost centers. The submitted research further indicates fairly substantial variation in the CCRs for the responding hospitals in the HBOT-related cost centers. In light of this, we agree to adopt the last recommended alternative, which is to calculate the median using the overall CCR. As several commenters noted, defaulting to the hospital's overall CCR is standard OPPS policy when an appropriate cost center cannot be assigned to a revenue code. We estimate an overall, hospital-weighted, median CCR for all hospitals of 0.33 and a hospital-weighted, median CCR for respiratory therapy for all hospitals of 0.27. Using the overall CCR to estimate costs from charges associated with HCPCS code C1300, we calculated a median cost of $93.26 using 38,505 claims in the final rule data. We used this median to set the final CY 2005 payment for APC 0659.

Comment: One commenter conducted an internal study of 11 member hospitals and reported a median total cost of $126.42. The study findings acknowledged that we found billing anomalies in the claims with single units, but noted that our proposed approach will have unintended financial consequences. The commenter requested that we review our claims data to ensure HBOT rates that reflect the full cost of providing HBOT services.

Response: As discussed above, we agree that the proposed cost for HBOT was too low because it relied solely on the respiratory therapy CCR. However, based on the volume and consistency of claims for HBOT, we still believe that the claims data are correct. As already discussed, we will base payment for HBOT on a median calculated using the overall hospital CCR. Further, the purpose of OPPS is not to pay the full cost of a service for any given hospital, but rather to proportionally redistribute total OPPS dollars in a manner that reflects relative resource use. APC payment rates are based on the median cost of a group of services, or in this case, one service, to achieve the averaging effect of a prospective payment system and are not intended to reimburse the full cost to a specific hospital. The costs for these 11 member hospitals may fall above the median cost for all hospitals billing HBOT.

Comment: One commenter reviewed CMS claims with multiple units and found an overall average of 15 units of HBOT per claim. This commenter recommended that CMS review a sample of medical records.

Response: We expect that this finding is the result of outlier claims and unit coding errors. In our analyses of HBOT claims for the proposed rule, we found that the vast majority of claims, 93 percent, were for 3 to 5 units of service. Further, The Lewin Group analysis reviewed above did not dispute the appropriateness of using claims with multiple units for calculating a median cost. As discussed above, we believe that the appropriate concern in estimating a median cost for HBOT is the disparity in charging and cost reporting practices among hospitals and not with the claims themselves, a finding that mitigates the need for medical record review.

Comment: One commenter recommended that CMS continue to compile claims data on HBOT and refer this issue to the APC Panel before making changes.

Response: By using claims with multiple units, we believe that we have ample claims data. However, the APC Panel is an official public forum designed to consider and advise us on APC-related issues. If this is a particular concern to the public, the public is invited to present this concern at the next APC Panel meeting.

After carefully reviewing all comments received, we are basing payment for HBOT on a median calculated using the overall hospital CCR rather than the respiratory therapy CCR as proposed. As discussed above, using the overall CCR to estimate costs from charges associated with HCPCS code C1300, we calculated a final CY 2005 payment for APC 0659 of $90.75.

3. Other APC Median Cost Issues

a. APC 0312 Radioelement Applications

Comment: Some commenters stated that the payment rate for APC 0312 (Radioelement Applications) is inadequate to pay for the staff, supplies and appliances that are needed to furnish the service. The commenters further stated that the APC payment should be similar to that for APC 0651.

Response: The median for APC 0312 has increased significantly from the CY 2004 payment median of $199.90 to the CY 2005 OPPS final rule with comment period median of $326.65. Moreover, we were able to use 28 percent of the total claims in CY 2003 for this APC to set the median cost for the CY 2005 OPPS. Therefore, we see no reason to adjust the median for this APC to the level of APC 0651.

b. Percutaneous Radiofrequency Ablation of Liver Tumors

Comment: Some commenters objected to the proposal to move CPT code 47382 (Percutaneous radiofrequency of liver tumors), from a New Technology APC to clinical APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures) because they believe that there is an inadequate number of claims on which to base median costs, and that median costs are inappropriately low because device costs associated with performing this procedure are underreported. They indicated that the proposed reimbursement does not cover the costs of the single use catheters used in performing the service. The commenters stated that revenue codes should be used to screen for appropriately coded claims. They contended that if CMS cannot complete this analysis for this final rule with comment period, CMS should retain CPT code 47382 in a new technology APC at the CY 2004 payment rate until more representative cost data are available. They argued that this latter approach is consistent with how CMS has handled APC payments for PET services since CY 2001. The commenters also recommended that CPT codes 76362 (CT guidance for and monitoring of visceral tissue ablation), 76394 (Magnetic resonance imaging for and monitoring of visceral tissue ablation), and 76940 (Ultrasound guidance for and monitoring of visceral tissue ablation) be added to the bypass list so that more single bills could be used to set the median for CPT code 47382.

Response: We believe that the claims volume is sufficiently adequate to remove CPT code 47382 from New Technology APC 1557 and place it in a clinical APC. Moreover, the median cost, $1,801.84, derived from the CY 2003 claims data for APC 0423, is very close to the payment that was made for New Technology APC 1557 of $1,850. Therefore, as proposed, this service will be placed in clinical APC 0423 and paid based on its historic claims data for services furnished for the CY 2005 OPPS.

In addition, the three CPT codes that the commenter recommended we add to the bypass list do not meet the CY 2005 criteria for inclusion on the list. However, we will consider their inclusion when we next review items for inclusion in CY 2006.

c. Heparin Coated Stents

Comment: One commenter objected to CMS' policy that heparin coated stents should be coded under C1874 (Stent, coated/cov w/del sys) because the commenter believes that to do so will adversely affect the median cost of the stents. The commenter urged us to create a unique C-code if HCPCS codes G0290 and G0291, which are used for placement of drug eluting stents, are retired.

Response: HCPCS codes G0290 and G0291 will remain active codes for CY 2005 and we see no reason to create another C-code at this time. We will determine whether there is a need for another C-code to differentiate between stents if and when HCPCS codes G0290 and G0291 are retired.

d. Aqueous Drainage Assist Device

Comment: One commenter asked that CMS ensure that the costs of code C1783 (Aqueous drainage assist device) are packaged with the costs of the procedures with which the device is most commonly billed. The commenter stated that codes C1783, L8610 and L8612 would usually be billed with procedures that are in APC 0673.

Response: We package the costs of devices that are billed on the same claim with the procedural APCs into the cost of the procedural APC. Thus, the extent to which the costs of these devices are packaged into the median cost for the procedure depends upon the extent to which the hospitals include the charges for the devices on the claim, with or without including the code for the device. To the extent that hospitals included charges for these devices on the claims for the procedures in which they were used, those charges would be converted to costs and packaged into the median cost for the procedure.

4. Required Use of C-Codes for Devices

An important ancillary issue in regard to using hospital outpatient claims data to calculate median costs for a device-dependent APC is whether to require that hospitals bill the HCPCS codes for the devices that are required for use in the provision of the services in these APCs. We deleted HCPCS codes for devices in CY 2003 because hospitals objected to the complexity of this coding, and we believed that hospitals would charge for the devices in appropriate revenue codes. Our review of the claims data does not support this belief. Hospitals do not appear to routinely include the charges for the devices they use when they bill for all of the related services in the device-dependent APCs. Therefore, as discussed in the August 16, 2004 proposed rule, we proposed requiring hospitals to code devices for APCs to improve the quality of the claims data in support of our transition to the use of all single claims to establish payment rates for those APCs. We made this proposal cautiously, as we realize that it imposes a burden on hospitals to code the devices.

For the CY 2005 OPPS, we proposed to require coding of devices required for APCs for which we proposed to adjust the median costs for the CY 2005 OPPS. The APCs and the devices that were proposed for device coding were published in Table 20 of the August 16, 2004 proposed rule (69 FR 50497 through 50499). Specifically, if one device is shown for one APC, that device would have to be billed on the claim for a service in that APC or the claim would be returned to the provider for correction. If more than one device is shown for one APC, the provider would be required to bill one of the device codes shown on the same claim with the service in that APC for the claim to be accepted.

We also proposed to require coding of C1900 (Left ventricular lead) required to perform the service described in APC 0418, Left Ventricular Lead, because the service cannot be done without the lead, and because the device has been billed separately for pass-through payment in CYs 2003 and 2004. We believe that continued coding of the device would not impose a burden on hospitals. Similarly, because of our concerns regarding the correct coding of claims for CPT code 61886 (Implant neurostim arrays), assigned to APC 0315 (discussed in greater detail in section III.C.2.a. of this preamble), we proposed to require device coding for APC 0315 (Level II Implantation of Neurostimulator) to improve the coding on claims for placement of a dual channel cranial neurostimulator pulse generator or receiver, just as we proposed to require device coding for APC 0039 (Implantation of Neurostimulator) for placement of a single channel cranial neurostimulator as noted below.

We solicited comments on the proposed C-code requirements.

In addition, we announced in the proposed rule that we are considering expanding the device coding requirements in the future. We believed that, by requiring device coding for a small subset of device-dependent APCs each year, we would minimize the marginal annual coding burden on hospitals and begin to improve data for these APCs, which have consistently proven to be problematic. We believed coding of devices was essential if we were to improve the accuracy of claims data sufficiently to better calculate the correct relative costs of device-dependent APCs in relation to the other services paid under the OPPS.

