PROPOSED RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; PHYSICIAN-OWNED HOSPITALS: DATA SOURCES FOR EXPANSION EXCEPTION; PHYSICIAN CERTIFICATION OF INPATIENT HOSPITAL SERVICES; MEDICARE ADVANTAGE ORGANIZATIONS AND PART D SPONSORS: APPEALS PROCESS FOR OVERPAYMENTS ASSOCIATED WITH SUBMITTED DATA

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) released the CY 2015[1] proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system, CMS-1613-P, on July 3, 2014; the rule was published in the July 14th *Federal Register*. CMS will consider comments received by 5:00 p.m. Eastern time on September 2nd. Comments can be filed electronically. A final rule will be published by November 1, with the policies generally taking effect on January 1, 2015.

The proposed rule updates payment policies under the OPPS and would apply to outpatient services provided to Medicare beneficiaries by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals as well as for partial hospitalization services in community mental health centers (CMHCs). The document also proposes updates and refinements to the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Other proposals would:

- modify the data sources used for expansion requests for physician owned hospitals under the physician self-referral regulations;
- change the underlying authority for the requirement of an admission order for all hospital inpatient admissions and changes to require physician certification for hospital inpatient admissions only for long-stay cases and outlier cases; and
- establish a three-level appeals process for Medicare Advantage (MA) organizations and Part D sponsors that would be applicable to CMS-identified overpayments associated with data submitted by these organizations and sponsors.

Details of the proposed rule are described in the summary below.

The Addenda containing relative weights, payment rates, wage indices and other payment information are available only on the CMS website. Addenda relating to the OPPS are available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-P.html.

[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

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SUMMARY OF PROPOSED RULE: MEDICARE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT FOR 2015

I. Overview

Estimated Impact of the Proposed Rule on Hospitals

CMS estimates policies in the proposed rule would increase expenditures under the OPPS for 2015 compared to 2014 by about $800 million excluding estimated changes in enrollment, utilization, and case-mix. Overall, the agency projects that OPPS expenditures will increase about $5.2 billion in 2015 compared to 2014 payments, with total OPPS expenditures of about $56.5 billion (including beneficiary cost-sharing) to the approximately 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and community mental health centers (CMHCs)).

The rule would increase payment rates under the OPPS by a fee schedule increase factor of 2.1 percent based on the proposed hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS)[2], minus the multifactor productivity (MFP) adjustment of 0.4 percentage points, and minus a 0.2 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 2.1 percent, while hospitals that do not will be subject to the statutory reduction of 2.0 percentage points in the update factor, resulting in a 0.1 percent update. The reduction in payments for hospitals not meeting the quality reporting requirements is implemented by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services. In 2014, 64 hospitals failed to satisfy reporting requirements and were subject to the reduction (46 hospitals chose not to participate in the quality reporting program and 18 hospitals reported but did not meet requirements).

The regulation's impact analysis models the effect of the annual update percentage and all policies in the proposed rule as well as the effect of other changes, including year-to-year variation in:

- outlier payments (an increase of 0.1 percent for the difference in estimated outlier payments between 2014 (0.9 percent) and 2015 (1.0 percent);
- estimated pass-through payments (a decrease of 0.01 percent for the proposed change in the pass-through estimate between 2014 and 2015; and
- application of the frontier State wage adjustment, which is not budget neutral and increases average payments 0.1 percent in 2015, the same as in 2014.

Changes to the APC weights, wage indices, continuation of a payment adjustment for rural sole community hospitals (SCHs), including essential access community hospitals (EACHs), and the payment adjustment for cancer hospitals do not affect aggregate OPPS payments because these changes are budget neutral.

[2] The OPPS percentage update is based on the IPPS market basket, as provided by statute.

The proposed rule's impact analysis projects that OPPS policies and rates for 2015 would increase payments by an average 2.2 percent for all hospitals and facilities. As shown in the table below and in the full impact analysis included in the appendix to this summary, the impact varies by major hospital category as well as across the more detailed breakouts shown in the full impact analysis. The variation arises primarily due to the differential effect of APC recalibration, which varies depending on a hospital's case-mix, and the updated wage index.

CMS estimates that urban hospitals would experience a decrease of -0.1 percent due to APC recalibration, while rural hospitals would experience an increase of 0.5 percent. The only rural bed size category losing is rural hospitals with 200 or more beds (average decrease of 0.6 percent). Urban hospitals by bed size have small gains (averaging up to 0.2 percent) except for the 874 midsize urban hospitals (200-500 beds), which show decreases averaging 0.2 to 0.3 percent. Major teaching hospitals would experience an average increase of 0.6 percent due to APC recalibration.

Recalibration would negatively affect lower volume hospitals, with losses in all categories by volume except urban hospitals with at least 90,000 billed lines and rural hospitals with at least 21,000 billed lines. CMHCs would see payments decrease 4.0 percent due to recalibration. Finally, the 561 hospitals without complete disproportionate share (DSH) numbers would see payments fall 6.6 percent due to recalibration with an overall impact of -4.5 percent considering all changes in the proposed rule. The hospitals for which complete DSH numbers are not available are primarily rehabilitation, psychiatric, and long-term care hospitals that are not paid under the IPPS.

Payment changes due to the updated wage index are small in most regions, with average increases or decreases of 0.5 percent or less (other than rural hospitals in the West South Central region having an average decrease of 0.6 percent). The notable exception is hospitals in the Pacific region, where urban gains average 1.0 percent and rural gains average 0.9 percent.

	APC Recalibration	**All Changes**
All Facilities	0.0%	2.2%
Urban	-0.1%	2.2%
Large Urban	-0.1%	2.3%
Other Urban	-0.1%	2.1%
Rural	0.5%	2.5%
Major Teaching	0.6%	2.9%
By type of ownership:		
Voluntary	0.1%	2.4%
Proprietary	-0.5%	1.7%
Government	0.0%	2.2%
CMHCs	-4.0%	-1.6%

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Weights

CMS proposes to recalibrate the APC relative payment weights for 2015 using the same basic methodology that was used for many years including 2014. The 2015 rule continues changes in the methodology used to calculate the relative weights for 2014, including the use of distinct cost-to-charge ratios (CCRs) for cardiac catheterization, CT scan, and MRI to calculate costs from billed charges. As discussed in succeeding sections, the proposed rule would make additional changes such as expanded packaging and establishing comprehensive APCs for 28 device-dependent services for which a single payment would be made for the comprehensive package of services incorporating all OPPS-payable charges on the claim.

For the 2015 proposed rule, CMS uses hospital claims for services furnished from January 1, 2013 through December 31, 2013 (and processed before December 31, 2013). Cost data are from the most recent cost reports, in most cases for cost reporting periods beginning in 2012. In a separate document available on the CMS website, CMS provides a detailed description of the claims preparation process and an accounting of claims used in the development of the proposed payment rates, including the number of claims available at each stage of the process: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1613-P-claims-accounting-narrative.pdf

Continuing the methodology used for many years, the proposed rule calculates the cost of each procedure only from single procedure claims and "pseudo" single claims created from bills containing multiple codes. As for years, CMS proposes to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to "pseudo" single procedure claims. Through bypassing specified codes that CMS believes do not have significant packaged costs, it is able to use more data from multiple procedure claims.

The list of codes on the bypass list is reviewed annually and open to comment.

- Table 1 in the proposed rule (pages 62-69 of display copy) contains the list of codes proposed for removal in creating the 2015 bypass list from the 2014 list because these codes either were deleted from the HCPCS before 2013 (and therefore were not covered OPD services in 2013) or are not separately payable codes under the proposed 2015 OPPS, including codes that would be affected by the proposed 2015 OPPS expanded packaging policy described in section II.A.3 below.
- The proposed rule considered codes for addition to the 2015 bypass list using empirical criteria unchanged from prior years; the packaged cost threshold used in the bypass criteria is indexed but after rounding remains at $55 for 2015.

