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Health care legislative and regulatory update



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CMS Releases Proposed Hospital Outpatient PPS Update and ASC Payment Changes for CY 2011

On July 2, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule updating the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system for Calendar Year (CY) 2011. The rule is on display at the *Federal Register* Office and is scheduled for publication on August 3rd. A [copy](#) of the 1,650 page document is on the *Federal Register* web site. The proposal provides for a 60-day comment period ending August 31.

The rule would provide for a market-basket (MB) update of 2.15 percent, for hospitals providing quality data elements and 0.15 percent for those that do not. The updates are reduced by 0.25 percent as mandated by the Affordable Health Care Act (ACA).

For ASCs, CY 2011 will be the first year of full payment rates under the revised ASC payment system payment methodology following a four-year transition.

Significant Proposals

CMS has highlighted the following as significant items in the proposed rule:

OPPS

- **OPPS Market Basket Update** – The ACA requires CMS to reduce the OPD fee schedule increase factor (commonly referred to as the hospital operating market basket increase factor) for CY 2011 OPPS payment by 0.25 percentage point. Therefore, as noted above, the proposed CY 2011 OPPS payment rates reflect a hospital operating market basket increase factor of 2.15 percent (that is, the estimated hospital operating market basket increase factor of 2.4 percent less the 0.25 percentage point reduction).
- **Quality Measures to be Reported** – CMS is proposing measures for three subsequent payment determinations. CMS is proposing to add six quality measures to the current list of 11 measures to be reported, bringing the total number of measures to 17 that are to be reported in CY 2011 for purposes of the CY 2012 payment determination. These new measures include one structural health information technology (HIT) measure, four claims-based imaging efficiency measures, and one chart-abstracted measure for the emergency department.

CMS is proposing to add seven measures to the list for reporting in CY 2012 for the CY 2013 payment determination (for a total of 24 measures). Of the proposed new measures, one is a structural measure on use of electronic health records and six are chart-abstracted measures for the emergency department.

CMS is also proposing to add six chart-abstracted measures for reporting in 2013 for the 2014 payment determination, bringing the total number of measures for reporting in CY 2013 to 30. These new measures include five chart-abstracted measures for diabetes mellitus and one chart-abstracted measure for exposure time for fluoroscopy procedures.

- **Validation of Quality Reporting** – For the CY 2011 payment determination, CMS implemented a hospital outpatient quality data reporting program (HOP QDRP) validation requirement to ensure that hospitals are accurately reporting measures using chart-abstracted data (however, the results of the validation will not affect the CY 2011 payment determination for any hospital). For the CY 2012 payment determination, CMS is proposing to validate data from 800 randomly selected hospitals. For each hospital, CMS is proposing to randomly select up to 12 cases per quarter. CMS is proposing to request the corresponding medical records for the cases, perform its own abstraction of the HOP QDRP chart-abstracted measures for the cases, and compare the results with the measures reported by the hospital. CMS is proposing to require hospitals to achieve a minimum 75 percent validation score based on this validation process to receive the full OPPS update in CY 2012.
- **Waiver of Beneficiary Cost-Sharing for Preventive Services** – The ACA waives the deductible and copayment for certain preventive services that are paid under the OPPS, including the initial preventive physical examination (IPPE) and preventive services that have been recommended by the United States Preventive Services Task Force with a grade of A or B.
- **Payment Adjustment for Certain Cancer Hospitals** – The ACA requires CMS to conduct a study to determine if outpatient costs incurred by cancer hospitals that meet the classification criteria set forth in the statute exceed outpatient costs incurred by other hospitals paid under the OPPS and to make an appropriate budget neutral payment adjustment if these cancer hospitals are found to be more costly. Based on the results of this analysis, CMS is proposing to adjust each cancer hospital's OPPS payment so that its payment-to-cost ratio (PCR) is equivalent to the average PCR of all other hospitals paid under the OPPS. Because the Medicare law holds such cancer hospitals harmless to payments before the OPPS was implemented, a cancer hospital still may be able to receive a transitional outpatient payment.
- **Frontier State Wage Provisions** – For services beginning in CY 2011, the wage adjustment factor applicable to any HOPD that is located in a state in which at least 50 percent of the counties have a population per square mile of less than 6 (excluding Alaska and Hawaii) may not be less than 1.0000. For CY 2011, CMS is proposing to adjust the wage index for all OPPS hospitals located in a frontier state in a non-budget neutral manner as specified by the ACA.
- **Supervision requirements for outpatient therapeutic services** – CMS is proposing to require direct supervision for the initiation of a service followed by general supervision after the initiation period for a limited set of “non-surgical extended duration services,” including observation services. Under current policy, direct supervision is required for the duration of all outpatient therapeutic services in both hospitals and critical access hospitals (CAHs), although CMS issued instructions to contractors to not enforce the direct supervision requirement in CAHs for CY 2010. The proposal to require direct supervision followed by general supervision for certain non-surgical extended duration services would apply to both hospitals and CAHs for CY 2011.
- **Partial hospitalization services, including services provided by CMHCs** – CMS is proposing to establish four separate PHP APC per diem payment rates, two for community mental health centers (CMHCs) PHPs and two for hospital-based PHPs, which are based on each provider type's data (see chart below for proposed per diem payment rates). In addition, section 1301 of the **Health Care and Education Reconciliation Act of 2010** (HCERA 2010), revised the definition of CMHC by adding a

requirement that the CMHC must provide at least 40 percent of its services to non-Medicare beneficiaries. HCERA further revised the definition of a PHP (provided by either a CMHC or HOPD) to exclude services furnished in a beneficiary's home or an inpatient or residential setting. CMS is also proposing to continue the CMHC multiple outlier threshold at 3.4 times the APC payment amount for higher intensity partial hospitalization days for CY 2011.

Proposed APC	Group Title	Proposed Median Per Diem Costs
172	Level 1 Partial Hospitalization (3 services) for CMHCs	\$118.19
173	Level II Partial Hospitalization (4 or more services) for CMHCs	\$123.35
175	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	\$184.47
176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	\$235.58

- **Drugs and pharmacy overhead** – For CY 2011, CMS is proposing to pay for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals without pass-through status at the average sales price (ASP) plus 6 percent. The proposed payment rate of ASP plus 6 percent is based upon the cost of separately payable drugs and biologicals, calculated from hospital claims and cost reports, with an adjustment for pharmacy overhead cost that reflects the redistribution of \$200 million of the pharmacy overhead cost currently attributed to packaged drugs and biologicals (both coded and uncoded) to separately payable drugs and biologicals without pass-through status.

Ambulatory Surgical Centers

- **ASC Payment Rate Updates** – CMS projects the percentage increase in the Consumer Price Index for All Urban Consumers that would update the ASC conversion factor for CY 2011 to be 1.6 percent. However, beginning in CY 2011, the ACA requires the annual update factor for the ASC payment system be reduced by a productivity adjustment, which is also estimated to be 1.6 percent for CY 2011. As a result, CMS is proposing a 0 percent update to the ASC payment system for CY 2011.

Comment

While ACA mandates a productivity adjustment for most provider services, the amount of the adjustment has not been reflected until now. Also, the ACA specifies that a provider's payment in a future year may be less than its current amount.

- **Changes To ASC Covered Surgical Procedures And Covered Ancillary Services** – CMS is proposing to add 5 surgical procedures to the list of procedures for which Medicare would pay when performed in an ASC. CMS is also proposing to newly designate six procedures as office-based procedures (subject to payment at the lesser of the national office practice expense payment to the physician or the national standard ASC rate) and to update the list of covered ancillary services to reflect the proposals in the OPPTS update.
- **Waiver Of Beneficiary Cost-Sharing For Preventive Services** – The ACA waives the deductible and coinsurance for certain preventive services that are paid under the ASC payment system and have been recommended by the United States Preventive Services Task Force with a grade of A or B.

Other

- **Affordable Care Act Provisions Affecting Physician-Owned Hospitals** – The physician self-referral law generally prohibits physicians from referring Medicare and Medicaid beneficiaries to entities with which they or an immediate family member have a financial relationship for certain designated health services, including inpatient and outpatient hospital services. However, the law allows physicians to refer patients to hospitals in which they have an ownership or investment interest if the ownership or investment is in the whole hospital, rather than in a particular department. An exception to the prohibition is also allowed for some rural hospitals.

ACA Section 6001 “narrows access” to the “rural provider” and “whole hospital” exceptions by prohibiting their use by new physician-owned hospitals, and limiting the ability of existing physician-owned hospitals to expand their capacity. Under section 6001, physician-owned hospitals that were converted from ASCs cannot qualify for the revised rural provider and whole hospital exceptions. Additional provisions in section 6001 are aimed at preventing conflicts of interest, ensuring that all ownership and investment interests are bona fide and promoting patient safety. The proposed rule incorporates these provisions into CMS regulations.