We asked that the public inform us of the device codes that are essential to the procedures contained in the device-dependent APCs listed in Table 20 of the proposed rule. The alphanumeric HCPCS codes for devices that were reactivated for CY 2004 OPPS can be found on the CMS Web site at *http://www.cms.hhs.gov/providers* under coding. They are in the section of alphanumeric codes that begin with the initial letter ''C.''

We received a number of comments regarding our request.

Comment: In general, commenters supported a requirement for mandatory device coding for all devices, not only those for which CMS proposed mandatory reporting. However, they had different views regarding what the requirement should contain and how it should be enforced. Some commenters asked that we require that all procedures for device-dependent APCs contain a C-code to identify the device used in the procedure. They indicated that they believed that this requirement is crucial to acquiring valid cost data for these services. Some commenters were concerned about the administrative burden that required C-coding imposes on hospitals and urged CMS to reassess the burden within 2 years if it imposes mandatory C-coding for devices. Other commenters urged CMS to implement a grace period of no less than 90 days after implementation of the CY 2005 OPPS to enable hospitals to be sure that they are prepared for device code edits. During this period, the commenters wanted intermediaries to accept the codes and not return incorrectly coded claims. The commenters indicated that the edits should be included in this final rule with comment period so that hospitals can begin to work on them as soon as possible. Those commenters suggested that the device codes for which edits will not be implemented in CY 2005 should not be required until CY 2006. The commenters indicated that both OCE and intermediary systems must be ready to handle this change, and that no edits should be implemented if they are not and if providers have not had at least 30 days notice. Some commenters urged CMS to base any edits or list of required device codes on CPT codes, not APCs, because in some cases, not all codes in an APC require the same device. One commenter objected to the use of edits to return to providers claims that contain a procedure code that cannot be done without a device but which contain no device code. The commenter indicated that CMS has been inconsistent in its policies governing coding of devices since the inception of the OPPS and should provide some greater period of stability in coding before it edits for the presence of the device codes.

Response: We appreciate the comments, but continue to believe coding of devices is vital to enhancing the device-dependent APC claims data. Therefore, as proposed, effective for services provided on or after January 1, 2005, we will require hospitals to include device category codes on claims when such devices are used in conjunction with procedures billed and paid for under the OPPS. While we are requiring use of these device codes for reporting all such devices effective January 1, 2005, we will not implement the edits contained in Table 19 until April 1, 2005, to provide time for further review and for hospitals to prepare for them. The edits will not apply to claims that contain a procedure code reported with a modifier 73 or 74 to signify an interrupted procedure because we recognize that in those cases, the procedure might have been interrupted before the device was implanted.

We will apply the edits at the CPT/HCPCS code level to be as precise as possible. Table 19 includes the edits that we expect to go into effect April 1, 2005. The table of edits and the definitions of the C-codes (Table 20 of this preamble) will be posted on the CMS Web site on the OPPS page. As noted on Table 19, there are some CPT codes for which edits cannot be established, for example, because of the optional nature of the use of a device when performing the service. Although there is no official comment period

associated with implementation of the edits, we welcome comments on the edits to be implemented on April 1, 2005, particularly from hospitals to whose claims the edits will apply and from medical specialties whose physicians use the devices in the procedures performed in hospital outpatient settings. Comments may be sent to *OutpatientPPS@cms.hhs.gov* if possible, by December 1, 2004.

In the future, we will consider edits for additional procedure codes in other device-dependent APCs. We will post all final edits on the CMS Web site with an announcement of the calendar quarter in which we expect to implement them. We will also provide them in a Medlearn Matters article. Any future edits will be implemented as always as part of the quarterly OCE release. We intend to expand the editing of device-dependent procedure codes for appropriate device C-codes as expeditiously but also as carefully as possible. The next group of device procedures for which we will consider edits will include those procedures in APCs for which we set the median cost at 95 percent of the CY 2004 payment median but for which we did not propose edits in the August 16, 2004 proposed rule.

Comment: One commenter asked that CMS encourage manufacturers to put the applicable HCPCS device C-code on the device package and that CMS work with FDA to expedite placement of C-codes on device packages. The commenter also urged CMS to simplify the C-codes to be consistent with the information routinely reported by physicians in operative reports. The commenter gave, as an example, the seven device codes used with APC 0087 (Noncoronary Angioplasty or Atherectomy), all of which could be reported using only one code for ''transluminal catheter''. The commenter stated that such simplification would greatly improve the likelihood that the device is coded on the claim because the description that distinguishes one of the seven codes from another is typically not documented in the hospital's record and is not information the coder would know. Other commenters asked that CMS actively undertake a program designed to educate providers on how to bill for devices and how to set charges for high cost devices so that future updates to the OPPS will more accurately reflect the costs of these services. Some commenters urged CMS to create and maintain a file on the CMS Web site that contains a complete crosswalk of devices codes to CPT codes in the device APCs. Some commenters asked that CMS provide a detailed revenue code to device code crosswalk so that hospitals will promote more uniformity in billing for devices.

Response: We will carefully examine how we can facilitate correct coding of devices, including possible communication with the FDA. We will also consider the extent to which we can simplify the HCPCS codes for devices to facilitate straightforward coding. Finally, we will determine the extent to which we can improve provider education regarding correct coding for devices. However, we will not undertake any activity designed to advise hospitals on how to set charges for their services or to designate what revenue codes hospitals should use on a device-specific basis.

The edits that we created to ensure the coding of devices for the selected APCs that are listed in Table 19 of this preamble are also available as an Excel file in the supporting documentation of this final rule with comment period that will be posted on the CMS Web site and will also be contained in the transmittals for the January 2005 OPPS update and OCE release. Moreover, as described above, we will post any added edits for device coding on the OPPS page of the CMS Web site so that providers can have ready access to them.

Comment: Some commenters asked that we add particular device and procedure combinations to the table of edits. Specifically, a commenter asked that we add APC 0259 (Cochlear Implant Surgery) as paired with device code L8614 (Cochlear implant), and APC 0040 paired with both device codes C1778 (Lead neurostimulator) and C1883 (Adapter/extension packing lead or neurostimulator lead). Another commenter asked that we add code C1787 (Patient programmer, neurostimulator) to the required devices for APC 0222. Another commenter asked that the same device codes be required for the CPT codes in APC 0087 as we proposed to require for APC 0085 because the commenter believes that the same devices are used in both APCs. Other commenters asked that we include edits for other APCs, for example, APC 0385 (Level I Prosthetic Urological Procedures) and APC 0386 (Level I Prosthetic Urological Procedures).

Response: Except as discussed below, we have not added any APCs to the list that we proposed be edited for device codes at this time. Although our policy to require hospitals to code all devices is effective January 1, 2005, we will not implement edits until April 1, 2005. We will consider the comments regarding additional edits for later implementation. We believe that it is preferable to focus first on the APCs most affected and to add subsequent edits after careful deliberation. In this manner we can minimize the potential for adverse effects on claims processing and hospitals' cash flow.

However, we have added one CPT code to the list of codes that will be edited for device codes. We inadvertently omitted a proposed edit for CPT code 33225 (Left ventricular pacing lead add-on), which we proposed to place in New technology APC 1525. This procedure uses the device code C1900 (Left ventricular lead), whose pass-through status expires in January 2005. We proposed that when the lead is implanted as a stand-alone procedure using CPT code 33224 (Insert pacing lead and connect), we would edit for the presence of the device code for the lead on the claim. However, we believe that it is also appropriate to edit for the presence of the lead on a claim for the add-on code, CPT code 33225, and that it should pose no additional burden on hospitals because hospitals have been required to bill the device code C1900 for pass-through payment since CY 2004.

Summary of provisions related to required use of C-codes for devices that we are making final beginning in CY 2005:

1. Hospitals are required to report device category codes on claims when such devices are used in conjunction with procedure(s) billed and paid for under the OPPS in order to improve the claims data used annually to update the OPPS payment rates.

2. Beginning April 1, 2005, the OCE will include edits to ensure that certain procedure codes are accompanied by an associated device category code.

3. CMS will post the OCE edits that are to be implemented beginning April 1, 2005 on the CMS Web site to give hospitals and the provider community ample opportunity to review them and provide feedback prior to implementation.

4. Edits will apply at the CPT/HCPCS code level rather than the APC level.

5. Edits will not apply when a procedure code is reported with a modifier −73 or −74 to designate an incomplete procedure.

6. CMS will add edits as needed in future quarterly updates of the OCE to ensure that hospitals are reporting device category codes appropriately with associated procedure codes. CMS will post future device category and procedure code edits on the CMS Web site to give hospitals and the provider

community ample opportunity for input prior to implementation.