For 2015, CMS proposes to bypass the 227 HCPCS codes that are identified in Addendum N to the proposed rule (which is available from the CMS website, http://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1613-P-Addenda.zip). The process used by CMS to split claims is described in detail in the proposed rule (pages 87-94 of display copy). This methodology enabled CMS to create approximately 46 million "pseudo" single procedure

claims, including multiple imaging composite "single session" bills, to add to the approximately 48 million "natural" single procedure claims for setting rates for the proposed rule.

1. Calculation and use of cost-to-charge ratios; packaged revenue codes

To convert charges on the outpatient claims to estimated costs, CMS multiplies billed charges by the cost-to-charge ratio (CCR) associated with each revenue code. To calculate CCRs for 2015, CMS employs the same basic approach used since APC rate construction for 2007. CMS applies the appropriate hospital-specific CCR to the hospital's charges at the most detailed level possible based on a revenue code-to-cost center crosswalk containing a hierarchy, for each revenue code, of CCRs for estimating costs from charges. The current crosswalk is available for review and continuous comment on the CMS website (http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files-Items/2014-Annual-Policy-Files.html?DLPage=1&DLSort=0&DLSortDir=ascending).

Table 4 of the proposed rule (pages 96-98 of display copy) identifies the revenue codes for which CMS packages charges when the revenue code is reported on the claim without HCPCS codes. CMS believes that the charges reported under these revenue codes continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes.

2. Charge compression

To address the continuing issue of charge compression and the resulting distortion of relative weights, for 2014 CMS finalized a proposal to calculate OPPS relative payment weights using distinct CCRs for cardiac catheterization, CT scan, and MRI and to continue using the distinct CCR for implantable medical devices which was first used for 2013. CMS proposes to continue using these new CCRs in 2015, including the policy finalized for the 2014 OPPS to exclude claims from providers that use a cost allocation method of "square feet" in calculating CCRs for CT and MRI. The affected APCs and the impact of the exclusion on their estimated cost is identified in Table 4 below. CMS intends to continue this exclusion through 2017 to allow hospitals sufficient time to use one of the more accurate cost allocation methods. Beginning in 2018, CMS will estimate the CT and MRI APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed.

TABLE 3.—PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCs WHEN EXCLUDING CLAIMS FROM PROVIDERS USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

Proposed 2015 APC	Proposed 2015 APC Descriptor	Percent Change
0283	Computed Tomography with Contrast	9.3%
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	4.2%
0331	Combined Abdomen and Pelvis CT without Contrast	12.0%

Proposed 2015 APC	Proposed 2015 APC Descriptor	Percent Change
0332	Computed Tomography without Contrast	14.1%
0333	Computed Tomography without Contrast followed by Contrast	12.1%
0334	Combined Abdomen and Pelvis CT with Contrast	10.1%
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.4%
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast f	6.0%
0383	Cardiac Computed Tomographic Imaging	4.3%
0662	CT Angiography	10.3%
8005	CT and CTA without Contrast Composite	12.7%
8006	CT and CTA with Contrast Composite	9.2%
8007	MRI and MRA without Contrast Composite	6.3%
8008	MRI and MRA with Contrast Composite	6.3%

3. Budget neutral weight scaler

To make the APC reclassification and recalibration changes budget neutral, CMS compares the estimated aggregate weight calculated using the proposed 2015 unscaled relative weights and service volume in the 2013 claims data to the aggregate weight using the final 2014 scaled relative weights and the service volume using the same 2013 claims data. Based on this comparison, the proposed rule unscaled APC payment weights were adjusted by a weight scaler of 1.3220. The effect of the adjustment is to increase the unscaled weights by about 32.2 percent. CMS continues to include payments to CMHCs in the budget neutrality calculation for 2015 as well as payments for "specified covered outpatient drugs" (SCODs) and brachytherapy sources; these policies are the same as for 2014.

In calculating the budget neutrality scaler, the proposed rule also adjusts for the payments that would previously have been made through the clinical laboratory fee schedule absent the 2014 final rule OPPS packaging policy for clinical laboratory tests. Thus, the final rule incorporates the estimated relative payment weights from those services in calculating the 2014 estimated OPPS aggregate weight which is used as the basis for comparison. These relative payment weights are based on payments for outpatient laboratory tests paid at the clinical laboratory fee schedule rates.

4. Recommendations of the APC Panel Regarding Data Development

In the proposed rule, CMS accepts all three recommendations pertaining to data development made by the APC Panel at its March 2014 meeting: that the work of the APC Panel's Data Subcommittee continue; that CMS provide the Panel with a list of APCs for which costs

fluctuate by more than 10 percent; and that CMS provide the Panel with data on comprehensive APCs as well as the effect of conditional packaging on visit codes.

5. Calculation of single procedure APC criteria-based costs

The calculation of median costs for some APCs follows various special rules, as described below.

Device-dependent APCs. Device-dependent APCs refer to HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. From 2005-2013, CMS' methodology for calculating median or mean costs of device-dependent APCs excluded claims that failed specified procedure-to-device and device-to-procedure edits. The edits aimed to ensure that the claims data used for rate-setting reflected the full cost of the required device.

For 2014, CMS finalized a proposal to implement comprehensive APCs for 29 of the 39 device-dependent APCs in 2015 and to eliminate procedure-to-device and device-to-procedure edits for all APCs also beginning in 2015. Many commenters had urged CMS to maintain the edits, but it concluded that the edits are unnecessary since hospitals have had several years of experience reporting procedures involving implantable devices and fully reporting device use and the charges and costs of those devices on their claims.

For 2015, CMS again proposes to eliminate procedure-to-device edits and device-to-procedure edits for any APC. CMS notes that hospitals are expected to adhere to the guidelines of correct coding and append the correct device code to the claim, when applicable. Claims would no longer be returned to providers when specific procedure and device code pairings do not appear on a claim, thus, CMS notes, eliminating a burden for both hospitals and Medicare contractors.

The proposed 2015 comprehensive APC policy (discussed in section II.A.6 below) would consolidate and restructure all of the 39 current device-dependent APCs into 26 (of the total 28) comprehensive APCs, thus eliminating use of device-dependent APCs beginning in 2015. With respect to elimination of the procedure-to-device and device-to-procedure edits, CMS notes that in addition to the experience that hospitals have in coding and reporting these claims fully, the comprehensive APCs will reliably reflect the cost of the more costly devices if their cost is included anywhere on the claim.

Nevertheless, considering stakeholders' past concerns, CMS proposes to create claims processing edits that require *any* of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any one of the 26 proposed comprehensive APCs listed in Table 5 below is reported on the claim. Table 5 provides a list of the 26 proposed 2015 comprehensive APCs, which CMS previously recognized as device-dependent APCs.