- **Implementing The Affordable Care Act’s Graduate Medical Education Provisions** – The ACA Act included a number of changes to the way CMS pays for graduate medical education (GME) under the Inpatient Prospective Payment System (IPPS). CMS is including its proposals to implement the GME provision in this OPPI/ASC proposed rule. The changes would affect how CMS counts time spent by residents furnishing care in non-provider settings, as well as resident time spent in didactic and scholarly activities, as well as other activities not directly relating to patient care. The ACA also provides for the redistribution of residency positions from hospitals training fewer residents than they may have under their caps and also redistributes the resident cap positions from closed hospitals

Comments

Once again, the OPPI update is both extensive and complex. Most of the proposed changes involve coding applications. The financial changes are simple and straightforward. However, a hospital’s bottom line is quite dependent of the changes being made by new codes, reassignment of codes, bundling of services, changes in APC groups, and revised and deleted APCs. The proposal is a fairly well written document that provides the history of the issues at hand. A further improvement would be if CMS provided additional “summaries” of the changes it is making.

CMS provides the following analysis:

Impact of Changes for CY 2011 Hospital Outpatient Prospective Payment System

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2,3) with Market Basket Update (5)	Frontier Wage Index Adjustment (6)	All Changes (7)
All Providers *	4,140	0	0	0	2.1	2.2	2.2
All Hospitals	3,871	0.5	0	-0.7	2	2.1	2.1
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS	2,893	0.5	0.1	-0.7	2.1	2.1	2.1
Large Urban	1,569	0.5	0.2	-0.7	2.2	2.2	2.2

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2,3) with Market Basket Update (5)	Frontier Wage Index Adjustment (6)	All Changes (7)
Other Urban	1,324	0.5	0	-0.7	1.9	2.1	2
RURAL HOSPITALS							
RURAL HOSPITALS	978	0.5	-0.3	-0.7	1.6	1.9	1.8
Sole Community	391	0.5	-0.4	-0.7	1.5	2	1.8
Other Rural	587	0.5	-0.3	-0.7	1.7	1.8	1.9
BEDS (URBAN)							
0 - 99 Beds	976	0.7	0	-0.7	2.2	2.4	2.4
100-199 Beds	855	0.6	0.1	-0.7	2.1	2.2	2.1
200-299 Beds	453	0.6	0	-0.7	2.1	2.2	2.2
300-499 Beds	413	0.5	0.1	-0.7	2.1	2.2	2.2
500 + Beds	196	0.4	0	-0.7	1.9	1.9	2
BEDS (RURAL)							
0 - 49 Beds	347	0.4	0.1	-0.7	1.9	2.2	2.2
50-100 Beds	375	0.6	-0.5	-0.7	1.6	1.7	1.7
101-149 Beds	146	0.5	-0.3	-0.7	1.7	1.9	1.8
150-199 Beds	62	0.6	-0.2	-0.7	1.9	2.4	2.3
200 + Beds	48	0.5	-0.6	-0.7	1.4	1.4	1.4
VOLUME (URBAN)							
LT 5,000 Lines	593	1.3	0.3	-0.7	3	3.2	3.3
5,000 – 10,999 Lines	159	1.1	0.5	-0.7	3.1	3.3	3.4
11,000 - 20,999 Lines	243	0.8	0.2	-0.7	2.5	2.5	2.6
21,000 - 42,999 Lines	528	0.6	0.3	-0.7	2.4	2.4	2.3
GT 42,999 Lines	1,370	0.5	0	-0.7	2	2.1	2.1
VOLUME (RURAL)							
LT 5,000 Lines	76	-0.4	0.4	-0.7	1.4	3.2	3.4
5,000 - 10,999 Lines	96	0.6	0.3	-0.7	2.3	2.4	2.5
11,000 - 20,999 Lines	198	0.5	0	-0.7	2	2.3	2.2
21,000 - 42,999 Lines	308	0.5	-0.2	-0.7	1.8	2	2
GT 42,999 Lines	300	0.5	-0.4	-0.7	1.5	1.8	1.7
REGION (URBAN)							
New England	150	0.5	-0.6	-0.7	1.4	1.4	1.3
Middle Atlantic	362	0.6	-0.2	-0.7	1.9	1.9	1.7
South Atlantic	447	0.6	-0.1	-0.7	2	2	2.1
East North Cent.	466	0.5	0.1	-0.7	2.1	2.1	2
East South Cent.	178	0.4	-0.3	-0.7	1.6	1.6	1.6
West North Cent.	187	0.5	-0.2	-0.7	1.8	2.5	2.5
West South Cent.	472	0.5	0.1	-0.7	2.1	2.1	2.2
Mountain	192	0.5	-0.1	-0.7	1.9	2.3	2.4
Pacific	391	0.5	1.1	-0.7	3	3	3.2
REGION (RURAL)							
New England	24	0.6	-1.9	-0.7	0.2	0.2	0.3
Middle Atlantic	67	0.6	-0.3	-0.7	1.8	1.8	1.9

	Number of Hospitals (1)	APC Recalibration (2)	New Wage Index and Rural Adjustment (3)	New Cancer Hospital Adjustment (4)	Comb (cols 2,3) with Market Basket Update (5)	Frontier Wage Index Adjustment (6)	All Changes (7)
South Atlantic	164	0.6	-0.3	-0.7	1.8	1.8	1.9
East North Cent.	127	0.5	-0.6	-0.7	1.4	1.4	1.3
East South Cent.	177	0.4	-0.3	-0.7	1.7	1.7	1.6
West North Cent.	103	0.5	-0.8	-0.7	1.2	2.3	2.1
West South Cent.	216	0.3	0.6	-0.7	2.4	2.4	2.4
Mountain	70	0.6	0.2	-0.7	2.2	4.1	3.9
Pacific	30	0.5	-0.1	-0.7	2	2	1.7
TEACHING STATUS							
Non-Teaching	2,890	0.5	0	-0.7	2	2.1	2.1
Minor	699	0.5	0	-0.7	1.9	2.1	2.1
Major	282	0.5	0	-0.7	2	2	2.1
DSH PATIENT PERCENT							
0	6	2.3	0	-0.7	3.7	3.7	4
GT 0 - 0.10	396	0.7	0.1	-0.7	2.2	2.3	2.3
0.10 - 0.16	395	0.5	0	-0.7	2	2.1	2
0.16 - 0.23	771	0.4	-0.2	-0.7	1.7	1.9	1.9
0.23 - 0.35	997	0.5	0	-0.7	2	2.1	2.1
GE 0.35	723	0.6	0.2	-0.7	2.2	2.2	2.4
DSH NOT AVAILABLE **	583	-1.8	0.5	-0.7	0.2	0.2	0.2
URBAN TEACHING/DSH							
Teaching & Dsh	889	0.5	0.0	-0.7	2.0	2.1	2.1
No Teaching/Dsh	1,445	0.6	0.1	-0.7	2.2	2.2	2.2
NO TEACHING/NO DSH	6	2.3	0.0	-0.7	3.7	3.7	4.0
DSH NOT AVAILABLE**	553	-1.5	0.5	-0.7	0.5	0.5	0.6
TYPE OF OWNERSHIP							
Voluntary	2,064	0.5	0.0	-0.7	1.9	2.1	2.0
Proprietary	1,230	0.6	0.1	-0.7	2.2	2.3	2.3
Government	577	0.5	0.0	-0.7	2.0	2.1	2.2
CMHCs	207	-44	0.9	-0.7	-41.7	-41.7	-41.7
Cancer Hospitals	11	0.3	0.1	40.5	43.2	43.2	39.9

Column (1) shows total hospitals.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the recalibration of APC weights based on 2009 hospital claims data.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2011 hospital inpatient wage index. CMS did not propose any changes to the rural adjustment.

Column (4) shows the budget neutral impact of applying a hospital-specific adjustment to all OPSS services at the 11 designated cancer hospitals.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the market basket update.

Column (6) shows the non-budget neutral impact of applying the frontier adjustment
Column (7) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds outlier payments. This column also shows the expiration of section 508 wages on September 30, 2010 and the application of the Frontier wage adjustment for CY 2011.

*These 4,140 providers include children and cancer hospitals, which are held harmless to pre-BBA payments, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

The discussion below follows the rule's order and is not reflective of major versus minor changes.