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Table 19.—Device Codes Required for Select Device-Dependent APCs

HCPCS	SI	Short Description	APC	Allowed Device Codes
36557	T	Insert tunneled cv cath	0032	C1751
36558	T	Insert tunneled cv cath	0032	C1751
36570	T	Insert tunneled cv cath	0032	C1751 C1788
36571	T	Insert tunneled cv cath	0032	C1751 C1788
36581	T	Replace tunneled cv cath	0032	C1751
36585	T	Replace tunneled cv cath	0032	C1751 C1788
36640	T	Insertion catheter, artery	0032	C1751
61885	S	Implant neurostim one array	0039	C1767
35458	T	Repair arterial blockage	0081	C1885 C1725
35459	T	Repair arterial blockage	0081	C1885 C1725
35460	T	Repair venous blockage	0081	C1885 C1725
35470	T	Repair arterial blockage	0081	C1885 C1725
35471	T	Repair arterial blockage	0081	C1885 C1725
35472	T	Repair arterial blockage	0081	C1885 C1725
35473	T	Repair arterial blockage	0081	C1885 C1725
35474	T	Repair arterial blockage	0081	C1885 C1725
35475	T	Repair arterial blockage	0081	C1885 C1725
35476	T	Repair venous blockage	0081	C1885 C1725

HCPCS	SI	Short Description	APC	Allowed Device Codes
35484	T	Atherectomy, open	0081	C1714 C1724
35485	T	Atherectomy, open	0081	C1714 C1724
35490	T	Atherectomy, percutaneous	0081	C1714 C1724
35491	T	Atherectomy, percutaneous	0081	C1714 C1724
35492	T	Atherectomy, percutaneous	0081	C1714 C1724
35493	T	Atherectomy, percutaneous	0081	C1714 C1724
35494	T	Atherectomy, percutaneous	0081	C1714 C1724
35495	T	Atherectomy, percutaneous	0081	C1714 C1724
61626	T	Transcath occlusion, non-cns	0081	C2628 C1887
92997	T	Pul art balloon repr, percut	0081	C1885 C1725
92998	T	Pul art balloon repr, percut	0081	C1885 C1725
92995	T	Coronary atherectomy	0082	C1714 C1724
92996	T	Coronary atherectomy add-on	0082	C1714 C1724
92982	T	Coronary artery dilation	0083	C1725 C1885
92984	T	Coronary artery dilation	0083	C1725 C1885
92986	T	Revision of aortic valve	0083	No edit; no suitable device code
92987	T	Revision of mitral valve	0083	No edit; no suitable device code
92990	T	Revision of pulmonary valve	0083	No edit; no suitable device code
93600	T	Bundle of His recording	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894

HCPCS	SI	Short Description	APC	Allowed Device Codes
93602	T	Intra-atrial recording	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93603	T	Right ventricular recording	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93609	T	Map tachycardia, add-on	0087	C1730 C1731 C1733
93610	T	Intra-atrial pacing	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93612	T	Intraventricular pacing	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93613	T	Electrophys map 3d, add-on	0087	C1732
93615	T	Esophageal recording	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93616	T	Esophageal recording	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894

HCPCS	SI	Short Description	APC	Allowed Device Codes
93618	T	Heart rhythm pacing	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93623	T	Stimulation, pacing heart	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
93631	T	Heart pacing, mapping	0087	C1730 C1731 C1733 C1766 C1892 C1893 C1732 C1894
33212	T	Insertion of pulse generator	0090	C1786 C2620
33210	T	Insertion of heart electrode	0106	No edit; no device code for some procedure options
33211	T	Insertion of heart electrode	0106	C1779
33216	T	Revise eltrd pacing-defib	0106	C1779 C1777 C1895 C1896 C1899
33217	T	Insert lead pace-defib, dual	0106	C1779 C1777 C1895 C1896 C1899
33218	T	Repair lead pace-defib, one	0106	No edit; code is for repair only
33220	T	Repair lead pace-defib, dual	0106	No edit; code is for repair only
G0297	T	Insert single chamber/cd	0107	C1722 C1882
G0298	T	Insert dual chamber/cd	0107	C1721 C1882
G0299	T	Inser/repos single icd+leads	0108	C1722 C1882

HCPCS	SI	Short Description	APC	Allowed Device Codes
G0300	T	Insert reposit lead dual+gen	0108	C1721 C1882
36260	T	Insertion of infusion pump	0119	C1772 C1891 C2626
36563	T	Insert tunneled cv cath	0119	C1772 C1891 C2626
36583	T	Replace tunneled cv cath	0119	C1772 C1891 C2626
63685	T	Implant neuroreceiver	0222	C1767
64590	T	Implant neuroreceiver	0222	C1767
61886	T	Implant neurostim arrays	0315	C1767
43219	T	Esophagus endoscopy	0384	No edit; no device code for some procedure options
43256	T	Uppr gi endoscopy w stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
43268	T	Endo cholangiopancreatograph	0384	No edit; no device code for some procedure options
43269	T	Endo cholangiopancreatograph	0384	No edit; device optional
44370	T	Small bowel endoscopy/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
44379	T	S bowel endoscope w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
44383	T	Ileoscopy w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877

HCPCS	SI	Short Description	APC	Allowed Device Codes
44397	T	Colonoscopy w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
45327	T	Proctosigmoidoscopy w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
45345	T	Sigmoidoscopy w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
45387	T	Colonoscopy w/stent	0384	C2617 C2625 C1874 C1875 C1876 C1877
33224	T	Insert pacing lead & connect	0418	C1900
55873	T	Cryoablate prostate	0674	C2618
33225	S	L ventricular pacing lead add-on	1525	C1900

Table 20.—Device Code Descriptors for Select Device-Dependent APCs

Device code	Descriptor
C1714	Catheter, transluminal atherectomy, directional
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1724	Catheter, transluminal atherectomy, rotational
C1725	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)
C1730	Catheter, electrophysiology, diagnostic, other than 3d mapping (19 or fewer electrodes)
C1731	Catheter, electrophysiology, diagnostic, other than 3d mapping (20 or more electrodes)
C1732	Catheter, electrophysiology, diagnostic/ablation, 3d or vector mapping
C1733	Catheter, electrophysiology, diagnostic/ablation, other than 3d or vector mapping, other than cool-tip
C1751	Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)
C1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away
C1767	Generator, neurostimulator (implantable)
C1772	Infusion pump, programmable (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1779	Lead, pacemaker, transvenous vdd single pass
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1788	Port, indwelling (implantable)
C1874	Stent, coated/covered, with delivery system
C1875	Stent, coated/covered, without delivery system
C1876	Stent, non-coated/non-covered, with delivery system
C1877	Stent, non-coated/non-covered, without delivery system
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1885	Catheter, transluminal angioplasty, laser
C1887	Catheter, guiding (may include infusion/perfusion capability)
C1891	Infusion pump, non-programmable, permanent (implantable)
C1892	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, peel-away
C1893	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)
C1900	Lead, left ventricular coronary venous system
C2617	Stent, non-coronary, temporary, without delivery system
C2618	Probe, cryoablation
C2620	Pacemaker, single chamber, non rate-responsive (implantabe)
C2625	Stent, non-coronary, temporary, with delivery system
C2626	Infusion pump, non-programmable, temporary (implantable)
C2628	Catheter, occlusion

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5. Submission of External Data

In the August 16, 2004 proposed rule, we stated that we would consider external data submitted with respect to any APC to the extent that such data enable us to verify or adjust claims data where we are convinced that such an adjustment to the median cost is appropriate. Further, we stated that all comments and any data we use would be available for public inspection and commenters should not expect that any data furnished as part of the comment

would be withheld from public inspection. We also stated that parties who submit external data for devices should also submit a strategy that can be used to determine what part of the median cost represents the device to which the external data applies. We stated in the proposed rule that external data that are likely to be of optimal use should meet the following criteria:

- Represent a diverse group of hospitals both by location (for example, rural and urban) and by type (for example, community and teaching). We preferred that commenters identify each hospital, including location with city and State, nonprofit vs. for profit status, teaching vs. nonteaching status, and the percent of Medicare vs. non-Medicare patients receiving the service. A pseudo identifier could be used for the hospital identification. Data should be submitted both ''per hospital'' and in the aggregate.
- Identify the number of devices billed to Medicare by each hospital as well as any rebates or reductions for bulk purchase or similar discounts and identify the characteristics of providers to which any such price rebates or reductions apply.
- Identify all HCPCS codes with which each item would be used.
- Identify the source of the data.
- Include both the charges and costs for each hospital for CY 2003.

Meeting the criteria would help enable us to compare our CY 2003 claims data to the submitted external data and help us determine whether the submitted data are representative of hospitals that submit claims under the OPPS.

We noted in the proposed rule that information containing beneficiary-specific information (for example, medical records, and invoices with beneficiary identification on it) must be altered, if necessary, to remove any individually identifiable information, such as information that identifies an individual, diagnoses, addresses, telephone numbers, attending physician, medical record number, and Medicare or other insurance number. Moreover, individually identifiable beneficiary medical records, including progress notes, medical orders, test results, and consultation reports must not be submitted to us. Similarly, photocopies of checks from hospitals or other documents that contain bank routing numbers must not be submitted to us.

We received a number of public comments concerning the submission of external data.

Comment: Some commenters supported use of claims data and strongly opposed use of data from external sources to set the OPPS payment rates. They believed that claims data more accurately reflects the costs hospitals incur to provide outpatient services. They strongly opposed use of external data because they believe that item specific adjustments will make OPPS unduly complex and result in unfair imbalances in payments. They believed that CMS should remain committed to the principles of prospective payment and the use of the averaging process rather than seeking to pay actual cost for one element of costs (for example, new technology) at the expense of all other items, which would result after application of mandated budget neutrality adjustments. Conversely, other commenters indicated that CMS should rely on external data in lieu of claims data for procedures that require high cost devices because the CMS methodology of applying a cost-to-charge ratio to charges to acquire costs will always result in costs that are below the actual acquisition cost of the device and that, barring a significant change in CMS' cost finding process, external data are the only means by which valid cost data for high cost devices can be introduced into the OPPS. Some commenters provided external data on the devices of interest to them and some provided specific amounts calculated using external data, which they asked that we substitute for claims data in setting the weight for the APC of interest to them.