TABLE 5.—PROPOSED APCs THAT WOULD REQUIRE A DEVICE CODE TO BE REPORTED ON A CLAIM WHEN A PROCEDURE ASSIGNED TO ONE OF THESE APCs IS REPORTED

APC	APC Title
0039	Level III Neurostimulator
0061	Level II Neurostimulator
0083	Level I Endovascular
0084	Level I EP
0085	Level II EP
0086	Level III EP
0089	Level III Pacemaker
0090	Level II Pacemaker
0107	Level I ICD
0108	Level II ICD
0202	Level V Female Reproductive
0227	Implantation of Drug Infusion
0229	Level II Endovascular
0259	Level VII ENT Procedures
0293	Level IV Intraocular
0318	Level IV Neurostimulator
0319	Level III Endovascular
0384	GI Procedures with Stents
0385	Level I Urogenital
0386	Level II Urogenital
0425	Level V Musculoskeletal
0427	Level II Tube/Catheter
0622	Level II Vascular Access
0648	Level IV Breast Surgery
0652	Insertion of IP/Pl. Cath.
0655	Level IV Pacemaker

Blood and blood products. The 2015 proposed rule would continue, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology that has been used unchanged since 2005. Specifically, CMS proposes to calculate the costs upon which the 2015 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

CMS further proposes to include blood and blood products in the comprehensive APCs, which would provide all-inclusive payments covering all services on the claim. When blood and blood products appear on claims with services assigned to the comprehensive APCs, their costs would be included in calculating the overall costs of these comprehensive APCs, with such costs determined based on the blood-specific CCR methodology. Because the costs of blood and blood products will be reflected in the overall costs of the comprehensive APCs – and thus the payment rates of the comprehensive APCs – beginning in 2015, no separate payment would be made for blood and blood products when they appear on the same claims as services assigned to the comprehensive APCs.

Brachytherapy source payment. The statute requires the Secretary to create additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) – i.e., "brachytherapy sources" – separately from other services or groups of services, in order to reflect the number, isotope, and radioactive intensity of the brachytherapy sources furnished. In addition, separate groups are required for palladium-103 and iodine-125 sources, and for stranded and non-stranded devices. Since 2010, CMS has used the standard OPPS prospective payment methodology for brachytherapy sources, with payment rates based on source-specific costs.

For 2015, CMS proposes to continue to set the payment rates for brachytherapy sources using the standard prospective payment methodology combined with the other payment policies for brachytherapy sources that CMS finalized and first implemented in the 2010 OPPS final rule. CMS invites public comments on the proposed policy and requests recommendations for new HCPCS codes to describe new brachytherapy sources consisting of a radioactive isotope, including a detailed rationale to support recommended new sources. Recommendations should be directed to the Division of Outpatient Care, Mail Stop C4-05-17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

CMS will continue to add new brachytherapy source codes and descriptors to its payment systems on a quarterly basis through program transmittals.

6. Establishment of comprehensive APCs

In the 2014 final OPPS rule, CMS finalized a proposal, effective January 1, 2015, to create 29 comprehensive APCs to replace 29 of the 39 existing device-dependent APCs with new APCs that would prospectively pay for 167 of the most costly device-dependent services. A comprehensive APC (C-APC) is a new classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS calculates a single payment for the entire hospital stay, defined by a single claim, regardless of the date of service span.

One important element of the C-APC proposal is that it revises the definition of OPPS services and expands the scope of services covered under the OPPS, as described below. For example, durable medical equipment, laboratory services and therapy services included on the claim with the primary service are considered adjunctive services that support the primary service and therefore can be considered OPPS services. Their costs are included in determining the relative

weights for the comprehensive APCs and the single payment for the C-APC constitutes payment for them; these services will not be billed and paid under the separate fee schedules as they are currently.

CMS believes that comprehensive APCs would improve the validity of payments to more accurately reflect costs; improve transparency for the beneficiary, physicians, and hospitals by creating a common reference point with a similar meaning for each stakeholder; reduce complexity and administrative burden; and increase flexibility for hospitals to develop increased efficiencies in the delivery of quality care. They also would reduce beneficiary copayments for most comprehensive APC services because the beneficiary will owe a single coinsurance amount for the comprehensive APC and no coinsurance for the individual services included in the comprehensive APC. In addition, the single coinsurance amount often would be capped by the statutory requirement that the beneficiary copayment cannot exceed the inpatient hospital deductible.

CMS received a large number of comments on the 2014 proposed rule C-APC policy and made numerous changes in the final rule, including creation of a complexity adjustment. Considering the overall complexity of the new policy and the introduction of complexity adjustments in the final rule, CMS modeled the dynamics of the policy as if we were implementing it for 2014, but delayed the effective date until January 1, 2015, to allow additional time for analysis, opportunity for public comment, and systems preparation.

The 2015 proposed rule reviews the policies finalized in the 2014 final rule; describes the proposed policy for 2015, which includes several clarifications and proposed modifications in response to public comments; and summarizes and responds to the public comments.

Proposed 2015 Policy for Comprehensive APCs

The basic steps for calculating the comprehensive APC payments are largely unchanged from those described in the 2014 final rule, except for the complexity adjustment criteria. The basic steps, which indicate both how the rates for the proposed rule were determined and how C-APC cases would be identified and paid under the proposed policy, are described below. For purpose of the C-APC policy, CMS defines a clinical family of comprehensive APCs as a set of clinically related comprehensive APCs that represent different resource levels of clinically comparable services.

Step 1: Select primary ("J1") services.

CMS selects HCPCS codes for primary services to be assigned to a C-APC and designates them by status indicator "J1" as listed in Addendum J and Addendum B to the proposed rule. To identify services for the C-APCs for the 2014 final rule, CMS ranked all APCs by 2012 costs and identified the APCs where it believed that the device-dependent APC was characterized by a costly primary service with relatively small cost contributions from adjunctive services. In the 2014 final rule, CMS clarified that there are 136 codes in the 2012 claims data used to set the 2014 payment rates, but due to coding changes, there are 148 codes in 2013 and if the policy

were being implemented in 2014, there would be 167 primary service codes associated with the 29 comprehensive APCs.

In a change from the 2014 final rule, the 2015 proposed rule would package all add-on codes and assign them status indicator "N" (unconditionally packaged), rather than assigning all add-on codes to status indicator J1. CMS further proposes to evaluate a limited set of add-on codes assigned to the current device-dependent APCs to consider whether a complexity adjustment is appropriate when these add-on codes are reported in conjunction with a primary service.

Step 2: Definition of the payment package (comprehensive service).

The C-APC packaging policy "packages" payment for all items and services typically packaged under the OPPS, but also packages payment for other items and services that are not typically packaged under the OPPS, except in the context of comprehensive APC payments. CMS proposes to define the C-APC payment packaging policy as including all covered OPD services on a hospital Medicare Part B claim reporting a primary service that is assigned to status indicator J1, excluding services that cannot be covered OPD services or that cannot by statute be paid under the OPPS. The proposed rule would consider the services in the list below to be typically integral, ancillary, supportive, dependent, or adjunctive to the primary service when provided during the delivery of the comprehensive service.

- diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure;
- visits and evaluations performed in association with the procedure;
- uncoded services and supplies used during the service;
- outpatient department services that are similar to therapy and delivered either by therapists or non-therapists as part of the comprehensive service;
- durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service;
- all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as packaged supplies; and
- any other components reported by HCPCS codes that are provided during the comprehensive service, except excluded services described below.

CMS noted in the 2014 OPPS final rule that it did not model a budget neutrality adjustment for newly included services that would otherwise be paid under non-OPPS fee schedules (for example, therapy and DMEPOS). The 2015 proposed rule includes these new costs (which CMS states are very low) in the proposed rule's annual adjustment for 2015 budget neutrality (see section XXI below).

The services that are excluded from the C-APC payment packaging policy are shown in table 6 below.