PROPOSED UPDATES AFFECTING OPPTS PAYMENTS

Proposed Recalibration of APC Relative Weights

1. Database

For the purpose of recalibrating the proposed APC relative payment weights for CY 2011, CMS says it used approximately 133 million final action claims for hospital outpatient department services furnished on or after January 1, 2009, and before January 1, 2010.

For CY 2011, CMS would bypass 448 HCPCS codes that are identified in Table 1 of the proposed rule.

2. Calculation of Cost-to-Charge Ratios (CCRs)

For CY 2011, CMS is proposing to continue using the hospital-specific overall ancillary and departmental CCRs to convert charges on the claims reported under specific revenue codes to estimated costs through application of a revenue code-to-cost center crosswalk.

Proposed Calculation of Single Procedure APC Criteria-Based Median Costs

1. Device-Dependent APCs

CMS is proposing to calculate the median costs for device-dependent APCs for CY 2011 using only the subset of single procedure claims from CY 2009 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than \$1.01) for devices; do not contain the "FB" modifier signifying that the device was furnished without cost to the provider, supplier, or practitioner, or where a full credit was received; and do not contain the "FC" modifier signifying that the hospital received partial credit for the device. The "FC" modifier became effective January 1, 2008, and was present for the first time on claims that were used in OPPTS rate setting for CY 2010.

The proposal's table 4 lists the APCs for which CMS is proposing to use its standard device-dependent APC rate setting methodology for CY 2011.

Also, CMS refers readers to the proposal's Addendum A for the proposed payment rates for these APCs.

2. Blood and Blood Products

For CY 2011, CMS would continue to establish payment rates for blood and blood products using its blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs.

CMS refer readers to Addendum B for the proposed CY 2011 payment rates for blood and blood products, which are identified with status indicator “R.”

3. Single Allergy Tests

CMS is proposing to continue differentiating single allergy tests (“per test”) from multiple allergy tests (“per visit”) by assigning these services to two different APCs. Multiple allergy tests are currently assigned to APC 0370 (Allergy Tests).

The proposed CY 2011 median cost for APC 0381 using the “per unit” methodology is approximately \$29.

4. Hyperbaric Oxygen Therapy (APC 0659)

CMS finalized a “per unit” median cost calculation for APC 0659 (Hyperbaric Oxygen) using only claims with multiple units or multiple occurrences of HCPCS code C1300 because delivery of a typical HBO_T service requires more than 30 minutes.

For CY 2011, CMS is proposing to continue using the same methodology to estimate a “per unit” median cost for HCPCS code C1300. This methodology results in a proposed APC median cost of approximately \$109.

5. Payment for Ancillary Outpatient Services When Patient Expires (APC 0375)

For CY 2011, CMS is proposing a median cost of approximately \$6,566 for APC 0375.

6. Pulmonary Rehabilitation (PR)

CMS is proposing to continue to require hospitals to report PR services provided under the comprehensive PR benefit in section 1861(fff) of the Act using HCPCS code G0424.

CMS says the proposed simulated median cost for HCPCS code G0424 and APC 0102 is approximately \$68. CMS notes that this proposed median cost is higher than the CY 2010 final rule median cost for HCPCS code G0424 and APC 0102 of approximately \$50 on which the CY 2010 payment is based.

Proposed Calculation of Composite APC Criteria-Based Median Costs

For CY 2011, CMS is proposing to continue its established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, mental health services, and multiple imaging services.

Proposed Changes to Packaged Services

CMS is not proposing any changes for inclusion or exclusion to the list of packaged services.

Proposed Conversion Factor (CF) Update

The ACA require a 0.25 percentage point reduction to the CY 2011 OPD fee schedule increase factor, resulting in a proposed CY 2011 OPPS market basket update of 2.15 percent (2.40 (as provided in the proposed hospital inpatient PPS for FY 2011)-0.25). The current OPPS CF factor is \$67.241.

Hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) are subject to a reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the CF.

The proposed budget neutrality factor for the rural adjustment is 1.0000. CMS has calculated a proposed overall budget neutrality factor of 1.0011 for wage index changes. In addition, to accommodate a proposed cancer hospital adjustment, CMS has calculated an additional proposed budget neutrality factor of 0.9934.

CMS has estimated that pass-through spending for both drugs and biologicals and devices for CY 2011 would equal approximately \$86.9 million, which represents 0.20 percent of total projected CY 2011 OPPS spending. Therefore, the CF factor would also be adjusted by the difference between the 0.14 percent estimate of pass-through spending for CY 2010 and the 0.20 percent estimate of CY 2011 pass-through spending. Finally, estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2011.

The proposed OPD fee schedule increase factor of 2.15 percent for CY 2011, the required proposed wage index budget neutrality adjustment of approximately 1.0011, the proposed cancer hospital budget neutrality adjustment of 0.9934, and the proposed adjustment of 0.06 percent of projected OPPS spending for the difference in the pass-through spending results in a proposed conversion factor for CY 2011 of **\$68.267**.

The proposed (reduced) conversion factor for those hospitals that fail to meet the HOP QDRP requirements would be \$66.930.

Proposed Wage Index Changes

CMS is proposing to use the final FY 2011 version of the IPPS wage index used to pay IPPS hospitals to adjust the CY 2011 OPPS payment rates and copayment amounts for geographic differences in labor cost for all providers that participate in the OPPS, including providers that are not paid under the IPPS (referred to in this section as “non-IPPS” providers). The ACA created a “Frontier state” adjustment. CMS is referencing this item, referring readers to the IPPS material and states it will make changes to the regulations. The frontier state wage index is the greater of 1.000 or the area’s value.

Proposed Statewide Average Default CCRs

CMS is proposing to update the default CCR ratios for CY 2011 using the most recent cost report data. The proposal’s Table 9 lists the proposed CY 2011 default urban and rural CCRs by State and compares them to last year’s default CCRs.

Proposed OPPS Payment to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes (TOPs)

The ACA extends the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for one year, for services provided before January 1, 2011. The ACA also extends the period of TOPs to SCHs (including EACHs) for 1 year, for services provided before January 1, 2011 removing the 100-bed limitation applicable to such SCHs.

2. Proposed Adjustment for Rural SCHs Implemented in CY 2006 (MMA)

For the CY 2011 OPPS, CMS is proposing to continue the policy of a budget neutral 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding

separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

Proposed OPPS Payments to Cancer Hospitals

There are 11 cancer hospitals that are exempted from payment under the inpatient prospective payment system (IPPS). Since the inception of the hospital OPPS, Medicare has paid cancer hospitals under the OPPS for covered outpatient hospital services.

The ACA instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals exceed the costs incurred by other hospitals furnishing services.

CMS says that it found “that cancer hospitals had a standardized cost per discounted unit of \$150.12 compared to a standardized cost per discounted unit of \$94.14 for all other hospitals.” Therefore, CMS is proposing a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital’s payment to cost ratio (PCR) to the weighted average PCR for all other hospitals paid under OPPS (0.868) in the CY 2011 dataset. This would be accomplished by adjusting each cancer hospital’s OPPS payment by the percentage difference between their individual PCR and the weighted average PCR of the other hospitals paid under OPPS. This proposed methodology would result in the proposed percentage payment adjustments for the 11 cancer hospitals appearing in the table below.

Proposed Hospital-Specific Adjustment for Cancer Hospitals without Regard to Tops and Outlier Payments

Provider Number	Hospital	Percent of Increase Without TOPs or Outlier Payment
050146	CITY OF HOPE HELFORD CLIN RESEARCH HOSP	5.90%
050660	USC KENNETH NORRIS JR CANCER HOSPITAL	11.50%
390196	HOSP OF THE FOX CHASE CANCER CENTER	13.60%
360242	JAMES CANCER HOSPITAL & SOLOVE RESEARCH INSTITUTE	15.70%
330354	ROSWELL PARK CANCER INSTITUTE	16.30%
100079	UNIV OF MIAMI HOSP & CLINIC	21.50%
100271	H LEE MOFFITT CANCER CENTER & RESEARCH INSTITUTE	29.40%
330154	MEM HOSP FOR CANCER AND ALLIED DISEASES	36.40%
220162	DANA-FARBER CANCER INSTITUTE	42.20%
500138	SEATTLE CANCER CARE ALLIANCE	47.60%
450076	UNIV OF TEXAS M D ANDERSON CANCER CENTER	82.60%
	Proposed Aggregate Adjustment	41.20%

CMS would update the hospital-specific cancer hospital payment adjustment using the more recent cost reports that become available for the CY 2011 OPSS/ASC final rule with comment period.

Proposed Hospital Outpatient Outlier Payment

Currently, the OPSS pays outlier payments on a service-by-service basis. For CY 2010, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,175 fixed-dollar threshold.