Response: We have not applied numbers from external data in our adjustments of median costs for the CY 2005 OPPS. While recognizing that external data aids in our general analysis of determining payment rates, we believe that generally such use of external data is not the optimal way to set payment rates for services in a relative weight system. As we discussed in section III.C.5. of this preamble, we believe that using external data has a significant potential for creating an unfair imbalance in a prospective payment system. However, we appreciate the efforts of some commenters in providing us with external data.

Comment: Some commenters urged us to use external data in the construction of APC rates and urged us to use confidential data for this purpose. Some commenters are concerned about the criteria CMS proposed for external data and urged us to expand the use of confidential external data to calculate future payment rates whenever such data are indicated and proven reliable based on the data's merits. The commenter did not suggest criteria for determining if confidential proprietary external data are reliable.

Response: As we indicated in the August 16, 2004 proposed rule, all information sent in response to comments will be made available to the public for review. We believe that all parties who are affected by the payment rates set under this system should have access to the information on which the rates are set.

Comment: One commenter indicated that CMS should use external data for all device APCs in which the device cost exceeds 5 percent of the total APC cost because to do otherwise would unfairly benefit some categories of services compared to other categories of services.

Response: We have not used external data to adjust any medians for the CY2005 OPPS. As discussed above, we applied the same adjustment rules to all device medians.

After carefully reviewing all public comments received, we have decided not to use any external data to adjust the median costs for the CY 2005 OPPS for the reasons discussed above.

D. Calculation of Scaled OPPS Payment Weights

Using the median APC costs discussed previously, we calculated the relative payment weights for each APC for CY 2005 shown in Addenda A and B to this final rule with comment period. As in prior years, we scaled all the relative payment weights to APC 0601 (Mid-Level Clinic Visit) because it is one of the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC. Using CY 2003 data, the median cost for APC 0601 is $57.32 for CY 2005.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a manner that assures that aggregate payments under the OPPS for CY 2005 are neither greater than nor less than the aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2004 relative weights to aggregate payments using the CY 2005 proposed relative weights. Based on this comparison, we proposed to make an adjustment to the weights for purposes of budget neutrality. The unscaled weights were adjusted by 0.984667135 for budget neutrality. The CY 2005

relative weights, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B to this final rule with comment period.

Section 1833(t)(14)(H) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, states that ''Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years.'' Section 1833(t)(14) provides the payment rates for certain specified covered outpatient drugs. Therefore, the incremental cost of those specified covered outpatient drugs (as discussed in section II.J. of this final rule with comment period) is excluded from the budget neutrality calculations but the base median cost of the drugs continues to be a factor in the calculation of budget neutrality. Accordingly, we calculated median costs for the specified covered outpatient drugs to which this section applies and used those medians and the frequencies in the calculation of the scaler for budget neutrality.

Under section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Pub. L. 108–173, payment for devices of brachytherapy consisting of a seed or seeds (or radioactive source) is to be made at charges adjusted to cost for services furnished on or after January 1, 2004 and before January 1, 2006. As we stated in our January 6, 2004 interim final rule, charges for the brachytherapy sources will not be used in determining outlier payments and payments for these items will be excluded from budget neutrality calculations, consistent with our practice under the OPPS for items paid at cost. (We provide a discussion of brachytherapy payment issues at section VII.G. of this final rule with comment period.)

IV. Payment Changes for Devices

A. Pass-Through Payments for Devices

1. Expiration of Transitional Pass-Through Payments for Certain Devices

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. This period begins with the first date on which a transitional pass-through payment is made for any medical device that is described by the category. In our November 7, 2003 final rule with comment period (68 FR 63437), we specified six device categories currently in effect that would cease to be eligible for pass-through payment effective January 1, 2005.

The device category codes became effective April 1, 2001, under the provisions of the BIPA. Prior to pass-through device categories, we paid for pass-through devices under the OPPS on a brand-specific basis. All of the initial category codes that were established as of April 1, 2001, have expired; 95 categories expired after CY 2002 and 2 categories expired after CY 2003. All of the categories listed in Table 21, along with their expected expiration dates, were created since we published the criteria and process for creating additional device categories for pass-through payment on November 2, 2001 (66 FR 55850 through 55857). We based the expiration dates for the category codes listed in that table on the date on which a category was first eligible for pass-through payment.

There are six categories for devices that would have been eligible for pass-through payments for at least 2 years as of December 31, 2004. In our November 7, 2003 final rule with comment period, we finalized the December 31, 2004 expiration dates for these six categories. (Three other categories listed in Table 21, as proposed, C1814, C1818, and C1819, will expire on December 31, 2005.) As indicated in Table 21, as proposed, the six categories that will expire as of December 31, 2004, are: C1783, C1884, C1888, C1900, C2614, and C2632. Each category includes devices for which pass-through payment was first made under the OPPS in CY 2002 or CY 2003.

In the November 1, 2002 final rule, we established a policy for payment of devices included in pass-through categories that are due to expire (67 FR 66763). For CY 2003, we packaged the costs of the devices no longer eligible for pass-through payments into the costs of the procedures with which the devices were billed in CY 2001. There were few exceptions to this established policy (brachytherapy sources for other than prostate brachytherapy, which is now also separately paid in accordance with section 621(b)(2) of Pub. L. 108–173). For CY 2004, we continued to apply this policy for categories that expired on January 1, 2004.

2. Proposed and Final Policy for CY 2005

In the August 16, 2004 proposed rule, we proposed to continue to base the expiration date for a device category on the earliest effective date of pass-through payment status of the devices that populate the category. This basis for determining the expiration date of a device category is the same as that used in CY 2003 and CY 2004.

We also proposed that payment for the devices that populate the six categories that would cease to be eligible for pass-through payment after December 31, 2004, would be made as part of the payment for the APCs with which they are billed. This methodology for packaging device cost is consistent with the packaging methodology that we describe in section III. of this final rule with comment period. To accomplish this, we proposed to package the costs of devices that would no longer be eligible for pass-through payment in CY 2005 into the HCPCS codes with which the devices are billed.

In the proposed rule, we noted that category C1819 (Tissue localization excision device) was added subsequent to our proposed rule for CY 2004. We first announced the start date and the proposed expiration date for this device category in our November 7, 2003 final rule with comment period. Therefore, we proposed to maintain the category's December 31, 2005 expiration date. We invited specific comments on the proposed expiration date for category C1819.

We received a number of public comments on our proposals relating to the expiration dates for transition pass-through devices.

Comment: One commenter noted that C1884 (Embolization protection system) is used for carotid stenting. The commenter recommended that CMS continue paying pass-through payment for C1884 until carotid stenting APC costs are established.

Response: Carotid stenting procedures are on the inpatient list for the OPPS and, therefore, are not paid by Medicare when performed in the outpatient hospital setting. To the extent that C1884 has been used with other procedures payable under the OPPS, we packaged the costs of C1884 into the APCs that include the procedures with which this device code was billed.

Comment: One commenter objected to our proposal to remove HCPCS code C1884 from pass-through status, effective January 1, 2005. The commenter believed that the service had been unfairly subjected to the device offset because it was totally new and did not replace any existing device. The commenter claimed that, for CY 2003, code C1884 inappropriately received very little pass-through payment when the device was used. The commenter indicated that CMS subsequently recognized its error by changing the offset policy for CY 2004, the second year of the device's pass-through status,

and, therefore should give the device a third year of pass-through payment.

Response: We disagree with the commenter that we inappropriately made little pass-through payments for C1884. The commenter is correct that, for CY 2004, following notice and comment rulemaking, we changed the policy for applying offsets. As of January 1, 2004, we apply offsets, on a device-category-specific basis, when we determine that an APC contains costs associated with the device. Under the policy in effect prior to CY 2004, we applied offsets when a device category was billed with any of the APCs on our device offset list. This policy change affected all the categories in effect in CYs 2003 and 2004, including C1884. Some of these categories went into effect as of January 1, 2003; thus their pass-through status will expire after exactly 2 years. Other categories began receiving pass-through payments in the middle of 2002. Therefore, their categories will have more than 2, but less than 3 years with pass-through payment. We would not be able to extend pass-through payment for the second group of categories for an additional year, because they would then have greater than the statutory maximum of 3 years of pass-through payment.

We see no reason to adopt the commenter's suggestions to only change the status for code C1884. In CY 2003, C1884, like all our other pass-through categories, was subject to the same offset policy. Therefore, we are not changing the expiration date of device category C1884.

This device will cease to be a pass-through device effective January 1, 2005, at which time it will have had 2 years of pass-through payment.

We note that the expiration dates of C1884 and most other categories (the exception being C1819, discussed below) that were in effect at the time of our final rule for CY 2004 (68 FR 63437) were made final in that same rule, having been proposed in the proposed rule for CY 2004. We are now merely reaffirming that policy.

A few commenters supported our proposal to remove the six device categories from further pass-through payments and our proposal to package the costs of these devices into the cost of the APCs with which they are billed. The commenters indicated that incorporating these technologies into the APC system will minimize special payment incentives to use certain devices over others.

Comment: One commenter was concerned that pass-through payment for a brachytherapy-related solution (C2632, Brachytherapy solution, Iodine-125, per mCi) would expire from pass-through payment after December 31, 2004, under our proposal, and requested a third year of pass-through payment, until December 31, 2005, because pass-through payment has been made only since January 1, 2003. The commenter claimed that this category still qualifies for another year of pass-through payment.