TABLE 6.—PROPOSED COMPREHENSIVE APC PAYMENT BUNDLING POLICY EXCLUSIONS FOR 2015

Ambulance services
Brachytherapy
Diagnostic and mammography screenings
Physical therapy, speech-language pathology and occupational therapy services - Therapy services reported on a separate facility claim for recurring services
Pass-through drugs, biologicals and devices
Preventive services defined in 42 CFR 410.2: • Annual wellness visits providing personalized prevention plan services • Initial preventive physical examinations • Pneumococcal, influenza, and hepatitis B vaccines and administrations • Mammography Screenings • Pap smear screenings and pelvic examination screenings • Prostate cancer screening tests • Colorectal cancer screening tests • Diabetes outpatient self-management training services • Bone mass measurements • Glaucoma screenings • Medical nutrition therapy services • Cardiovascular screening blood tests • Diabetes screening tests • Ultrasound screenings for abdominal aortic aneurysm • Additional preventive services (as defined in section 1861(ddd)(1) of the Act)[3]
Self-administered drugs - Drugs that are usually self-administered and do not function as supplies in the provision of the comprehensive service
Services assigned to OPPS status indicator "F" (Certain CRNA services, Hepatitis B vaccines and corneal tissue acquisition)
Services assigned to OPPS status indicator "L" (Influenza and pneumococcal pneumonia vaccines)
Certain Part B inpatient services – Ancillary Part B inpatient services payable under Part B when the primary "J1" service for the claim is not a payable Part B inpatient service (for example, exhausted Medicare Part A benefits, beneficiaries with Part B only)

The proposed rule notes that one preventive service (HCPCS code G0102 (Prostate cancer screening; digital rectal examination)) is proposed for continued packaging under the OPPS in 2015, both broadly and in the context of comprehensive services. Currently, this HCPCS code is packaged because it is included in evaluation and management services. Beneficiary cost-sharing is not waived for the service described by HCPCS code G0102.

[3] CMS defined and discussed these services in detail for hospital billing purposes in the 2011 OPPS final rule pursuant to coverage and payment provisions in the Affordable Care Act.

Step 3: Ranking of primary services initial comprehensive APC assignments.

(i) CMS designates each hospital Medicare Part B claim reporting a single unit of a single primary service assigned to status indicator "J1" as a single major procedure claim. These represent about 80 percent of the 2013 "J1" claims).
(ii) The proposed rule establishes a ranking of each status indicator J1 primary service (single unit only) based on the comprehensive geometric mean costs (i.e., including all items and services in the C-APC payment bundle). Add-on codes are included as packaged services rather than being treated as separate J1 services as they were in the 2014 final rule.
(iii) For the approximately 20 percent of claims reporting more than one primary service (including ones with multiple units) assigned to status indicator J1, CMS would designate one of the J1 services as the primary service for the claim based on the cost-based ranking and then would assign all of the multiple J1 procedures on the claim (including all packaged services) to the C-APC to which the primary service is assigned.
(iv) If the multiple J1 services map to different C-APCs, CMS designates the J1 service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the multiple J1 services map to the same C-APC, CMS uses a HCPCS-level comparison to identify the most costly primary service for that claim. When no claims data are available, CMS models a HCPCS-level geometric mean cost for the sole purpose of appropriately assigning the primary service reported on a claim.
(v) The C-APC assignment of each J1 procedure is confirmed by verifying that the APC assignment remains appropriate when considering the clinical similarity.

Step 4 - Complexity adjustments and determination of final comprehensive APC groupings.

In response to the 2014 OPPS/ASC final rule with comment, several commenters recommended alternative complexity adjustment criteria. For 2015, CMS proposes less stringent thresholds for both frequency and cost to be used to identify code combinations for potential complexity adjustments, as described in the proposed policy below.

(i) Certain combinations of comprehensive services would be recognized for higher payment using complexity adjustments. Qualifying J1 service code combinations or code combinations of a J1 services and certain add-on codes would be split from the originating C-APC (i.e., the C-APC to which the designated primary service is first assigned) to a higher paying C-APC in the same clinical family of comprehensive APCs.
(ii) CMS proposes to evaluate each single primary service designated for a claim in combination with each of the other procedure codes reported on the claim assigned to status indicator J1 (or certain add-on codes) to determine if they meet the complexity adjustment criteria.
(iii) CMS would consider the code combination to be a complex, costly form or version of the primary service when the following criteria are satisfied:
    a. Frequency of 25 or more claims reporting the code combination (i.e., the frequency threshold); and
    b. Violation of the 2 times rule, that is, the comprehensive geometric mean cost of the complex code combination exceeds the comprehensive geometric mean cost

of the lowest significant HCPCS code assigned to the comprehensive APC by more than 2 times (the cost threshold). ("Significant" means frequency >1000 claims, or frequency > 99 claims and contributing at least 2 percent of the single major claims used to establish the originating comprehensive APC's geometric mean cost, including the claims reporting the complex code pair).

Illustration of complexity criteria. Consider CPT code 33208 as the primary service reported in conjunction with HCPCS code C9600. CPT code 33208 is assigned to APC 0089. The lowest cost significant procedure assigned to APC 0089 is CPT code 33228, with a geometric mean cost of $8,669. There are 43 instances of the code combination of CPT code 33208 and HCPCS code C9600 in the 2013 claims data with a geometric mean cost of $21,914, which exceeds the geometric mean cost of CPT code 33228 ($8,669) by greater than two times ($21,914 >$17,338). Therefore, the code combination of CPT code 33208 and HCPCS code C9600 is assigned through a complexity adjustment to APC 0655, which is the next higher cost APC in the AIDCP clinical family of comprehensive APCs.

(iv) For code combinations satisfying these criteria, CMS proposes to move them to the next higher cost C-APC within the clinical family, unless the APC reassignment is not clinically appropriate, the reassignment would create a 2 times rule violation in the receiving APC, or the primary service is already assigned to the highest cost APC within the C-APC clinical family. The proposed rule would not create new APCs with a geometric mean cost that is higher than the highest cost C-APC in a clinical family just to accommodate potential complexity adjustments.

(v) *Complexity Test for Eligible Add-On Codes.* CMS proposes to evaluate add-on codes that are assigned to the current device-dependent APCs listed in Table 5 of the proposed rule (and included on page 11 above) for a possible complexity adjustment when they are reported with a designated primary J1 service. CMS limits the complexity evaluation of add-on codes to codes which are assigned to the current device-dependent APCs these represent procedure codes that may include additional medical device costs that would result in significantly more complex and costly procedures. To determine which combinations of primary service and add-on codes qualify for a complexity adjustment, the proposed rule uses the same criteria as (iii) above, testing claims reporting one unit of a single primary J1 service and any number of units of a single add-on code.

The proposed policies would result in 52 complexity adjustments, as listed in Addendum J to the proposed rule (and an attachment to this summary). Addendum J provides a list of code combinations (including add-on codes) qualifying for a complexity adjustment, with the resulting APC assignment; a breakdown of cost statistics for each code combination (including each primary code and add-on code combination); and summary cost statistics for each of the code combinations proposed to be reassigned under a given primary code[4].

[4] Addendum J does not provide cost statistics for primary J1 procedures including all combinations involving the procedure; the combined statistics reflecting all proposed reassigned complex code combinations are shown in the HCPCS cost statistics file. In that file, these aggregated codes are designated by an alphanumeric code with the last 4 digits of the primary J1 service followed by "A" (indicating adjustment).

CMS does not propose a complexity adjustment for one primary service and add-on code combination (CPT code 37225 and 37233) that satisfies the frequency and cost criteria because it believes that these claims are miscoded. Of the 35 qualifying claims reporting this code combination, only three claims contained the appropriate base code (CPT code 37228) for CPT add-on code 37233.

Additional Proposed Comprehensive APCs

For 2015, CMS proposes to:

- restructure and consolidate the current device-dependent APCs including some procedure code reassignments to improve clinical and resource homogeneity;
- create two new comprehensive APCs, C-APC 0067 for single-session cranial stereotactic radiosurgery (SRS) and C-APC 0351 for intraocular telescope implantation; and it proposes to reassign CPT codes 77424 and 77425 that describe intraoperative radiation therapy treatment (IORT) to C-APC 0648 (Level IV Breast and Skin Surgery); and
- convert all device-dependent APCs to C-APCs (including those that were not included in the 2014 final rule).