For CY 2011, CMS is proposing to continue the policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. A portion of that 1.0 percent, specifically 0.04 percent, would be allocated to CMHCs for PHP outlier payments.

For CY 2011, CMS is proposing that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a **\$2,025** fixed-dollar threshold.

CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC 0173, exceeds 3.40 times the payment for APC 0173, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 0173 payment rate.

Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The proposed national unadjusted payment rate for most APCs contained in the proposal's Addendum A and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B was calculated by multiplying the proposed CY 2011 scaled weight for the APC by the proposed CY 2011 conversion factor.

The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the "full" national unadjusted payment rate. The national unadjusted payment rate is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its HOP QDRP requirements in order to receive the full CY 2011 OPSS increase factor.

PROPOSED OPPTS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES

A. Proposed OPPTS Treatment of New HCPCS and CPT Codes

CPT and HCPCS code changes that affect the OPPTS are published both through the annual rulemaking cycle and through the OPPTS quarterly update Change Requests (CRs).

CMS recognizes the following codes on OPPTS claims: (1) Category I CPT codes, which describe medical services and procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

1. Proposed Treatment of New Level II HCPCS Codes and Category I CPT Vaccine Codes and Category III CPT Codes for which CMS is Soliciting Public Comments

For CY 2011, CMS is soliciting public comments on the proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category I vaccine codes and Category III CPT codes that are newly recognized in April or July 2010 through the respective OPPTS quarterly update CRs. These codes are listed in the rules Tables 13, 14, and 15.

2. Proposed Process for New Level II HCPCS Codes and Category I and Category III CPT Codes for which CMS will be Soliciting Public Comments on the CY 2011 OPPTS/ASC Final Rule With Comment Period

CMS is proposing to include in Addendum B to the CY 2011 OPPTS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2011 (including those Category I vaccine and Category III CPT codes that were released by the AMA in July 2010) that would be incorporated in the January 2011 OPPTS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2010, or January 1, 2011, that would be released by CMS in its October 2010 and January 2011 OPPTS quarterly update CRs. These codes would be flagged with comment indicator “NI” in Addendum B to the CY 2011 OPPTS/ASC final rule with comment period to indicate that CMS has assigned them an interim OPPTS payment status. Their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment in the CY 2011 OPPTS/ASC final rule with comment period and would be finalized in the CY 2012 OPPTS/ASC final rule with comment period.

B. Proposed OPPTS Changes – Variations within APCs

The proposal’s Addendum B identifies with comment indicator “CH” those HCPCS codes for which CMS is proposing a change to the APC assignment or status indicator that were initially assigned in the April 2010 Addendum B update (via Transmittal 1924, Change Request 6857, dated February 26, 2010).

The following table identifies 17 APCs that CMS would exempt from the APC two times rule.

Proposed CY 2011 APC	Proposed CY 2011 APC Title
51	Level III Musculoskeletal Procedures Except Hand and Foot
57	Bunion Procedures
58	Level I Strapping and Cast Application
80	Diagnostic Cardiac Catheterization
105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
138	Level II Closed Treatment Fracture Finger/Toe/Trunk

Proposed CY 2011 APC	Proposed CY 2011 APC Title
142	Small Intestine Endoscopy
173	Level II Partial Hospitalization (4 or more services)
235	Level I Posterior Segment Eye Procedures
245	Level I Cataract Procedures without IOL Insert
303	Treatment Device Construction
325	Group Psychotherapy
340	Minor Ancillary Procedures
344	Level IV Pathology
432	Health and Behavior Services
604	Level 1 Hospital Clinic Visits
664	Level I Proton Beam Radiation Therapy

C. New Technology APCs

CMS says that there are currently 82 New Technology APCs, ranging from the lowest cost band assigned to APC 1491 (New Technology – Level IA (\$0-\$10)) through the highest cost band assigned to APC 1574 (New Technology – Level XXXVII (\$9,500-\$10,000)).

CMS is proposing to reassign HCPCS G-code G0416 from New Technology APC 1505 to clinical APC 0661 (Level V Pathology), which has an APC median cost of approximately \$165, and HCPCS G-code G0417 from New Technology APC 1507 (New Technology – Level VII (\$500 to \$600)) to New Technology APC 1506 (New Technology - Level VI (\$400 - \$500)).

D. Proposed OPPS APC-Specific Policy: Skin Repair (APCs 0134 and 0135)

CMS is proposing to continue to assign the Apligraf application CPT codes 15340 and 15341 and the Dermagraft application CPT codes 15365 and 15366 to APC 0134, and is proposing to continue to assign the Oasis application CPT codes 15430 and 15431 to APC 0135.

Further, CMS is proposing to create two new Level II HCPCS G-codes to report the application of Apligraf or Dermagraft specific to the lower extremities.

The proposed HCPCS codes are: GXXX1 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less); and GXXX2 (Application of tissue cultured allogeneic skin or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm).

PROPOSED OPPS PAYMENT FOR DEVICES

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

There currently are no device categories eligible for pass-through payment, and there are no categories for which CMS would propose expiration of pass-through status.

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

For CY 2011, CMS is proposing to continue the following policies related to pass-through payment for devices: (1) treating implantable biologicals, that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status on or after January 1, 2010, as devices for purposes of the OPSS pass-through evaluation process and payment methodology; (2) including implantable biologicals in calculating the device APC offset amounts; (3) using the device APC offset amounts to evaluate whether the cost of a device (defined to include implantable biologicals) in an application for a new device category for pass-through payment is not insignificant in relation to the APC payment amount for the service related to the category of devices; and (4) reducing device pass-through payments based on device costs already included in the associated procedural APCs.

3. Proposed Adjustment to OPSS Payment for Partial or Full Credit Devices

CMS is proposing to continue the policy of reducing OPSS payment for specified APCs by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

The first table below lists the proposed APCs to which the payment reduction policy for no cost/full credit and partial credit devices would apply in CY 2011 and displays the proposed payment reduction percentages for both no cost/full credit and partial credit circumstances.

The second table below lists the proposed devices to which this policy would apply in CY 2011.

Proposed APCs to Which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Would Apply

Proposed CY 2011 APC	Proposed CY 2011 APC Title	Proposed CY 2011 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2011 Device Offset Percentage for Partial Credit Case
39	Level I Implantation of Neurostimulator Generator	85%	43%
40	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
61	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes	63%	31%
89	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%	35%
90	Insertion/Replacement of Pacemaker Pulse Generator	72%	36%
106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	46%	23%
107	Insertion of Cardioverter-Defibrillator	88%	44%
108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%	44%
225	Implantation of Neurostimulator Electrodes, Cranial Nerve	78%	39%
227	Implantation of Drug Infusion Device	81%	41%
259	Level VII ENT Procedures	86%	43%
315	Level II Implantation of Neurostimulator Generator	88%	44%
385	Level I Prosthetic Urological Procedures	61%	30%
386	Level II Prosthetic Urological Procedures	71%	36%
418	Insertion of Left Ventricular Pacing Elect.	72%	36%
425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
648	Level IV Breast Surgery	45%	23%
654	Insertion/Replacement of a permanent dual chamber pacemaker	73%	37%
655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%	37%
680	Insertion of Patient Activated Event Recorders	71%	35%

Proposed Devices to Which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Would Apply

CY 2010 HCPCS Code	CY 2010 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)

CY 2010 HCPCS Code	CY 2010 Short Descriptor
C1777	Lead, AICD, endo single coil
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1789	Prosthesis, breast, imp
C1813	Prosthesis, penile, inflatab
C1815	Pros, urinary sph, imp
C1820	Generator, neuro rechg bat sys
C1881	Dialysis access system
C1882	AICD, other than sing/dual
C1891	Infusion pump, non-prog, perm
C1895	Lead, AICD, endo dual coil
C1896	Lead, AICD, non sing/dual
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1899	Lead, pmkr/AICD combination
C1900	Lead coronary venous
C2619	Pmkr, dual, non rate-resp
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual
C2622	Prosthesis, penile, non-inf
C2626	Infusion pump, non-prog, temp
C2631	Rep dev, urinary, w/o sling
L8600	Implant breast silicone/eq
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

PROPOSED OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

1. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Proposed CY 2011 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” as indicated in Addenda A and B.

CMS’ proposed OPPS pass-through payment estimate for drugs and biologicals for CY 2011 is \$15 million.

2. Proposed Drugs and Biologicals with Expiring Pass-Through Status in CY 2010

CMS is proposing that the pass-through status of 18 drugs and biologicals would expire on December 31, 2010, as listed in the table below.