Response: Because the brachytherapy solution in question, C2632, is a brachytherapy source separately payable under the OPPS according to section 621(b) of Pub. L. 108–173, it will continue to receive cost-based payment as of January 1, 2005, based on those statutory provisions, rather than on the pass-through payment provisions. Section VII.G. of this final rule with comment period explains those provisions and includes code C2632 for cost-based payment in CY 2005. As indicated, in regard to other comments concerning expired categories, this brachytherapy device will have had 2 years of pass-through status on January 1, 2005. Our policy is that pass-through devices are removed from pass-through status as soon as permitted under the statute. Therefore, this device will cease to be a pass-through device effective January 1, 2005, at which time it will have had 2 years of pass-through payment.

Comment: A few commenters were concerned that pass-through payment for C2614 (Probe, percutaneous lumbar diskectomy) in APC 0220 (Level I Nerve Procedures) would expire from pass-through payment after December 31, 2004, under our proposal, and requested that CMS continue to pay for this device category separately on a pass-through basis. The commenters were under the impression that the methodology used to determine whether or not a device category would continue to be eligible for payment in CY 2005 was if it showed ''that there were no close or identifiable costs associated with the devices relating to the respective APCs that are normally billed with them.''

One commenter indicated that the payment for APC 0220 is not sufficient to cover the cost of the high end disposable RF lumbar probe coded under C2614. The commenter was also concerned that this device, which is used in performing CPT code 62287 (Percutaneous diskectomy), and which costs $1,150, will cease to be eligible for pass-through payments effective January 2005. The commenter stated that the device has increased effectiveness and reduced recovery time for patients but unless CMS increases the payment for APC 0220 for which we proposed to pay $996.69, hospitals will be forced to cease using it in 2005. The commenter urged that CMS continue pass-through payment for C2614 until such time as the payment rate for APC 0220 is adequate to cover the cost of the probe.

Response: The commenters are incorrect in their understanding of our criteria for proposing to expire device categories. We proposed to expire C2614 because it has received pass-through payment for at least 2 years, which is also the basis for our proposal to expire the other five device categories listed for expiration in CY 2005 in our proposed rule. A device with no close or identifiable costs associated with the devices relating to the respective APCs that are normally billed with them is actually a factor in determining whether to apply an offset, which would reduce the pass-through payment amount, as explained in the August 16, 2004 proposed rule (69 FR 50501). As indicated, similar to other responses in regard to other comments concerning other categories due to expire, this disc decompression device will have had 2 years of pass-through status on January 1, 2005. Our policy is that pass-through devices are removed from pass-through status as soon as permitted under the statute. Therefore, this device will cease to be a pass-through device effective January 1, 2005, at which time it will have had 2 years of pass-through payment.

We have considered the commenter's concern regarding placement of code C2614, the code for a device that is used in performing CPT code 62287, in APC 0220 and find that the resource costs for CPT code 62287 may be more appropriate for APC 0221 (Level II Nerve Procedures). Therefore, we have reassigned CPT code 62287 to APC 0221, for which the CY 2005 payment rate is $1,635.87.

Comment: One commenter recommended that CMS continue to pay for C2614 as a pass-through device category until CMS determines how the procedure, percutaneous lumbar diskectomy, is coded for determination of accurate APC cost weighting.

Response: As explained previously, we packaged costs of the C-code devices into the APCs that include the procedures with which the device codes were billed. We are packaging the costs related to code C2614 in this manner.

Comment: One commenter, a device manufacturer, recommended that CMS extend the expiration date for pass-through payment of C1819 (Tissue localization excision device) until December 31, 2006, instead of ending pass-through payment after CY 2005. The commenter claimed that CMS will have only a partial year of data for the

CY 2006 year, unless it extends the date that the category is effective for pass-through payment. This commenter claimed that the proposed payment for APC 0028, in which therapeutic breast cancer procedures, CPT codes 19125 and 19160, are placed, increased by only $100 and does not represent any device codes. The commenter asserted that CMS needs to collect data over 2 years and increase payment for APC 0028 to at least $1,345 starting in CY 2007. The commenter also pointed out that two categories set to expire after December 31, 2005, C1814 (Retinal tamonade device, silicone oil) and C1818 (Integrated keratoprosthesis), would be paid as pass-through devices several months longer than C1819, resulting in a greater amount of data for ratesetting than will be available for C1819.

Response: We believe it is premature to make any conclusions and recommendations concerning the payment rate for APC 0028 for CY 2006 or CY 2007. Presumably, after the pass-through period ends, the device costs of category code C1819 will be included in the median costs of APC 0028 if the device is billed with procedures that are included in that APC. We reiterate that, as with other categories due to expire, this tissue localization device will have had 2 years of pass-through status on January 1, 2006. Our policy is that pass-through devices are removed from pass-through status as soon as permitted under the statute. Therefore, this device will cease to be a pass-through device effective January 1, 2006.

In this final rule with comment period, we are finalizing the proposed expiration dates for device categories as specified in the proposed rule, as indicated in Table 21 below.

Table 21.--List Of Current Pass-Through Device Categories By Expiration Date

HCPCS Codes	Category Long Descriptor	Date(s) Populated	Expiration Date
C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
C1888	Catheter, ablation, noncardiac, endovascular (implantable)	7/1/02	12/31/04
C1900	Lead, left ventricular coronary venous system	7/1/02	12/31/04
C1884	Embolization protective system	1/1/03	12/31/04
C2614	Probe, percutaneous lumbar discectomy	1/1/03	12/31/04
C2632	Brachytherapy solution, iodine-125, per mCi	1/1/03	12/31/04
C1814	Retinal tamponade device, silicone oil	4/1/03	12/31/05
C1818	Integrated keratoprosthesis	7/1/03	12/31/05
C1819	Tissue localization excision device	1/1/04	12/31/05

B. Provisions for Reducing Transitional Pass-Through Payments to Offset Costs Packaged into APC Groups

1. Background

In the November 30, 2001 final rule, we explained the methodology we used to estimate the portion of each APC rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904). Beginning with the implementation of the CY 2002 OPPS update (April 1, 2002), we deducted from the pass-through payments for the identified devices an amount that reflected the portion of the APC payment amount that we determined was associated with the cost of the device, as required by section 1833(t)(6)(D)(ii) of the Act. In the November 1, 2002 final rule, we published the applicable offset amounts for CY 2003 (67 FR 66801).

For the CY 2002 and CY 2003 OPPS updates, to estimate the portion of each APC rate that could reasonably be attributed to the cost of an associated pass-through device eligible for pass-through payment, we used claims data from the period used for recalibration of the APC rates. Using those claims, we calculated a median cost for every APC without packaging the costs of associated C-codes for device categories that were billed with the APC. We then calculated a median cost for every APC with the costs of the associated device category C-codes that were billed with the APC packaged into the median. Comparing the median APC cost without device packaging to the median APC cost including device packaging enabled us to determine the percentage of the median APC cost that is attributable to the associated pass-through devices. By applying those percentages to the APC payment rates, we determined the applicable amount to be deducted from the pass-through payment, the ''offset'' amount. We created an offset list comprised of any APC for which the device cost was at least 1 percent of the APC's cost.

As first discussed in our November 1, 2002 final rule (67 FR 66801) the offset list that we publish each year is a list of offset amounts associated with those APCs with identified offset amounts developed using the methodology described above. As a rule, we do not know in advance which procedures and APCs may be billed with new categories. Therefore, an offset amount is applied only when a new device category is billed with an APC appearing on the offset list. The list of potential offsets for CY 2004 is currently published on the CMS Web site: *http://www.cms.hhs.gov,* as ''Device-Related Portions of Ambulatory Payment Classification Costs for 2004.''

For CY 2004, we modified our policy for applying offsets to device pass-through payments. Specifically, we indicated that we would apply an offset to a new device category only when we could determine that an APC contains costs associated with the device. We continued our existing methodology for determining the offset amount, described above. We were able to use this methodology to establish the device offset amounts for CY 2004 because providers reported device codes (C-codes) on the CY 2002 claims used for CY 2004 OPPS. However, for the CY 2005 update to the OPPS, we proposed to use CY 2003 claims that do not include device coding. (Section III. of this final rule with comment period contains a fuller discussion of our proposed and final requirement for use

of C-codes for CY 2005.) In the CY 2004 OPPS update, we reviewed the device categories eligible for continuing pass-through payment in CY 2004 to determine whether the costs associated with the device categories are packaged into the existing APCs. Based on our review of the data for the categories existing in CY 2004, we determined that there were no close or identifiable costs associated with the devices relating to the respective APCs that are normally billed with them. Therefore, for those device categories, we set the offset to $0 for CY 2004.

2. Proposed and Final Policy for CY 2005

As we proposed in the August 16, 2004 proposed rule, in this final rule with comment period for CY 2005, we are continuing to review each new device category on a case-by-case basis as we did in CY 2004 to determine whether device costs associated with the new category are packaged into the existing APC structure. We are setting the offsets to $0 for the currently established categories that would continue for pass-through payment into CY 2005. If, during CY 2005, we create a new device category and determine that our data contain identifiable costs associated with the devices in any APC, we will adjust the APC payment if the offset is greater than $0. If we determine that device offsets greater than $0 are appropriate for any new category that we create during CY 2005, we will announce the offset amounts in the program transmittal that announces the new category.