Proposed Reconfiguration and Restructuring of the Comprehensive APCs

CMS proposes to reorganize, combine, and restructure the comprehensive APCs to improve resource and clinical homogeneity among the services assigned to certain comprehensive APCs and to eliminate APCs for clinically similar services, but with overlapping geometric mean costs. The following bullets summarize the changes:

- *Endovascular clinical family (renamed Vascular Procedures, VASCX).* Combine C-APCs 0082, 0083, 0104, 0229, 0319, and 0656 as illustrated in 2014 final rule to form three proposed levels of comprehensive endovascular procedure APCs: C-APC 0083 (Level I Endovascular Procedures); C-APC 0229 (Level II Endovascular Procedures); and C-APC 0319 (Level IV Endovascular Procedures).
- *Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices (AICDP).* Combine C-APCs 0089, 0090, 0106, 0654, 0655, and 0680 as illustrated for 2014 to form three proposed levels of C-APCs within a broader series of APCs for pacemaker implantation and similar procedures: APC 0105 (Level I Pacemaker and Similar Procedures), a non-comprehensive APC; C-APC 0090 (Level II Pacemaker and Similar Procedures); C-APC 0089 (Level III Pacemaker and Similar Procedures); and C-APC 0655 (Level IV Pacemaker and Similar Procedures).
- *Event Monitoring.* Delete this clinical family, which only had one C-APC (C-APC 0680 (Insertion of Patient Activated Event)) with a single CPT code 33282 as illustrated for 2014. Reassign CPT code 33282 to C-APC 0090, which contains clinically similar procedures.
- *Urogenital family.* Employ two levels instead of three levels for Urogenital Procedures and reassign several codes from APC 0195 to C-APC 0202 (Level V Female Reproductive Procedures).

- *Orthopedic Surgery* (*renamed arthroplasty family).* Reassign several codes from APC 0052 to C-APC 0425, renamed to "Level V Musculoskeletal Procedures Except Hand and Foot."
- *Electrophysiologic procedures.* Employ three levels, using the current inactive APC "0086" instead of APC 0444, to have consecutive APC grouping numbers for this clinical family and renaming APC 0086 "Level III Electrophysiologic Procedures." Replace composite APC 8000 with proposed C-APC 0086 as illustrated in the 2014 final rule.
- *New clinical families.* Establish three new clinical families: Gastrointestinal Procedures (GIXXX) for gastrointestinal stents, Tube/Catheter Changes (CATHX) for insertion of various catheters, and Radiation Oncology (RADTX), which would include C-APC 0067 for single session cranial SRS.

Table 7 below lists the 28 APCs proposed under the 2015 comprehensive APC policy.

TABLE 7—2015 PROPOSED COMPREHENSIVE APCs

Clinical Family	Proposed 2015 C-APC	APC Title	Proposed 2015 APC Geometric Mean Cost
AICDP	0090	Level II Pacemaker and Similar Procedures	$6,961.45
AICDP	0089	Level III Pacemaker and Similar Procedures	$9,923.94
AICDP	0655	Level IV Pacemaker and Similar Procedures	$17,313.08
AICDP	0107	Level I ICD and Similar Procedures	$24,167.80
AICDP	0108	Level II ICD and Similar Procedures	$32,085.90
BREAS	0648	Level IV Breast and Skin Surgery	$7,674.20
CATHX	0427	Level II Tube or Catheter Changes or Repositioning	$1,522.15
CATHX	0652	Insertion of Intraperitoneal and Pleural Catheters	$2,764.85
ENTXX	0259	Level VII ENT Procedures	$31,273.34
EPHYS	0084	Level I Electrophysiologic Procedures	$922.84
EPHYS	0085	Level II Electrophysiologic Procedures	$4,807.69
EPHYS	0086	Level III Electrophysiologic Procedures	$14,835.04
EYEXX	0293	Level IV Intraocular Procedures	$9,049.66
EYEXX	0351	Level V Intraocular Procedures	$21,056.40
GIXXX	0384	GI Procedures with Stents	$3,307.90
NSTIM	0061	Level II Neurostimulator & Related Procedures	$5,582.10
NSTIM	0039	Level III Neurostimulator & Related Procedures	$17,697.46
NSTIM	0318	Level IV Neurostimulator & Related Procedures	$27,283.10
ORTHO	0425	Level V Musculoskeletal Procedures Except Hand and Foot	$10,846.49
PUMPS	0227	Implantation of Drug Infusion Device	$16,419.95
RADTX	0067	Single Session Cranial Stereotactic Radiosurgery	$10,227.12
UROGN	0202	Level V Female Reproductive Procedures	$4,571.06

Clinical Family	Proposed 2015 C-APC	APC Title	Proposed 2015 APC Geometric Mean Cost
UROGN	0385	Level I Urogenital Procedures	$8,019.38
UROGN	0386	Level II Urogenital Procedures	$14,549.04
VASCX	0083	Level I Endovascular Procedures	$4,537.95
VASCX	0229	Level II Endovascular Procedures	$9,997.53
VASCX	0319	Level III Endovascular Procedures	$15,452.77
VASCX	0622	Level II Vascular Access Procedures Catheters	$2,635.35

Clinical Family Descriptor Key:
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices
BREAS = Breast Surgery
CATHX = Tube/Catheter Changes
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EYEXX = Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
UROGN = Urogenital Procedures
VASCX = Vascular Procedures

Response to Public Comments

CMS received nine public comments from device manufacturers, the hospital community, and others on the 2014 OPPS/ASC final rule period concerning the policy for C-APCs. Commenters generally supported broader payment bundles provided they are appropriately and accurately structured and provide adequate payment. Most comments addressed specific devices or drugs, or a specific clinical family of C-APCs. The 2015 proposed rule includes detailed responses to these comments and notes where changes were made in the C-APC policy for 2015. All of these changes have been previously discussed in this section.

7. Calculation of composite APC criteria-based costs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS does not propose new composite APCs for 2015, but proposes to continue composite policies for extended assessment and management services, low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services.

For 2015, CMS proposes to discontinue the composite APC payment policies for cardiac electrophysiologic evaluation and ablation services (APC 8000) and to pay for these services

through comprehensive APC 0086 (Level III Electrophysiologic Procedures), as discussed in the previous section of this summary. APC 8000 would be deleted for 2015.

Similarly, for 2015, CMS proposes to implement the policy which it finalized in the 2014 OPPS final rule to pay for cardiac resynchronization therapy services through comprehensive APC 0108 (proposed to be renamed "Level II ICD and Similar Procedures").

1. Extended Assessment and Management Composite APCs (APCs 8002 and 8003)

For 2014, CMS established a new single composite APC, entitled "Extended Assessment and Management (EAM) Composite" (APC 8009), to provide payment for all qualifying extended assessment and management encounters rather than recognizing two levels of EAM Composite APCs as in prior years. The change conformed the extended assessment and management composite APC to the new single level code for clinic visits implemented in 2014. Prior to the 2014 adoption of a single clinic visit code irrespective of level, payment criteria for the EAM composite required a high level visit in conjunction with observation care represented by HCPCS code G0378.

For 2015, CMS proposes to continue the 2014 policy to provide payment for all qualifying extended assessment and management encounters through composite APC 8009. Specifically, it proposes to continue to allow a clinic visit, a Level 4 or Level 5 Type A ED visit, or a Level 5 Type B ED visit furnished by a hospital or a direct referral for observation (identified by HCPCS code G0379) performed in conjunction with observation services of substantial duration (8 hours or more) to qualify for payment through composite APC 8009 (provided the observation is not furnished on the same day as surgery or post-operatively).