**Proposed Drugs and Biologicals for Which Pass-Through Status Would Expire
 December 31, 2010**

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
A9581	Injection, gadoxetate disodium, 1 ml	N	N/A
C9248	Injection, clevidipien butyrate, 1 mg	K	9248
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter	N	N/A
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9358
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	N	N/A
J1267	Injection, doripenem, 10 mg	N	N/A
J1453	Injection, fosaprepitant, 1 mg	K	9242
J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	1214
J1571	Injection, hepatitis b immune globulin (hepagam b), intramuscular, 0.5 ml	K	946
J1573	Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5ml	K	1138
J1953	Injection, levetiracetam, 10 mg	N	N/A
J2785	Injection, regadenoson, 0.1 mg	K	9244
J2796	Injection, romiplostim, 10 micrograms	K	9245
J9033	Injection, bendamustine hcl, 1 mg	K	9243
J9207	Injection, ixabepilone, 1 mg	K	9240
J9225	Histrelin implant (vantas), 50 mg	K	1711
J9226	Histrelin implant (supprelin la), 50 mg	K	1142
Q4114	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc	K	1251

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2011

CMS is proposing to continue pass-through status in CY 2011 for 31 drugs and biologicals. None of these products will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2010. These items, which were approved for pass-through status between April 1, 2009 and July 1, 2010, are listed in the table below. The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator “G” in Addenda A and B.

Proposed Drugs and Biologicals with Pass-Through Status in CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	G	9247
A9583	Injection, gadofosveset trisodium, 1 ml	G	1299
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	G	9250

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
C9255	Injection, paliperidone palmitate, 1 mg	G	9255
C9256	Injection, dexamethasone intravitreal implant, 0.1 mg	G	9256
C9258	Injection, telavancin, 10 mg	G	9258
C9259	Injection, pralatrexate, 1 mg	G	9259
C9260	Injection, ofatumumab, 10 mg	G	9260
C9261	Injection, ustekinumab, 1 mg	G	9261
C9263	Injection, ecallantide, 1 mg	G	9263
C9264	Injection, tocilizumab, 1 mg	G	9624
C9265	Injection, romidepsin, 1 mg	G	9625
C9266	Injection, collagenase clostridium histolyticum, 0.1 mg	G	9266
C9267	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	G	9267
C9268	Capsaicin, patch, 10cm2	G	9268
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	G	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	G	9361
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	G	9362
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	G	9363
C9364	Porcine implant, Permacol, per square centimeter	G	9364
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
J0598	Injection, C1 esterase inhibitor (human), 10 units	G	9251
J0641	Injection, levoleucovorin calcium, 0.5 mg	G	1236
J0718	Injection, certolizumab pegol, 1 mg	G	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	G	1290
J2562	Injection, plerixafor, 1 mg	G	9252
J8705	Topotecan, oral, 0.25 mg	G	1238
J9155	Injection, degarelix, 1 mg	G	1296
J9328	Injection, temozolomide, 1 mg	G	9253
Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	G	1297
Q2025	Fludarabine phosphate, oral, 1 mg	G	9262

CMS is proposing to pay for pass-through drugs and biologicals at ASP+6 percent, which is equivalent to the rate these drugs and biologicals would receive in the physician’s office setting in CY 2011.

4. Proposed Provisions for Reducing Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals and Contrast Agents to Offset Costs Packaged into APC Groups

CMS is proposing to continue to package payment for all non-pass-through diagnostic radiopharmaceuticals and contrast agents.

a. Proposed Payment Offset Policy for Diagnostic Radiopharmaceuticals

There is currently one radiopharmaceutical with pass-through status under the OPPI, HCPCS code A9582 (Iobenguane, I-123, diagnostic, per study dose, up to 10 millicuries). HCPCS code A9582 was granted pass-through status beginning April 1, 2009 and will continue on pass-through status in CY 2011.

CMS is proposing for CY 2011 to instruct hospitals to report the “FB” modifier on the line with the procedure code for the nuclear medicine scan in the APCs listed in the proposal’s Table E3 in which the no cost/full

credit diagnostic radiopharmaceutical is used. When a hospital bills an FB with the nuclear medicine scan, the payment amount for procedures in the APCs would be reduced by the full “policy-packaged” offset amount appropriate for diagnostic radiopharmaceuticals.

b. Proposed Payment Offset Policy for Contrast Agents

CMS is proposing to continue to recognize that when a contrast agent with pass-through status is billed with any procedural APC listed in the table below, a specific offset based on the procedural APC would be applied to payment for the contrast agent to ensure that duplicate payment is not made for the contrast agent.

APCs to Which a Contrast Agent Offset May be Applicable for CY 2011

Proposed CY 2011 APC	Proposed CY 2011 APC Title
80	Diagnostic Cardiac Catheterization.
82	Coronary or Non-Coronary Atherectomy.
83	Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty.
93	Vascular Reconstruction/Fistula Repair without Device.
104	Transcatheter Placement of Intracoronary Stents.
128	Echocardiogram with Contrast.
152	Level I Percutaneous Abdominal and Biliary Procedures.
229	Transcatheter Placement of Intravascular Shunts.
278	Diagnostic Urography.
279	Level II Angiography and Venography.
280	Level III Angiography and Venography.
283	Computed Tomography with Contrast.
284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast
333	Computed Tomography without Contrast followed by Contrast.
337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast.
375	Ancillary Outpatient Services When Patient Expires.
383	Cardiac Computed Tomographic Imaging.
388	Discography.
418	Insertion of Left Ventricular Pacing Elect.
442	Dosimetric Drug Administration.
653	Vascular Reconstruction/Fistula Repair with Device.
656	Transcatheter Placement of Intracoronary Drug-Eluting Stents.
662	CT Angiography.
668	Level I Angiography and Venography.
8006	CT and CTA with Contrast Composite.
8008	MRI and MRA with Contrast Composite.

5. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status

Under the CY 2010 OPPS, CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment into the payment for the associated service; or separate payment (individual APCs).

CMS is proposing to package items with a per day cost less than or equal to \$70 and identified items with a per day cost greater than \$70 as separately payable.

6. Proposed Packaging of Payment for Diagnostic Radiopharmaceuticals, Contrast Agents, and Implantable Biologicals (“Policy-Packaged” Drugs and Devices)

CMS is proposing to continue packaging payment for all contrast agents and diagnostic radiopharmaceuticals, collectively referred to as “policy-packaged” drugs, regardless of their per day costs. CMS is also proposing to continue to package the payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure and to package the payment for contrast agents into the payment of the associated echocardiography imaging procedure, regardless of whether the contrast agent met the OPPI drug packaging threshold.

CMS is proposing to continue to package payment for non-pass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, referred to as devices.

7. Proposed Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

For CY 2011, CMS is proposing to continue its CY 2010 pharmacy overhead adjustment methodology. CMS is proposing to redistribute \$150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with reported ASP data and to redistribute \$50 million from the cost of uncoded packaged drugs and biologicals without an ASP, for a total redistribution of \$200 million in drug cost from the cost of coded and uncoded packaged drugs to the cost of separately payable drugs. CMS estimates the overhead cost for coded packaged drugs to be \$438 million (\$593 million in total cost for coded packaged drugs and biologicals with a reported ASP less \$155 million in total ASP dollars for coded packaged drugs and biologicals with a reported ASP).

This would result in a proposed CY 2011 payment rate for separately payable drugs and biologicals of ASP+6 percent.

b. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

CMS is proposing to continue to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals under the ASP+X payment level established using the proposed pharmacy overhead adjustment based on a redistribution methodology to set payment for separately payable drugs and biologicals based on ASP information, if available, for a “patient ready” dose and updated on a quarterly basis for products for which manufacturers report ASP data.

8. Proposed Payment for Blood Clotting Factors

For CY 2011, CMS would pay for blood clotting factors at ASP+6 percent.

PROPOSED ESTIMATE of OPPS TRANSITIONAL PASS-THROUGH SPENDING for DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND DEVICES

CMS estimates that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2011 and those device categories, drugs, and non-implantable biologicals that first become eligible for pass-through payment during CY 2011 would be approximately \$86.9 million, which represents 0.20 percent of total OPPS projected total payments for CY 2011.

PROPOSED OPPS PAYMENT FOR BRACHYTHERAPY SOURCES

CMS is proposing to pay for brachytherapy sources at prospective payment rates based on their source-specific median costs for CY 2011. The separately payable brachytherapy source HCPCS codes, long descriptors, APCs, status indicators, and approximate APC median costs that are presented in the table below.