Further, as we proposed, in this final rule with comment period for CY 2005, we are using the device percentages (portion of the APC median cost attributable to the packaged device) that we developed for potential offsets in CY 2004 and apply these percentages to the CY 2005 payment amounts to obtain CY 2005 offset amounts, in cases where we determine that an offset is appropriate. As proposed, we are using the device percentage developed for CY 2004 because, as noted above, for the CY 2005 update to the OPPS, we are using CY 2003 claims that do not include device codes. Therefore, we are not easily able to determine the device portions of APCs for CY 2003 claims data. We have posted the list of device-dependent APCs and their respective device portions on the CMS Web site: *http://www.cms.hhs.gov* for CY 2004 We will update the device portions as a percentage of final CY 2005 APC payments and post these on the CMS Web site.

We did not receive any public comments on our proposed policy for reducing transitional pass-through payments to offset costs packaged into APC groups.

C. Criteria for Establishing New Pass-Through Device Categories

Comment: Several commenters from the medical device community asked that CMS revise the criteria under which it evaluates applications for pass-through status for new device categories. The commenters specifically requested that CMS eliminate the current requirement that items that are included in new pass-through device categories must be surgically inserted or implanted through a surgically created incision. The commenters expressed concern that the current requirement may prevent access to innovative and less invasive technologies, particularly in the areas of gynecologic, urologic, colorectal and gastrointestinal procedures. These commenters asked that CMS change the surgical insertion or implantation criterion to allow pass-through payment for potential new device categories that include items introduced into the human body through a natural orifice, as well as through a surgically created incision.

Several of the commenters recommended that CMS allow the creation of a new pass-through category for items implanted or inserted through a natural orifice, as long as the other existing criteria are met. The commenters do not believe that such an expansion of the criteria would significantly increase the amount spent on pass-through device categories and asked that CMS implement this change in January 2005. A few commenters predicted that this modification would result in expenditures of less than one quarter of the total amount available for pass-through payments. A few commenters further asked that CMS allow new categories, even if the name or terminology associated with the requested category resembles an expired category, even if that entails modifying the description of the expired category. One commenter claimed that manufacturers of technologies that are implanted through a surgically created opening have two options for incremental payment: (1) Pass-through payment; and (2) new technology APC, and that those not requiring a surgical incision have only one option for additional payment (the new technology APC).

Response: We share the views of the commenters about the importance of ensuring access for Medicare beneficiaries to new technologies that offer substantial clinical improvement in the treatment of their medical conditions. We also recognize that, since the initial implementation of the OPPS, there have been beneficial changes in the methods by which some conditions are treated. These are issues that the agency takes very seriously and considers in the context of both pass-through device categories and payment for new, complete procedures through assignment to either a new technology APC or an existing clinical APC.

We note that other payment mechanisms exist within the OPPS for complete procedures that use new technology. These other payment mechanisms (establishment of a new code, where appropriate, and assignment to either a new technology APC or to a clinical APC) are already available, and do not require the implantation of a device through a surgical incision.

We are also interested in hearing the views of other parties and receiving additional information on these issues. While we appreciate and welcome additional comments on these issues from the medical device makers, we are also interested in hearing the views of Medicare beneficiaries, of the hospitals that are paid under the OPPS and of physicians and other practitioners who attend to patients in the hospital outpatient setting. For that reason, we are soliciting additional comments on this topic within the 60-day comment period for this final rule with comment period. (See the **ADDRESSES** section of this preamble for information on submitting comments. When submitting comments on this issue, please include the caption ''Device Categories'' at the beginning of your comment.) In framing their comments, commenters are asked to consider the following questions:

1. The comments discussed above refer to devices introduced into the body through natural orifices. We are seeking comments on whether this includes orifices that are either naturally or surgically created, as in the case of ostomies? If you believe this includes only natural orifices, why do you distinguish between natural and surgically created orifices?

2. How would you define ''new,'' with respect to time and to predecessor technology? What additional criteria or characteristics do you believe distinguish ''new'' devices that are surgically introduced through an existing orifice from older technology that also is inserted through an orifice?

3. What characteristics do you consider to distinguish a device that might be eligible for a pass-through category even if inserted through an

existing orifice from materials and supplies such as sutures, clips or customized surgical kits that are used incident to a service or procedure?

4. Are there differences with respect to instruments that are seen as supplies or equipment for open procedures when those same instruments are passed through an orifice using a scope?

Concerning the request that we allow new categories for new devices by modifying the descriptors of existing categories, we note there are systems difficulties with changing a descriptor of an existing HCPCS code, such as payment considerations of claims prior to when a modification would be made. Moreover, both hospitals and manufacturers have informed us in the past that coding changes have led to confusion on the part of hospital coders. Modifying established device category C-codes would only exacerbate any such coding confusion. Therefore, we note that we are not inclined to change the descriptors of existing C-codes at this time.

Comment: One commenter recommended that CMS revise the cost significant criterion for establishing new device categories for pass-through payment. The commenter stated that medical devices are sometimes used as part of procedures that are secondary to a primary procedure, and in these cases the cost significance threshold of at least 25 percent of the APC rate associated with the services performed with the device should be adjusted downward to reflect the lower APC payment made for the secondary service. The commenter provided as an example those cases when the secondary procedure would be subject to the multiple procedure discount, thus lowering the APC payment associated with the procedure by 50 percent. The commenter indicated that this scenario happens infrequently.

Response: We disagree that our cost significance criterion for a proposed new device category for pass-through payment requires revision or adjustment. The criterion commented on requires that the estimated average reasonable cost of devices in a proposed new device category exceeds 25 percent of the applicable APC payment amount for the service associated with the device category (67 FR 66785). Very few new device category applications are denied for pass-through payment because they do not meet this cost criterion. If the proposed category of devices can be billed with more than one APC, we generally use the lowest APC payment rate applicable for use with the nominated device when we test against this cost criterion, thus increasing the probability the device will pass the cost significance criterion. We do not believe any further adjustment is needed for this cost criterion.

Therefore, we are not making any additional changes to our policy for CY 2005.

V. Payment Changes for Drugs, Biologicals, Radiopharmaceutical Agents, and Blood and Blood Products

A. Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biological agents. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107–186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as ''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of BIPA (Pub. L. 106–554), on December 21, 2000).

Transitional pass-through payments are also required for certain ''new'' drugs, devices and biological agents that were not being paid for as a hospital OPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. In Addenda A and B to this final rule with comment period, pass-through drugs and biological agents are identified by status indicator ''G.''

The process to apply for transitional pass-through payment for eligible drugs and biological agents can be found on pages of our CMS Web site: *http://www.cms.hhs.gov.* If we revise the application instructions in any way, we will post the revisions on our Web site and submit the changes to the Office of Management and Budget (OMB) for approval, as required under the Paperwork Reduction Act (PRA). Notification of new drugs and biological application processes is generally posted on the OPPS Web site at: *http://www.cms.hhs.gov/hopps.*

2. Expiration in CY 2004 of Pass-Through Status for Drugs and Biologicals

Section 1833(t)(6)(C)(i) of the Act specifies that the duration of transitional pass-through payments for drugs and biologicals must be no less than 2 years and no longer than 3 years. The drugs whose pass-through status will expire on December 31, 2004, meet that criterion. In the August 16, 2004 proposed rule, Table 22 listed the 13 drugs and biologicals for which we proposed that pass-through status would expire on December 31, 2004.

Comment: One commenter, a national hospital association, supported our proposal to remove these 13 drugs from the pass-through status on December 31, 2004.

Response: We appreciate the commenters' support for our proposal.

For this final rule with comment period, in Table 22 below, we are specifying the drugs and biologicals for which pass-through status will expire on December 31, 2004. This listing is the same as that published in the proposed rule.

Table 22.--List of Drugs and Biologicals for Which Pass-Through Status Expires December 31, 2004

HCPCS	APC	Long Descriptor	Trade Name
J0583	9111	Injection, Bivalirudin, per 1 mg	Angiomax Inj (single source)
C9112	9112	Injection, Perflutren lipid microsphere, per 2 ml	Definity (single source)
C9113	9113	Injection, Pantoprazole sodium, per vial	Protonix (single source)
J1335	9116	Injection, Ertapenem sodium, per 500 mg	Invanz (single source)
J2505	9119	Injection, Pegfilgrastim, per 6 mg single dose vial	Neulasta (single source)
J9395	9120	Injection, Fulvestrant, per 25 mg	Faslodex (single source)
C9121	9121	Injection, Argotroban, per 5 mg	Acova (single source)
C9200	9200	Orcel, per 36 square centimeters	Orcel (single source)
C9201	9201	Dermagraft, per 37.5 square centimeters	Dermagraft (single source)
J2324	9114	Injection, Nesiritide, per 0.5 mg	Natrecor (single source)
J3315	9122	Injection, Triptorelin pamoate, per 3.75 mg	Trelstar depot Trelstar LA (single source)
J3487	9115	Injection, Zoledronic acid, per 1 mg	Zometa (single source)
Q0137	0734	Injection, Darbepoetin Alfa, 1 mcg (non-ESRD use)	Aranesp® (single source)

3. Drugs and Biologicals With Pass-Through Status in CY 2005

As we proposed in the August 16, 2004 proposed rule, we are continuing pass-through status for CY 2005 for 18 drugs and biologicals listed in Table 23 of this final rule with comment period. The APCs and HCPCS codes for drugs and biologicals that will have pass-through status in CY 2005 are assigned status indicator ''G'' in Addendum A and Addendum B, respectively, to this final rule with comment period.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108–173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we proposed in the August 16, 2004 proposed rule, in CY 2005, we will pay under the OPPS for drugs and biologicals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108–173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule published elsewhere in this issue.