The proposed 2015 geometric mean cost using this methodology for EAM composite APC 8009 is approximately $1,287.

2. Low Dose Rate (LDR) Prostate Brachytherapy Composite APC

For 2015, CMS proposes to continue the composite APC policy that has been applied since 2008 for LDR Prostate Brachytherapy. Under this policy, the OPPS provides a single payment when the composite service, identified by CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex), is furnished in a single hospital encounter. CMS bases the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims that contain both CPT codes 55875 and 77778 for the same date of service and that do not contain other separately paid codes which are not on the bypass list. When these services are billed individually, hospitals receive separate payments for the individual services.

Using a partial year of 2013 claims data available for the 2015 proposed rule, CMS calculates a proposed geometric mean cost for composite APC 8001 for 2015 of approximately $3,669 based on 379 claims containing both CPT codes 55875 and 77778.

3. Mental Health Services Composite APC (APC 0034)

For 2015, CMS proposes to continue the longstanding payment policy of limiting the combined payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization, which the agency considers to be the most resource intensive of all outpatient mental health treatment. Using the claims processing software, when the total payment for the individual services for specified mental health services – based on the payment rates associated with those APCs – provided by one hospital to a single beneficiary on one date of service exceeds the maximum per diem partial hospitalization payment, those specified mental health services are assigned to APC 0034 (Mental Health Services Composite). The hospital is paid one unit of APC 0034. CMS assigns the payment rate of APC 0176 to APC 0034 because APC 0176, applicable for partial hospitalization involving 4 or more services and furnished in a hospital, is the most resource intensive partial hospitalization service.

4. Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Prior to 2009, hospitals received a full APC payment for each imaging service on a claim, regardless of how many procedures were performed during a single session using the same imaging modality or whether the procedures were performed on contiguous body areas. For 2015, CMS proposes to continue the multiple imaging composite APC policies that it has applied since 2009. Under the multiple imaging policy:

i. CMS utilizes five multiple imaging composite APCs:
   - APC 8004 (Ultrasound Composite);
   - APC 8005 (CT and Computed tomographic angiography (CTA) without Contrast Composite);
   - APC 8006 (CT and CTA with Contrast Composite);
   - APC 8007 (MRI and magnetic resonance angiography (MRA) without Contrast Composite); and
   - APC 8008 (MRI and MRA with Contrast Composite).

ii. CMS provides one composite APC payment when a hospital bills more than one procedure described by HCPCS codes within an OPPS imaging family (as designated in each year's regulation) on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital would receive payment for the "with contrast" composite APC.

iii. When the conditions in ii. above for a composite APC payment do not apply, CMS makes payment according to the standard OPPS methodology through the standard (sole service) imaging APCs; this rule applies when a single imaging procedure is performed, or when the imaging procedures performed have HCPCS codes assigned to different OPPS imaging families.

iv. CMS assigns the status indicator "S" to the proposed composite APCs, thus signifying that payment for the APC would not be reduced when appearing on the same claim with other significant procedures.

v. CMS continues current billing practices whereby hospitals use the same HCPCS codes to report imaging services and the integrated outpatient code editor (I/OCE) determines

when combinations of imaging procedures would qualify for composite APC payment or would map to standard APCs for payment.

Table 8 of the proposed rule (pages 181-185 of display copy) lists the HCPCS codes that are proposed to be subject to the multiple imaging composite policy for 2015 and their respective families and approximate composite APC geometric mean costs for 2015 based on partial 2013 claims data. For the proposed rule, CMS identified approximately 636,000 "single session" claims out of an estimated 1.6 million potential composite APC cases, approximately 40 percent of all eligible claims, to calculate the proposed 2015 geometric mean costs for the multiple imaging composite APCs.

8. Changes to packaged services

For 2015, CMS proposes to expand packaging to a subset of ancillary services and to prosthetic devices and also to revise the policy for packaging add-on codes, a change made initially for 2014.

Proposed Revisions of a Packaging Policy Established in 2014--Procedures Described by Add-On Codes

The 2014 final rule packaged all add-on codes in the OPPS with the exception of add-on codes for drug administration services and add-on codes that were assigned to device-dependent APCs in 2014, but with a policy finalized that after 2014, these device-dependent add-on codes would be paid under the comprehensive APC policy. For 2015, CMS proposes to package all of the procedures described by add-on codes that are currently assigned to device-dependent APCs, all of which will be replaced by comprehensive APCs in 2015. The device-dependent add-on codes that are separately paid in 2014 but which would be packaged in 2015 are listed in Table 9 below.

TABLE 9.—ADD-ON CODES ASSIGNED TO DEVICE-DEPENDENT APCS FOR 2014 THAT ARE PROPOSED TO BE PACKAGED IN 2015

2014 Add-on Code	Short Descriptor	2014 APC
19297	Place breast cath for rad	0648
33225	L ventric pacing lead add-on	0655
37222	Iliac revasc add-on	0083
37223	Iliac revasc w/stent add-on	0083
37232	Tib/per revasc add-on	0083
37233	Tibper revasc w/ather add-on	0229
37234	Revsc opn/prq tib/pero stent	0083
37235	Tib/per revasc stnt & ather	0083
37237	Open/perq place stent ea add	0083
37239	Open/perq place stent ea add	0083
49435	Insert subq exten to ip cath	0427
92921	Prq cardiac angio addl art	0083

2014 Add-on Code	Short Descriptor	2014 APC
92925	Prq card angio/athrect addl	0082
92929	Prq card stent w/angio addl	0104
92934	Prq card stent/ath/angio	0104
92938	Prq revasc byp graft addl	0104
92944	Prq card revasc chronic addl	0104
92998	Pul art balloon repr precut	0083
C9601	Perc drug-el cor stent bran	0656
C9603	Perc d-e cor stent ather br	0656
C9605	Perc d-e cor revasc t cabg b	0656
C9608	Perc d-e cor revasc chro add	0656

Proposed Packaging Policies for 2015

1) Ancillary Services

"Ancillary services," status indicator "X," currently receive a separate payment under the OPPS. By definition, these services, which include many minor diagnostic tests and procedures, are ancillary to primary services with which they are typically performed, although they also are occasionally performed as a stand-alone service. In the 2014 proposed rule, CMS proposed to package all ancillary services when they are performed with another service and to continue to pay separately for them when they are performed alone. In response to comments, CMS did not finalize the ancillary packaging policy for 2014, concluding that further evaluation was necessary.

For 2015, CMS proposes to conditionally package most ancillary services with a proposed geometric mean cost of less than or equal to $100 (prior to application of the conditional packaging status indicator). The proposed rule indicates that this represents an initial set of APCs to be conditionally packaged and that additional ancillary services likely would be packaged in the future. Under the proposed policy, ancillary services which are conditionally packaged in 2015 because they have geometric mean cost less than or equal to $100 would continue to be packaged in subsequent years even if their geometric mean cost is above the threshold in later years. CMS states that it will review the conditionally packaged status of ancillary services annually.

CMS notes that limiting the packaging to lower cost ancillary services is responsive to public comments expressing concern that the 2014 proposal would have packaged certain low volume but relatively costly ancillary services into high volume but relatively inexpensive primary services (for example, a visit). In such a scenario, the payment would increase only a small amount due to the packaging but the cost of the service, when needed by a particular patient, would be high, creating potential access or patient selection issues.

The 2015 proposed rule also notes that the proposed $100 geometric mean cost limit is less than the geometric mean cost of APC 0634, the APC for the single clinic visit code G0463, which has a 2015 proposed rule geometric mean cost of $102.68.