Proposed Separately Payable Brachytherapy Sources for CY 2011

CY 2010 HCPCS Codes	CY 2010 Long Descriptor	Proposed CY 2011 APC	Proposed CY 2011 SI	Proposed CY 2011 Approximate APC Median Cost
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie	2632	U	\$21
C1716	Brachytherapy source, nonstranded, Gold-198, per source	1716	U	\$188
C1717	Brachytherapy source, nonstranded, High Dose Rate Iridium-192, per source	1717	U	
C1719	Brachytherapy source, nonstranded, Non-High Dose Rate Iridium-192, per source	1719	U	
C2616	Brachytherapy source, non-stranded, Yttrium-90, per source	2616	U	\$17,108
C2634	Brachytherapy source, non-stranded, High Activity, Iodine-125, greater than 1.01 mCi (NIST), per source	2634	U	\$53
C2635	Brachytherapy source, non-stranded, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source	2635	U	\$30
C2636	Brachytherapy linear source, non-stranded, Palladium-103, per 1MM	2636	U	\$37
C2638	Brachytherapy source, stranded, Iodine-125, per source	2638	U	\$39
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	2639	U	\$37
C2640	Brachytherapy source, stranded, Palladium-103, per source	2640	U	\$65
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	2641	U	\$64
C2642	Brachytherapy source, stranded, Cesium-131, per source	2642	U	\$117
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	2643	U	\$64
C2698	Brachytherapy source, stranded, not otherwise specified, per source	2698	U	*\$39
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	2699	U	*\$23

*Median cost is that of the lowest cost stranded or non-stranded source upon which CY 2011 payment for the NOS HCPCS code would be based.

PROPOSED OPPS PAYMENT FOR DRUG ADMINISTRATION SERVICES

CMS is proposing to continue to use the full set of CPT codes for reporting drug administration services and to continue to pay separately for the same set of drug administration codes under the CY 2011 OPPS as were paid separate in the CY 2010 OPPS.

The proposal's Table 30 displays the proposed configuration of the five drug administration APCs for CY 2011 and the proposed median cost for each.

PROPOSED OPPTS PAYMENT FOR HOSPITAL OUTPATIENT VISITS

Currently, hospitals report visit HCPCS codes to describe three types of OPPTS services: clinic visits; emergency department visits; and critical care services.

CMS is proposing to continue to recognize those CPT and HCPCS codes describing clinic visits, Type A and Type B emergency department visits, critical care services, and trauma team activation provided in association with critical care services for CY 2011. The proposal's table 31 contains a list of the codes.

The table below displays the proposed median costs for each level of Type B emergency department visit APCs under the proposed CY 2011 configuration, compared to the proposed median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

Comparison of Proposed Median Costs for Clinic Visit APCs, Type B Emergency Department Visit HCPCS Codes, and Type A Emergency Department Visit HCPCS Codes

Visit Level	Proposed CY 2011 Clinic Visit Approximate APC Median Cost	Proposed CY 2011 Type B Emergency Department Approximate APC Median Cost	Proposed CY 2011 Type A Emergency Visit Approximate APC Median Cost
Level 1	\$52	\$44	\$54
Level 2	\$74	\$65	\$92
Level 3	\$95	\$104	\$146
Level 4	\$125	\$169	\$234
Level 5	\$172	\$270	\$347

PROPOSED PAYMENT FOR PARTIAL HOSPITALIZATION PROGRAM SERVICES (PHP)

Partial hospitalization is an intensive outpatient program of psychiatric services provided to patients as an alternative to inpatient psychiatric care for individuals who have an acute mental illness.

CMS is proposing to compute four separate PHP APC per diem payment rates, two for CMHC PHPs (for Level I and Level II services using only CMHC data) and two for hospital-based PHPs (Level I and Level II services using only hospital-based PHP data). CMS is requesting public comments on its proposal.

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS is proposing to remove the following codes from the inpatient only procedure list:

Procedures Proposed for Removal from the Inpatient List and Their Proposed APC Assignments for CY 2011

CPT Code	Long Descriptor	Proposed CY 2011 APC Assignment	Proposed CY 2011 Status Indicator
21193	Reconstruction of mandibular rami; horizontal, vertical, C, or L osteotomy; without bone graft	256	T
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft	256	T
25909	Amputation, forearm, through radius and ulna; reamputation	49	T

OPPS NONRECURRING TECHNICAL AND POLICY CHANGES AND CLARIFICATIONS

Proposed Policies for Supervision of Outpatient Therapeutic Services in Hospitals and CAHs

CMS says that it is proposing modest changes to its supervision policy for therapeutic services that reflect the agency’s continuing commitment to require direct supervision for the provision of therapeutic services in the hospital outpatient setting as a requirement for payment. CMS says further that it is proposing these changes for all hospitals, including CAHs, because it believes that “Medicare should purchase a basic quality of service for all Medicare beneficiaries.”

CMS is proposing to identify a limited set of services with a significant monitoring component that can extend for a sizable period of time, that are not surgical, and that typically have a low risk of complication after assessment at the beginning of the service, as “non-surgical extended duration therapeutic services.” CMS is proposing for these services that there would be a requirement for direct supervision for the initiation of the service followed by general supervision for the remainder of the service.

In summary, CMS is proposing to require direct supervision as defined in §410.27(a)(1)(iv) during an initiation period, followed by a minimum standard of general supervision as defined in §410.32(b)(3)(i) for the duration of the service, for a limited set of “non-surgical extended duration therapeutic services” identified in the proposal’s Table 37.

Proposed Payment for Preventive Services (PPPS)

CMS notes that it is specifying proposals to implement the coverage and payment provisions for PPPS in the CY 2011 Medicare Physician Fee Schedule (MPFS) proposed rule.

The following displays the HCPCS codes (paid under the OPPS or at reasonable cost) that CMS is proposing as “preventive services.” The table also provides the most recent USPSTF grade, if any, that is the basis for CMS’ proposed policy with regard to waiver of the deductible and coinsurance,

Proposed CY 2011 Deductible and Coinsurance for OPPTS Preventive Services

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
Initial Preventive Physical Examination (IPPE)	G0402	Initial preventive physical examination; face to face visits, services limited to new beneficiary during the first 12 months of Medicare enrollment	*Not Rated	Coinsurance applies and deductible is waived	Waived
	G0404	Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination		Not Waived	Not Waived
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)	G0389	Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) ultrasound screening	B	Coinsurance applies and deductible is waived	Waived
Screening Pap Test	Q0091	Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory	A	Coinsurance applies and deductible is waived	Waived
Screening Pelvic Exam	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination	A	Coinsurance applies and deductible is waived	Waived
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	B	Not Waived	Waived
Bone Mass Measurement	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77083	Radiographic absorptiometry (eg, photodensitometry, radiogrammetry), 1 or more sites		Not Waived	Waived
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method		Not Waived	Waived
Colorectal Cancer Screening	G0104	Colorectal cancer screening; flexible sigmoidoscopy	A	Coinsurance applies and deductible is waived	Waived
	G0105	Colorectal cancer screening; colonoscopy on individual at high risk		Coinsurance applies and deductible is	Waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
				waived	
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk		Coinsurance applies and deductible is waived	Waived
	G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	*Not Rated	Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived
	G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.		Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived
Prostate Cancer Screening	G0102	Prostate cancer screening; digital rectal examination	D	Not Waived	Not Waived
Glaucoma Screening	G0117	Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist	I	Not Waived	Not Waived
	G0118	Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist		Not Waived	Not Waived
Influenza Virus Vaccine	90655	Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use	B	Waived	Waived
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use		Waived	Waived
	90657	Influenza virus vaccine, split virus, when administered to children 6-35 months of age, for intramuscular use		Waived	Waived
	90658	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use		Waived	Waived
	90660	Influenza virus vaccine, live, for intranasal use		Waived	Waived
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use		Waived	Waived
	G0008	Administration of influenza virus vaccine		Waived	Waived
	G9141	Influenza a (h1n1) immunization administration (includes the physician counseling the patient/family)		Waived	Waived
	G9142	Influenza a (h1n1) vaccine, any route of administration		Waived	Waived
Pneumo-coccal Vaccine	90669	Pneumococcal conjugate vaccine, polyvalent, when administered to children younger than 5 years, for intramuscular use	B	Waived	Waived
	90670	Pneumococcal vacc, 13 val im		Waived	Waived
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use		Waived	Waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating ¹	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
	G0009	Administration of pneumococcal vaccine		Waived	Waived
Hepatitis B Vaccine	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use	A	Not Waived	Waived
	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use		Not Waived	Waived
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use		Not Waived	Waived
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use		Not Waived	Waived
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use		Not Waived	Waived

*This table lists only the preventive services, as defined by the Affordable Care Act, that are paid under the OPPS or at reasonable cost, and excludes preventive services such as screening mammography and cardiovascular screening blood tests that are paid under another fee schedule such as the MPFS or the Clinical Laboratory Fee Schedule. A listing of all services defined by the Affordable Care Act as preventive services can be found in the CY 2011 MPFS proposed rule. We note that any preventive service must meet the Medicare coverage guidelines for the service including being appropriate to the beneficiary to whom it is being furnished.