Section 1833(t)(6)(D)(i) of the Act also sets the amount of additional payment for pass-through eligible drugs and biologicals (the pass-through payment amount). The pass-through payment amount is the difference between the amount authorized under section 1842(o) of the Act, and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological.

In this final rule with comment period, we are adopting as final our proposal to amend § 419.64 of the regulations to conform this section to these changes. Specifically, we are revising paragraph (d) to provide that, subject to any reduction determined under § 419.62(b), the payment for a drug or biological with pass-through status equals the amount determined under section 1842(o) of the Act, minus the portion of the APC payment amount that we determine is associated with the drug or biological.

As we explained in the August 16, 2004 proposed rule, we will make separate payment, beginning in CY 2005, for new drugs and biologicals with an HCPCS code consistent with the provisions of section 1842(o) of the Act, as amended by Pub. L. 108–173, at a rate that is equivalent to the payment they would receive in a physician office setting, whether or not we have received a pass-through application for the item. Accordingly, beginning in CY 2005, the pass-through payment amount for new drugs and biologicals that we determine have pass-through status equals zero. That is, when we subtract the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act, as amended by Pub. L. 108–173, from the portion of the otherwise applicable fee schedule amount, or the APC payment rate associated with the drug or biological that would be the amount paid for drugs and biologicals under section 1842(o) of the Act as

amended by Pub. L. 108–173, the resulting difference is equal to zero.

We have used the second quarter ASP numbers for budget neutrality estimates, impact analysis, and for completing Addenda A and B because those were the most recent numbers available to us in time for publication. Changes in program payments due to quarterly updates of ASP for pass-through drugs are factored into our budget neutrality estimates. To be consistent with the ASP-based payments that will be made when these drugs and biologicals are furnished in physician offices, we plan to make any appropriate adjustments to the amounts shown in Addendum A and B if later quarter ASP submissions indicate that adjustments to the payment rate are necessary. We will announce such changes in our program instructions to implement quarterly releases and post any revisions to the Addenda on the *http://cms.hhs.gov* Web site.

In the proposed rule, we listed in Table 23 the drugs and biologicals for which we proposed pass-through status continuing in CY 2005. We also included in Addendum B to the proposed rule the proposed CY 2005 rates for these pass-through drugs and biologicals based on data reported to CMS as of April 30, 2004. Since publication of the proposed rule on August 16, 2004, we have approved two additional drugs and biologicals for pass-through payment beginning on or after October 1, 2004. These products are Vidaza that has been assigned HCPCS code C9218 (Injection, azacitidine, per 1 mg) and Myfortic that has been assigned HCPCS code J7518 (Mycophenolic acid, oral, per 180 mg). (*See* Change Request 3420, Transmittal 290 issued August 27, 2004.) In addition, three more products have been approved for pass-through status beginning or after January 1, 2005. They are Orthovice (HCPCS code C9220, Sodium Hyaluronate per 30 mg dose, for intra-articular injection), GraftJacket (Repair)(HCPCS code C9221, Acellular dermal tissue, matrix per 16cm2), and GraftJacket (Soft Tissue)(HCPCS code C9222, Decellularized Soft Tissue Scaffold, per 1 cc). These new eligible pass-through items are listed in Table 23 below.

We received several public comments on the proposed listing and payment rates for drugs and biologicals for pass-through status continuing in CY 2005.

Comment: Two commenters stated that the proposed payment rate for HCPCS code C9203 (Injection, Perflexane lipid microsphere, per single use vial) is inappropriate and should be re-examined. They state that the methods used to price the drug are inconsistent with the Pub. L. 108–173, which requires that payments for pass-through drugs be based at either 106 percent of reported average sales price (ASP) or 83 percent of the average wholesale price (AWP). Pricing at 95 percent of AWP for C9203 creates a competitive disadvantage for contrast agents no longer being paid as pass-through drugs.

One commenter suggests that CMS create a class of echocardiography contrast agents similar to the class established for anti-emetic drugs. This allows for a uniform methodology to price drugs and ensures patient access to all drugs in the same therapeutic class. An alternative proposal identified by the commenter, is to base the payment for Imagent on the method applicable to the pricing for all other specified covered outpatient drugs (that is, 83 percent of the AWP). Yet another proposal included either maintaining pass-through status for all contrast agents or removing Imagent from pass-through designation. Another commenter recommended that the payment rate for all contrast agents be based on median costs reflected in hospital outpatient claims data.

Response: Whereas separate payment was already being made for the contrast agents, either as a pass-through item or as a ''specified covered outpatient drug,'' the 5HT3 anti-emetic products varied in their payment status, that is, some were packaged and some were paid separately. Although we are making final our proposal to pay separately for the 5HT3 anti-emetic products in CY 2005 in this final rule with comment period, the intent of this policy discussed in section IV.B.2. of this preamble is not to standardize payment for already separately payable drugs. For this reason, the policy does not apply to the echocardiography contrast agents. Therefore, we are not accepting the commenter's recommendation that we create a class of echocardiography contrast agents similar to the class for anti-emetic drugs.

Other proposals to: (1) Change the pass-through payment status for Imagent to a ''specified covered outpatient drug,'' (2) extend the pass-through payment status for other contrast agents, or (3) use hospital claims data to establish payment for Imagent are not provided for under the statute. Imagent obtained pass-through status effective on April 1, 2003, and will remain a pass-through drug for CY 2005.

Since the ASP for contrast agents was not reported in time for use in developing the APC payments for this final rule with comment period, the CY 2005 first quarter APC payment for Imagent is based on 95 percent of the AWP reported as of May 1, 2003. As previously stated, we plan to update payments for pass-through drugs on a quarterly basis. Beginning in April 2005, payment for Imagent will be based on 106 percent of the reported ASP.

Comment: Several commenters wrote in support of our proposal to remove 13 drugs and biologic agents from the pass-through table as the pass-through period for these items will end on January 1, 2005. Many commenters were very much in favor of our proposal for setting the pass-through payment portion of drugs. They wrote that zero pass-through payments ensures pass-though drugs and biologicals receive the full payment while at the same time eliminates the risk of a pro-rata reduction from occurring. Other commenters urged CMS to update ASP based payment rates for therapies with transitional pass-through status on a quarterly basis as is done for the drugs and biologicals administered in physician offices and paid for in accordance with the same statutory requirements as the drugs and biologicals with pass-through status under the OPPS. Otherwise, they argued, patient access to innovative drug and biological therapies in appropriate outpatient settings could be jeopardized.

Response: We appreciate the comments that support our decision to remove 13 drugs pass-through and biologicals for which pass-through status expires at the end of CY 2004 from the table. With respect to those drugs and biologicals that will continue to be on pass-through status or that may be granted pass-through status in CY 2005, we agree that our payment rules and amounts should be consistent with the ASP-based payments that will be made when these drugs and biologicals are furnished in physician offices since payment for both settings is governed by the same provisions of the Act. Therefore, we plan to make any appropriate adjustments to the amounts shown in Addendum A and B if later quarter ASP submissions indicate that adjustments to the payment rate are necessary. Changes in total payments due to quarterly updates of ASP for pass-through drugs are factored into our budget neutrality estimates.

In this final rule with comment period, we are not making any changes to the listing as a result of public comments. Table 23 below lists the drugs and biologicals that will have pass-through status in CY 2005. Addendum B of this final rule with

comment period lists the final CY 2005 rates for these pass-through drugs and biologicals, which are assigned status indicator "G" based on data reported to CMS as of July 30, 2004.

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Table 23.-- List of Drugs and Biologicals With Pass-Through Status in CY 2005

HCPCS Code	APC	Long Descriptor	Trade Name
C9123	9123	TransCyte, per 247 sq. cm	TransCyte
C9205	9205	Injection, Oxaliplatin, per 5 mg	Eloxatin
C9203	9203	Injection, Perflexane lipid microspheres, per single use vial	Imagent
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg	Geodon
C9211	9211	Injection, IV, Alefacept, per 7.5 mg	Amevive
C9212	9212	Injection, IM, Alefacept, per 7.5 mg	Amevive
J9041	9207	Injection, IV, Bortezomib, per 0.1 mg	Velcade
J0180	9208	Injection, IV, Agalsidase beta, per 1 mg	Fabrazyme
J1931	9209	Injection, IV, Laronidase, per 0.1 mg	Aldurazyme
J2469	9210	Injection, IV, Palonosetron HCI per 0.025 mg (25 microgram)	Aloxi
J0878	9124	Injection, daptomycin, per 1 mg	Cubicin
J2794	9125	Injection, risperidone, per 0.5 mg	Risperdal Consta
J2783	0738	Injection, rasburicase, 0.5 mg	Elitek
J9305	9213	Injection, Pemetrexed, per 10 mg	Alimta
J9035	9214	Injection, Bevacizumab, per 10 mg	Avastin
J9055	9215	Injection, Cetuximab, per 10 mg	Erbitux
J0128	9216	Abarelix for Injectable Suspension, per 10 mg	Plenaxis
J2357	9300	Injection, Omalizumab, per 5 mg	Xolair
C9218	9218	Injection, azacitidine, per 1 mg	Vidaza[1]
J7518	9219	Mycophenolic acid, oral, per 180 mg	Myfortic[1]
C9220	9220	Sodium Hyaluronate per 30 mg dose, for intra-articular injection	Orthovisc
C9221	9221	Acellular dermal tissue, matrix, per 16cm2	GraftJacket (Repair)
C9222	9222	Decellularized Soft Tissue Scaffold, per 1 cc	GraftJacket (Soft Tissue)

[1]Approved for pass-through payment beginning on or after October 1, 2004

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B. Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

1. Background

Under the OPPS, we currently pay for drugs, biologicals including blood and blood products, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment and separate payment (individual APCs). We explained in the April 7, 2000 final rule (65 FR 18450) that we generally package the cost of drugs and radiopharmaceuticals into the APC payment rate for the procedure or treatment with which the products are usually furnished. Hospitals do not receive separate payment from Medicare for packaged items and supplies, and hospitals may not bill beneficiaries separately for any packaged items and supplies whose costs are recognized and paid for within the national OPPS payment rate for the associated

procedure or service. (Program Memorandum Transmittal A–01–133, issued on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.)