Under the proposed policy, CMS would exclude preventive services from the packaging policy even if they are assigned to an APC with a geometric mean cost of less than or equal to $100. The preventive services to be paid separately are listed in Table 10 below.

TABLE 10.—PREVENTIVE SERVICES EXEMPTED FROM THE ANCILLARY SERVICE PACKAGING POLICY

HCPCS Code	Short Descriptor	APC
76977	Us bone density measure	0340
77078	Ct bone density axial	0260
77080	Dxa bone density axial	0261
77081	Dxa bone density/peripheral	0260
G0117	Glaucoma scrn hgh risk direc	0260
G0118	Glaucoma scrn hgh risk direc	0230
G0130	Single energy x-ray study	0230
G0389	Ultrasound exam aaa screen	0265
G0404	Ekg tracing for initial prev	0450
Q0091	Obtaining screen pap smear	0450

CMS does not propose to package certain psychiatry and counseling-related services which it believes are similar to a visit and which, at this time, the agency does not consider to be ancillary services. It also does not propose to package certain low cost drug administration services because it is examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes.

Finally, CMS would delete status indicator “X” (Ancillary Services) because, under the proposed policy, the majority of services assigned to status indicator “X” would be assigned to status indicator “Q1” (STV-Packaged Codes); these services are packaged when provided on the same date as a service assigned status indicator “S,” “T,” or “V” and otherwise are paid separately. For the services that are currently assigned status indicator “X” and which are not proposed to be conditionally packaged in 2010, CMS would assign them to status indicator “S” (“Procedure or Service, Not Discounted When Multiple”), indicating separate payment and not subject to the multiple procedure reduction.

The APCs that CMS proposes for conditional packaging as ancillary services in 2015 are listed in Table 11 below.

TABLE 11.--APCs FOR PROPOSED CONDITIONALLY PACKAGED ANCILLARY SERVICES FOR 2015

APC	Proposed 2015 OPPS Geometric Mean Cost	Proposed 2015 OPPS SI	Group Title
0012	$76.29	Q1	Level I Debridement & Destruction
0060	$20.64	Q1	Manipulation Therapy
0077	$52.08	Q1	Level I Pulmonary Treatment
0099	$81.27	Q1	Electrocardiograms/Cardiography
0215	$104.63	Q1	Level I Nerve and Muscle Services
0230	$55.00	Q1	Level I Eye Tests & Treatments
0260	$62.43	Q1	Level I Plain Film Including Bone Density Measurement
0261	$99.85	Q1	Level II Plain Film Including Bone Density Measurement
0265	$96.51	Q1	Level I Diagnostic and Screening Ultrasound
0340	$64.78	Q1	Level II Minor Procedures
0342	$56.99	Q1	Level I Pathology
0345	$78.83	Q1	Level I Transfusion Laboratory Procedures
0364	$42.69	Q1	Level I Audiometry
0365	$123.21	Q1	Level II Audiometry
0367	$166.31	Q1	Level I Pulmonary Tests
0420	$130.93	Q1	Level III Minor Procedures
0433	$190.21	Q1	Level II Pathology
0450	$29.91	Q1	Level I Minor Procedures
0624	$83.61	Q1	Phlebotomy and Minor Vascular Access Device Procedures
0690	$37.25	Q1	Level I Electronic Analysis of Devices
0698	$106.17	Q1	Level II Eye Tests & Treatments

2) Prosthetic Devices

According to longstanding OPPS policy, implantable DME, implantable prosthetics, and medical and surgical supplies are paid under the OPPS and, in the 2014 OPPS final rule, CMS clarified that all supplies on the DMEPOS fee schedule except prosthetic supplies are included in medical and surgical supplies paid under the OPPS. Current regulations (42 CFR 419.22(j)) specifically exclude prosthetic supplies from payment under the OPPS; they are paid under the DMEPOS fee schedule, even when they are provided in the HOPD.

Effective in 2015, CMS proposes to delete the “prosthetic supplies” exclusion from the regulations at § 419.22(j) so that these items would be paid under the OPPS. CMS further proposes that prosthetic supplies be packaged covered OPD services in the OPPS beginning in 2015. Thus, prosthetic supplies provided in the HOPD would be included in “medical and surgical supplies” (as are all other supplies currently provided in the HOPD) under § 419.2(b)(4).

The proposed rule observes that implantable prosthetic devices are packaged in the OPPS and that such device systems include both *"the implantable part or parts of the overall device system and certain non-implantable prosthetic supplies that are integral to the overall function of the medical device, part of which is implanted and part of which is external to the patient."* CMS believes that the non-implantable prosthetic supplies are integral to the implantable prosthetic because *"typically shortly after the surgical procedure to implant the implantable prosthetic device in the hospital, the surgeon and/or his or her colleagues will have to attach, fit, and program certain prosthetic supplies that are not surgically implanted into the patient but are a part of a system and that are essential to the overall function of an implanted device."*

Based on these observations, CMS concludes that these prosthetic supplies are integral, ancillary, supportive, dependent, or adjunctive to a primary service and therefore satisfy the criteria to be packaged.

The proposed rule also would package all other prosthetic supplies, not just those that are components of device systems. CMS believe that these are typical medical and surgical supplies and that packaging them would be consistent with the change made in the 2014 OPPS final rule to package all non-prosthetic DMEPOS supplies.

The HCPCS codes for prosthetic supplies that CMS proposes to package for 2015 are displayed in Addendum B to the proposed rule.

B. Conversion Factor Update

The OPPS conversion factor for 2014 is $72.672. To calculate the proposed conversion factor for 2015, the 2014 conversion factor was adjusted by the fee schedule increase factor and further adjusted by various budget neutrality factors. The fee schedule increase factor equals the hospital inpatient market basket percentage increase, which is 2.7 percent, reduced by a multifactor productivity adjustment (MFP) of 0.4 percentage points as required by the ACA, and further reduced by an additional 0.2 percentage points as also required by the ACA. Thus, CMS proposes a fee schedule increase factor of 2.1 percent for the 2015 OPPS (2.7 percent hospital market basket increase, less the proposed 0.4 percentage points MFP adjustment, less the 0.2 percentage point additional adjustment).

Hospitals that fail to meet the reporting requirements of the hospital Outpatient Quality Reporting program (OQR) are subject to a reduction of 2.0 percentage points, as discussed in section XIII below, resulting in a fee schedule increase factor of 0.1 percent for such hospitals.

CMS proposes these additional adjustments for 2015: a wage index budget neutrality factor of 0.9998 and a budget neutrality adjustment of 1.0000 for the proposed cancer hospital adjustment. The rural adjustment factor is 1.000 – and therefore does not affect the conversion factor – because CMS proposes no change in the rural adjustment policy for 2015. CMS estimates that 2015 pass-through spending for drugs, biological and devices will be $15.5 million, or 0.03 percent of total spending, compared with pass-through spending representing 0.02 percent of total payments in 2014, and an adjustment of -0.01 percentage points is made to reflect this

differential. Estimated payments for outliers remain at 1.0 percent, unchanged from 2014. The table below shows the calculation of the proposed conversion factor for 2015.

2014 Final Rule Conversion Factor	Remove 2014 Pass - Through Adjustment	Apply 2015 Pass - Through Adjustment	Apply 2015 Wage Index Budget Neutrality Adjustment	Apply 2015 Cancer Adjustment Budget Neutrality	Apply 2015 Fee Schedule Increase Factor	2015 Final Rule Conversion Factor
$72.672	0.9998	0.9997	0.9998	1.0000	1.021	
	$72.687	$72.665	$72.650	$72.650	$74.176	$74.176

The combined effect of these factors yields a proposed conversion factor for 2015 of $74.176 for hospitals satisfying the requirements of the quality reporting program, which is an increase of $1.504, or 2.1 percent. To calculate the 2015 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the OQR, the proposed rule applies a reduced fee schedule increase factor of 0.1 percent, rather than 2.1 percent, keeping all other adjustments the same, resulting in a reduced conversion factor for 2015 of $72.692.