¹ U.S. Preventive Services Task Force Recommendations:

A -- The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. (The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.)

B -- The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. (The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.)

C -- The USPSTF makes no recommendation for or against routine provision of [the service]. (The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.)

D -- The USPSTF recommends against routinely providing [the service] to asymptomatic patients. (The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.)

I -- The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. (Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.)

Extension of Waiver of Deductible to Services Furnished in Connection with or in Relation to a Colorectal Cancer Screening Test That Becomes Diagnostic or Therapeutic

ACA Section 4104(c) waives the Part B deductible for colorectal cancer screening tests that become diagnostic regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.

CMS is proposing that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

CMS is proposing to implement this provision by creating a HCPCS modifier.

Payment for Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Services Furnished to Hospital Outpatients

CMS is clarifying that a CAH outpatient department is considered a covered setting for PR, CR and ICR programs, provided that the programs meet all of the regulatory requirements, including, but not limited to, direct supervision of all services by a physician.

Expansion of Multiple Procedure Reduction under the Medicare Physician Fee Schedule (MPFS) to Therapy Services

Hospitals are paid for outpatient physical therapy (which includes speech language pathology services) and outpatient occupational therapy under the Medicare Physician Fee Schedule (MPFS). CMS notes that it is proposing to revise the MPFS to apply a multiple procedure reduction to payment for all outpatient physical and occupational therapy services paid under the MPFS.

OPPS Payment Status and Comment Indicators

The proposal's section XIII contains a description of the various codes used to identify payment status and comment indicators. This material begins on page 456. For the most part, CMS is not proposing any changes to these codes.

PROPOSED UPDATE OF THE REVISED AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

ACA Section 3401(k) requires that, effective for CY 2011 and subsequent years, any annual update under the ASC payment system be reduced by a productivity adjustment, which is equal to the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Application of this productivity adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

The use of the productivity adjustment will affect most provider payment updates in the years ahead. Its introduction for ASC payment purposes represents the first application.

Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2010

Through the April 2010 ASC quarterly update (Transmittal 1943, CR 6866, dated April 6, 2010), CMS added six new drug and biological Level II HCPCS codes to the list of covered ancillary services. Through the July 2010 quarterly update (Transmittal 1984, Change Request 7008, dated June 11, 2010), CMS added seven new drug and biological Level II HCPCS codes. These items are listed in the tables below.

New Level II HCPCS Codes for Covered Ancillary Services Implemented in April 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator
C9258	Injection, telavancin, 10 mg	K2
C9259	Injection, pralatrexate, 1 mg	K2
C9260	Injection, ofatumumab, 10 mg	K2
C9261	Injection, ustekinumab, 1 mg	K2
C9262*	Fludarabine phosphate, oral, 1 mg	D5
C9263	Injection, ecallantide, 1 mg	K2

*Level II HCPCS code C9262 was deleted June 30, 2010, and replaced with Q2025 effective July 1, 2010. Because Addendum BB to this proposed rule is based on the codes effective in April, C9262 appears as having a proposed payment indicator of "K2."

New Level II HCPCS Codes for Covered Ancillary Services Implemented in July 2010

CY 2010 HCPCS Code	CY 2010 Descriptor	Proposed CY 2011 Payment Indicator	Proposed CY 2011 ASC Payment Rate*
C9264	Injection, tocilizumab, 1 mg	K2	\$3.52
C9265	Injection, romidepsin, 1 mg	K2	\$223.78
C9266	Injection, collagenase clostridium histolyticum, 0.1 mg	K2	\$382.78
C9267	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	K2	\$122.07
C9268	Capsaicin, patch, 10cm2	K2	\$11.18
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K2	\$4.35
Q2025**	Fludarabine phosphate oral, 10mg	K2	\$8.18

* Based on July 2010 ASP information.

**Level II HCPCS code Q2025 replaced C9262

Through the July 2010 quarterly update CR, CMS also implemented ASC payment for seven new Category III CPT codes and one new Level II HCPCS code as ASC covered surgical procedures, effective July 1, 2010. These codes are listed in the table below.

New Category III CPT Codes and Level II HCPCS Code Implemented in July 2010 as ASC Covered Surgical Procedures

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator**	Proposed CY 2011 ASC Payment Rate
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	R2*	\$26.78
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	\$231.07
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	G2	\$288.11
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)	G2	\$148.93
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	G2	\$288.11
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)	G2	\$148.93
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	R2*	\$26.78
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	\$177.60

* If designation is temporary.

**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, CMS will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

Proposed Update to the Lists of ASC Covered Surgical Procedures and Covered Ancillary Services

CMS is proposing to update the ASC list of covered surgical procedures by adding 5 procedures as shown in the table below.

Proposed New ASC Covered Surgical Procedures for CY 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 ASC Payment Indicator**
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck	G2
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel	P3
37206	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	P3
37210	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed (Do not report 52649 with 52000, 52276, 52281, 52601, 52647, 52648, 53020, 55250)	P3
50593	Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the procedure	P2

** (refer footnote above)

Proposed Covered Surgical Procedures Designated as Office-Based

CMS is proposing to designate 6 new procedures as office-based for CY 2011 as shown in the table below.

ASC Covered Surgical Procedures Proposed for Office-Based Designation for CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
20697	Application of multiplane (pins or wires in more than one plane), unilateral, external fixation with stereotactic computer-assisted adjustment (eg, spatial frame), including imaging; exchange (ie, removal and replacement of strut, each	G2	P2
27767	Closed treatment of posterior malleolus fracture; without manipulation	G2	P2
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel	X5	P3
37206	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	X5	P3
37210	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed (Do not report 52649 with 52000, 52276, 52281, 52601, 52647, 52648, 53020, 55250)	X5	P3
50593	Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the procedure	X5	P2

** (refer footnote above)

CMS is proposing to make permanent the office-based designations for the three procedures for CY 2011, shown below.

CY 2010 Temporarily Designated Office-Based ASC Covered Surgical Procedures Proposed for Permanent Office-Based Designation for CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
46930	Destruction of internal hemorrhoid(s) by thermal energy (e.g., infrared coagulation, cautery, radiofrequency)	P3*	P3
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (e.g., Morton's neuroma)	P3*	P3
64632	Destruction by neurolytic agent; plantar common digital nerve	P3*	P3

(refer footnotes above)

ASC Covered Surgical Procedures Designated as Device-Intensive

CMS is proposing to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive procedure payment methodology for CY 2011. The extensive list is shown in the proposal's table 47.

ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2010

CMS is proposing to remove three procedures from the OPPS inpatient list for CY 2010 as shown in the table below.

Procedures Proposed for Exclusion from the ASC List of Covered Procedures for CY 2011 that Are Proposed for Removal from the CY 2011 OPPS Inpatient List

CY 2010 HCPCS Code	CY 2010 Long Descriptor
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)
25909	Amputation, forearm, through radius and ulna; re-amputation

Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2011

CMS is proposing to update ASC payment rates for CY 2011 using the established rate calculation methodologies under §416.171. Under §416.171(c)(4), the transitional payment rates are no longer used for CY 2011 and subsequent calendar years.

Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

CMS is proposing to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2011. Refer to the rule's tables 50 and 51 for a description of the items.

Proposed Waiver of Coinsurance and Deductible for Certain Preventive Services

Similar to the OPPS waivers, discussed above, ASCs will also be subject to the same changes.

Intraocular Lenses (IOLs)

The proposed CY 2011 ASC payment rates for IOL insertion procedures are provided in the rule's Addendum AA.

Calculation of the ASC Conversion Factor and ASC Payment Rates

CMS says that for this proposed rule, for the 12-month period ending with the midpoint of CY 2011, the Secretary estimates that the CPI-U is 1.6 percent. The Secretary estimates that the productivity adjustment factor (MFP) is 1.6. Therefore, CMS is proposing to reduce the CPI-U of 1.6 percent by the MFP adjustment specific resulting in an MFP-adjusted CPI-U updated factor of 0 percent. Therefore, CMS is proposing to apply to the ASC conversion factor a 0 percent MFP-adjusted update.