Packaging costs into a single aggregate payment for a service, procedure, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services. As discussed in the November 7, 2003 OPPS final rule with comment period (68 FR 63445), in CY 2004 we packaged payment for drugs, biologicals, and radiopharmaceuticals into the APCs with which they were billed if the median cost per day for the drug, biological, or radiopharmaceutical was less than $50. We established a separate APC payment for drugs, biologicals, and radiopharmaceuticals for which the median cost per day exceeded $50. Our rationale for establishing a $50 threshold was also discussed in the November 7, 2003 OPPS final rule with comment period (68 FR 63444 through 63447).

2. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

Section 621(a)(2) of Pub. L. 108–173 amended section 1833(t)(16) of the Act by adding a new subparagraph (B) to require that the threshold for establishing separate APCs for drugs and biologicals be set at $50 per administration for CYs 2005 and 2006. For CY 2005, we proposed to continue our policy of paying separately for drugs, biologicals, and radiopharmaceuticals whose median cost per day exceeds $50 and packaging the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per day is less than $50 into the procedures with which they are billed.

We calculated the median cost per day using claims data from January 1, 2003, to December 31, 2003, for all drugs, biologicals, and radiopharmaceuticals that had an HCPCS code during this time period and were paid (via packaged or separate payment) under the OPPS. Items such as single indication orphan drugs, certain vaccines, and blood and blood products were excluded from these calculations and our treatment of these is discussed separately in sections V.F., E., and I., respectively, of this preamble. In order to calculate the median cost per day for drugs, biologicals, and radiopharmaceuticals to determine their packaging status in CY 2005, in the August 16, 2004 proposed rule, we proposed to use the methodology that was described in detail in the CY 2004 OPPS proposed rule (68 FR 47996 through 47997) and finalized in the CY 2004 final rule with comment period (68 FR 63444 through 63447). We requested comments on the methodology we proposed to continue to use to determine the median cost per day of these items.

We proposed to apply an exception to our packaging rule to one particular class of drugs, the injectible and oral forms of anti-emetic treatments. The HCPCS codes to which our exception to the packaging rule for CY 2005 would apply were listed in Table 24 of the proposed rule (69 FR 50506). Our calculation of median cost per day for these products showed that, if we were to apply our packaging rule to these items, two of the injectible products would be packaged and one would be separately payable. In addition, two of the oral products would be separately payable and one would be packaged. Chemotherapy is very difficult for many patients to tolerate as the side effects are often debilitating. In order for beneficiaries to achieve the maximum therapeutic benefit from chemotherapy and other therapies with side effects of nausea and vomiting, anti-emetic use is often an integral part of the treatment regimen. We wanted to ensure that our payment rules did not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician. Therefore, we proposed to pay separately for all six injectible and oral forms of anti-emetic products in CY 2005.

We received several public comments on our proposed criteria for packaging payment for drugs, biologicals, and radiopharmaceuticals.

Comment: Many commenters supported our proposal to continue paying separately for drugs, biologicals, and radiopharmaceuticals whose median costs per day exceed $50. The commenters encouraged CMS to continue to maintain the threshold at $50 after CY 2006 and recommended that any additional packaging threshold be examined carefully prior to future implementation so that beneficiary access to therapies will not be compromised as a result. One of the commenters, however, remained concerned about the packaging of other drugs and biologicals that fell below the $50 threshold and recommended that CMS make separate payments for drugs and biologicals that meet one or both of the following criteria: products with median cost per day of at least $50; or products that are eligible for separate payment in other outpatient sites of care and that received a separate payment previously under the OPPS. Another commenter expressed concern about the site of service incentives presented by some drugs being paid when furnished in the physicians' offices, while being packaged in the hospital setting. The commenter urged CMS to consider several options, including: Making separate payment for all drugs in CY 2005 that were separately paid under a previous OPPS payment rate and are separately paid for in physicians' offices; lowering the packaging threshold, for example, to $10 or $20; paying separately for all drugs for which the 106 percent of ASP payment amount in the physicians' office is at least $10; or establishing procedures to ensure that drugs used for similar indications (including off-label uses) are either all packaged or all paid separately. MedPAC, to the contrary, expressed concern about the use of an arbitrary cut-off of $50 per administration for separate payment of drugs. It stated that separate payment for certain more expensive drugs gave hospitals an incentive to use those drugs rather than those that are packaged, and the threshold also gave manufacturers an incentive to price their drugs to ensure that they are above $50 per administration. MedPAC recommended that CMS should carefully analyze alternative thresholds or the creation of larger bundles to allow for alternative approaches once the MMA provision requiring a $50 threshold expires in CY 2007.

Response: We appreciate the support of many commenters for our packaging policy for CY 2005. Section 621(a)(2) of Pub. L. 108–173 requires that the threshold for establishing separate APCs for drugs and biologicals be set at $50 per administration for CYs 2005 and 2006. Therefore, we cannot change the threshold amount for CY 2005 as some of the commenters have suggested. We will take all of the commenters' recommendations into consideration as

we work on our packaging proposal for the CY 2007 OPPS.

However, in light of the commenters' concerns, we have decided to apply our equitable adjustment authority to establish several exceptions to the packaging threshold. We note that there were seven drugs and biologicals that we proposed to pay separately for in our proposed rule. However, when we recalculated their median costs per day using all of the hospital claims used for this final rule with comment period, their median costs per day were less than $50. We considered several payment options for these drugs and biologicals, such as packaging all of the items in CY 2005 or paying separately for all of them as we had proposed. However, after evaluating these drugs carefully, we decided to finalize the following payment policy for these items:

- Drugs and biologicals that were paid separately in CY 2004 and have median costs per day less than $50 based on the hospital claims data being used for the CY 2005 final rule with comment period would continue to receive separate payment in CY 2005.
- Those drugs and biologicals that are packaged in CY 2004 and that have median costs per day less than $50 based on the hospital claims data being used for the CY 2005 final rule with comment period would remain packaged in CY 2005.

We believe these policies are the most equitable for this particular set of drugs given the fluctuations in median hospital cost relative to the $50 threshold and their status in CY 2004.

Table 24 lists the seven drugs and biologicals to which this policy will apply along with their CYs 2004 and 2005 payment status indicator. The four items that will be separately paid under this policy meet the definition of sole source ''specified covered outpatient drugs'' and will be paid between 83 percent and 95 percent of their AWP in CY 2005.

Table 24.-- Drugs and Biologicals with Median Costs Per Day Less than $50[1] (Proposed for separate payment)

HCPCS	Description	CY 2004 Status Indicator	CY 2005 Status Indicator
J1450	Inj Fluconazole, 200 mg	N	N
J1730	Inj, Diazoxide, up to 300 mg	N	N
J3400	Inj, Trifluprom azine, Hcl, up to 20 mg	N	N
J0350	Inj, Anistreplase, per 30 units	K	K
J1830	Inj, Interferon beta-1B, 0.25 mg	K	K
J8510	Busulfan, oral, 2 mg	K	K
J9151	Daunorubicin citrate, liposomal formulation, 10 mg	K	K

[1]Median costs are based on CY 2003 final rule claims.

Comment: One commenter indicated that CMS was proposing a packaging policy that appeared to be different from the MMA requirement because a particular drug may be administered more than once per day. Therefore, the commenter added, a drug with a cost per administration of less than $50 that is administered more than once per day would qualify for separate payment under CMS' proposed policy, but would not qualify for separate payment under the MMA requirement. The commenter indicated that the overall impact of this discrepancy is that there will be less packaging of drugs under the OPPS than Congress intended. The commenter was unclear as to whether CMS had the authority to deviate from the statute in this way.

Response: We note that the hospital claims data do not indicate whether there were multiple administrations of the same drug on a single day. Accordingly, we must assume that for all cases there was only a single administration of each drug per day. For packaging purposes, the median cost per day for each drug and biological must, therefore, serve as a proxy for its cost per administration. We will, however, continue to explore ways to distinguish single versus multiple drug administrations for future OPPS updates.

Comment: Numerous commenters, including several manufacturers of pharmaceutical products, individual hospitals, and hospital associations, strongly supported CMS' proposed exception to exclude the six injectible and oral forms of 5HT3 anti-emetic products from the packaging threshold and allow separate payment for all of them. One commenter indicated that CMS' claims data used to determine median cost per day may not be a reliable source for accurate median costs for these products and may understate their actual acquisition and related costs. Another commenter stated that if the $50 threshold were applied to this class of drugs, it would have created an incentive for hospitals to choose therapies based on the opportunity for payment and not their appropriateness for each individual patient. The commenters agreed that this policy would help to ensure beneficiary access to the most appropriate anti-emetic drug for cancer care. Several commenters also urged CMS to give careful thought to the effects of packaging on patient access to other types of drugs and biological therapies. However, one commenter indicated that, in recent months, the