For CY 2011, CMS is also proposing to adjust the CY 2010 ASC conversion factor (\$41.873) by the wage adjustment for budget neutrality of 1.0006 in addition to the MFP-adjusted update factor of 0 discussed above, which results in a proposed CY 2011 ASC conversion factor of **\$41.898**.

The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the CPI-U update factor as reduced by the productivity adjustment

REPORTING QUALITY DATA FOR ANNUAL PAYMENT RATE UPDATES

Proposed HOP QDRP Quality Measures for the CY 2012 Payment Determination

For the CY 2012 payment determination, CMS is proposing to retain the 11 existing HOP QDRP measures for the CY 2011 payment determination, to add one new structural measure, four new claims-based imaging efficiency measures, and one new chart-abstracted measure for the ED AMI population. Submission of data regarding the new structural measure would begin with January 1, 2011 discharges using a Web-based collection tool available on the QualityNet Web site.

CMS is proposing to calculate the four imaging measures using Medicare claims from calendar year 2010. Data collection for the chart-abstracted measure would begin with January 1, 2011 discharges, and data would be submitted quarterly beginning with the first quarter of 2011, as with all other chart-abstracted measures.

The complete list of 17 proposed measures for the CY 2012 payment determination is shown below.

Proposed HOP QDRP Measurement Set to be Used for the CY 2012 Payment Determination
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received within 60 minutes of arrival.*

* Proposed new measure for CY 2012 payment determination

Proposed HOP QDRP Quality Measures for the CY 2013 Payment Determination

CMS says it is proposing to add one structural measure to the HOP QDRP measurement set for the CY 2013 payment determination: ***Tracking Clinical Results between Visits***. EHRs enable providers to issue reminders when clinical results are not received within a predefined timeframe. This measure assesses the extent

to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies (including common preventive screenings) or patient referrals.

CMS is proposing to also add six new chart-abstracted measures to the HOP QDRP measurement set for the CY 2013 payment determination. The six new chart-abstracted measures are: 1) Median Time from ED Arrival to ED Departure for Discharged ED Patients, 2) Transition Record with Specified Elements Received by Discharged Patients, 3) Door to Diagnostic Evaluation by a Qualified Medical Professional, 4) ED-Median Time to Pain Management for Long Bone Fracture, 5) ED-Patient Left Before Being Seen, and 6) ED-Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation Within 45 minutes of Arrival.

Proposed HOP QDRP Quality Measures for the CY 2014 Payment Determination

CMS is proposing to adopt six new chart-abstracted measures for the CY 2014 payment determination. Five of the six measures are Diabetes Care measures for HOPDs, and one measure is an additional imaging efficiency measure. The six measures are: (1) Hemoglobin A1c Poor Control in Diabetic Patients; (2) Low Density Lipoprotein (LDL-C) Control in Diabetic Patients; (3) High Blood Pressure Control in Diabetic Patients; (4) Dilated Eye Exam in Diabetic Patients; (5) Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients; and (6) Exposure Time Reported for Procedures Using Fluoroscopy.

The complete list of 30 proposed measures for the CY 2014 payment determination is shown below.

Proposed HOP QDRP Measurement Set to be Used for the CY 2014 Payment Determination
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received within 60 minutes of arrival *
Tracking Clinical Results between Visits**
Median Time from ED Arrival to ED Departure for Discharged ED Patients**
Transition Record with Specified Elements Received by Discharged Patients**
Door to Diagnostic Evaluation by a Qualified Medical Professional**
ED- Median Time to Pain Management for Long Bone Fracture **
ED- Patient Left Before Being Seen**
ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **
Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetic Patients***
Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetic Patients***
Diabetes Mellitus: High Blood Pressure Control in Diabetic Patients***
Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients***
Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients***
Exposure Time Reported for Procedures Using Fluoroscopy***

* Proposed new measure for CY 2012 payment determination

** Proposed new measure for CY 2013 payment determination

*** Proposed new measure for CY 2014 payment determination

Proposed Changes Relating to Payments to Hospitals for Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs

ACA section 5503 provides for reductions in the statutory FTE resident caps under Medicare for certain hospitals and authorizes a “redistribution” of the FTE resident slots resulting from the reduction in the FTE resident caps to other hospitals.

CMS spends more than 150 pages describing in detail how it plans to implement this change.

Counting Resident Time in Non-provider Settings (ACA Section 5504)

Section 5504(a) allows a hospital to count all the time that a resident trains in a non-hospital site so long as the hospital incurs the costs of the residents' salaries and fringe benefits for the time. Section 5504(b) made similar changes for IME payment purposes.

For GME payments, the provision is effective for cost reporting periods beginning on or after July 1, 2010; for IME payments, the provision is effective for discharges occurring on or after July 1, 2010.

Section 5504(c) specifies that the amendments made by the provisions of sections 5504(a) and (b) shall not be applied in a manner that would require the reopening of settled cost reports except in limited circumstances.

Sections 5504(a) and (b) provide that when more than one hospital incurs these costs, either directly or through a third party, those hospitals "shall count a proportional share of the time, as determined by written agreement between the hospitals." CMS is proposing that hospitals must use some reasonable basis for establishing that proportion and has defined options.

CMS also is proposing that, to meet this documentation requirement, hospitals only need to maintain records of the total unweighted direct GME FTE count (before application of the direct GME FTE resident cap) of resident training time in non-hospital settings.

Counting Resident Time for Didactic and Scholarly Activities and Other Activities (ACA Section 5505)

This allows a hospital to count the time that residents spend training in an approved program in a "non-provider setting that is primarily engaged in furnishing patient care" for direct GME purposes, even if those residents are engaged in non-patient care activities, such as didactic conferences and seminars.

Section 5505(a) clarifies that hospitals may count residents' vacation, sick leave, and other approved leave time toward the hospitals' direct GME FTE resident count, so long as the leave does not prolong the total time the resident participates in his or her approved program.

Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes (ACA Section 5503)

Section 5503 provides for reductions in the statutory FTE resident caps for direct GME under Medicare for certain hospitals, and authorizes a "redistribution" to other hospitals of the estimated number of FTE resident slots resulting from the reductions.

For most hospitals, the permanent FTE cap is based on: (1) for an urban hospital, the number of unweighted allopathic and osteopathic FTE residents in the hospital's most recent cost reporting period ending on or before December 31, 1996 (the "1996 cap"); (2) for a rural hospital, 130 percent of the 1996 cap, and (3) other statutory allowed adjustments.

CMS is proposing, effective for portions of cost reporting periods beginning on or after July 1, 2011, it will permanently reduce a hospital's FTE resident cap by 65 percent of the difference between the reference resident level and the hospital's otherwise applicable resident limit for IME and direct GME respectively. For example, if a hospital's otherwise applicable resident limit for the reference period is 100, and its reference resident level is 80 FTEs, CMS will reduce the hospital's FTE resident cap by 13 FTEs $[0.65 (100 - 80)] = 13$.

CMS says that a rural hospital that has fewer than 250 beds in its most recent cost reporting period ending on or before March 23, 2010, would not be subject to a possible reduction to its FTE resident cap(s).

CMS says that to ensure that it is able to begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2011, it is proposing to set a date by which it will have determined a hospital's reference resident level and compared it to the hospital's otherwise applicable FTE resident cap(s) to estimate whether, and by how much, the hospital's FTE cap(s) would be reduced. CMS is proposing that this date be May 1, 2011, and that date would apply for all hospitals for purposes of determining an estimate of whether and by how much their FTE resident caps should be reduced.

CMS is proposing that all cap determinations made after July 1, 2011 and through December 2011 will be effective retroactively to July 1, 2011.

CMS notes that the ACA states that in no case will any hospital receive an FTE cap increase of more than 75 FTE positions as a result of the redistribution.

CMS is proposing that, in order to be eligible for consideration for an increase a hospital must first demonstrate the likelihood that it will be able to fill the slots within the first three cost reporting periods beginning on or after July 1, 2011, by meeting at least one of three criteria and by providing documentation that it meets the criterion in its application for an increase to its FTE resident cap:

In order for hospitals to be considered for increases to their FTE resident caps, CMS is proposing to require that each qualifying hospital submit a timely application by December 1, 2010. CMS has detailed specifics as part of this rule making.

CMS has outlined extensive steps it will use to evaluate any changes and redistribution of unused residency slots. The ACA mandates, in part, that preference be given to states that fall within the lowest quartile of resident-to-population ratios and to rural areas. CMS has provided that information in the proposal.

Comment

The subject of payments, counting of FTEs, and caps regarding GME and IME has been an ongoing complex subject. Teaching hospitals need to carefully analyze the material presented in this proposed rule.

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