C. Wage Index Changes

CMS proposes to retain the OPPS labor-related share of 60 percent for purposes of applying the wage index for 2015 and notes that the wage index adjustment is made in a budget neutral manner.

CMS proposes to continue its policy to adopt the final fiscal year IPPS wage index as the OPPS calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. The wage index tables are available by clicking the appropriate link at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

CMS proposes to continue to implement the wage index adjustments called for in the ACA in the same manner as it has since 2011. That includes the "frontier state" adjustment requiring a wage index floor of 1.0 in certain cases if the otherwise applicable wage index (including reclassification, rural floor, and rural floor budget neutrality adjustment) is less than 1.0. In the case of a HOPD affiliated with a multi-campus hospital system, the HOPD would continue to receive the wage index value of the specific inpatient hospital with which it is associated. If that hospital is in a frontier state, the frontier state wage index adjustment for that hospital would apply to the HOPD.

CMS proposes to retain its policy allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a county designated as an out-migration county under section 505 of the MMA. Those counties eligible for this out-migration adjustment, as well as the non-IPPS hospitals, are available at Addendum L to the proposed rule.

CMS proposes for the FY 2015 IPPS to continue the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015. For purposes of the 2015 OPPS, CMS is also proposing to apply the imputed floor policy to hospitals paid under the OPPS but not under the IPPS.

CMS proposes in OPPS, consistent with proposed changes to the IPPS wage index, using different labor market areas in 2015 than it used for 2014 based on new geographical boundaries of Core-Based Statistical Areas (CBSAs) established by OMB. OMB issued Bulletin No.13-01 on February 28, 2013, which established revised definitions or delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on OMB 2010 standards and 2010 Census population data. A copy of OMB No. 13-01 bulletin can be found at http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf. CMS noted in its FY 2015 IPPS/LTCH PPS proposed rule that, while the revisions OMB published on February 28, 2013 are not as sweeping as the changes OMB announced in 2003 (and adopted in the FY 2005 IPPS final rulemaking), the bulletin does contain a number of significant changes including new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart.

CMS notes that adopting the new OMB labor market area delineations would create a more accurate wage index system, but may cause some short-term instability in hospital payments. CMS proposes transition periods to mitigate any short-term instability and negative payment impacts. These transition periods also apply to those hospitals paid under the OPPS but not under the IPPS.

- CMS is proposing a 3-year transition period for hospitals currently located in urban counties that would become rural under the new OMB delineations. Such hospitals would maintain the wage index of the CBSA in which they are physically located for FY 2014 for the next 3 calendar years. This proposed policy would impact six hospitals that are paid under the OPPS but not under the IPPS.

- CMS is proposing a 1-year blended wage-index for all hospitals that would experience any decrease in their actual payment wage index solely due to the proposed implementation of the new OMB delineations. The blended wage index would be computed based as follows: 50 percent based on the wage index computed under the new OMB delineations and 50 percent based on the prior OMB delineations. These computations would be based on the post-reclassified wage index with the rural and imputed floors applied.

For CMHCs, CMS is proposing to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, CMS is proposing similar transition periods: a 1-year, 50/50 blended wage index to CMHCs that would receive a lower wage index due to the new CBSA delineations, and a 3-year transition period for CMHCs currently located in urban counties that would become rural under the new OMB delineations. CMS notes that consistent with its current policy, the wage index that applies to CMHCs includes both the imputed floor adjustment and

the rural floor adjustment, but does not include the out-migration adjustment (only applies to hospitals).

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for rate-setting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. Default CCRs are used for hospitals for which the MACs cannot calculate a valid CCR, including certain hospitals that are new, hospitals that appear to have a CCR falling outside the predetermined ceiling threshold for a valid CCR, and hospitals whose most recent cost report reflects all-inclusive rate status.

In the proposed rule, CMS:

- updates the statewide average default CCRs for 2015 using the most recent cost report data; and
- continues its standard method for calculating this update for 2015, and for Maryland continues to use an overall weighted average CCR for all hospitals in the nation.

Table 12 in the proposed rule (pages 218-220 of display copy) sets out statewide default CCRs for urban and rural areas in each state for 2015 and the comparable final default CCRs for 2014.

E. Adjustment for Rural SCHs and EACHs under Section 1833(t)(13)(B) of the Act

For 2015, CMS proposes to continue to apply a 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. The adjustment is budget neutral and applied before calculating outliers and copayments.

F. OPPS Payments to Cancer Hospitals

Medicare law exempts 11 cancer hospitals meeting statutory classification criteria for exclusion from payment under the IPPS. Since the inception of the OPPS, Medicare has paid these hospitals under the OPPS for covered outpatient hospital services. The ACA requires a budget neutral adjustment to the extent that the Secretary determines that the 11 cancer hospitals' OPPS costs are greater than other OPPS hospitals' costs, including consideration of the cost of drugs and biologicals. Cancer hospitals remain eligible for transitional outpatient payments (TOPs), which are not budget neutral, and outlier payments, which are budget neutral.

For 2015, CMS proposes to continue the cancer adjustment policy used since 2012 whereby it makes additional payments to the 11 cancer hospitals sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals. Rather than a claims-based adjustment, CMS makes an aggregate payment, as necessary, to each cancer hospital at cost report settlement. CMS determines the cancer hospital's PCR (before a cancer hospital payment adjustment) and determines the lump sum amount necessary (if any) to make the cancer

hospital's final PCR equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of the development of this proposed rule. If a cancer hospital's PCR (before the cancer hospital payment adjustment) is above the target PCR, the cancer hospital payment adjustment equals zero.

CMS sets the most recent submitted or settled cost report data that are available at the time of the final rule.

CMS recalculates the payment adjustment annually, in part because it believes that the ACA's expansion of the 340B drug purchasing program to cancer hospitals may lower their drug acquisition costs in the future. The target PCR is set in advance and is calculated using the same extract of cost report data from HCRIS as is used for OPPS rate-setting. For the FY 2015 proposed rule, CMS calculates a target PCR of 0.89, which is unchanged from 2014.

Table 13 in the proposed rule, copied below, shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2015 ranging from 15.5 percent to 60.1 percent. As noted, the actual amount of the 2015 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's 2015 payments and costs.

The 2015 proposed rule budget neutrality adjustment to the OPPS conversion factor is 1.0000 for the cancer hospital adjustment reflecting CMS' projection that aggregate cancer hospital adjustments will be largely unchanged in 2015 compared to 2014.

TABLE 13.— ESTIMATED 2015 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for 2015
050146	City of Hope Comprehensive Cancer Center	15.5
050660	USC Norris Cancer Hospital	22.0
100079	Sylvester Comprehensive Cancer Center	15.8
100271	H. Lee Moffitt Cancer Center & Research Institute	19.9
220162	Dana-Farber Cancer Institute	47.6
330154	Memorial Sloan-Kettering Cancer Center	45.7
330354	Roswell Park Cancer Institute	16.6
360242	James Cancer Hospital & Solove Research Institute	35.1
390196	Fox Chase Cancer Center	18.5
450076	M.D. Anderson Cancer Center	60.1
500138	Seattle Cancer Care Alliance	53.3

G. Hospital Outpatient Outlier Payments

The OPPS pays outlier payments on a service-by-service basis when the cost of a service exceeds the outlier threshold. For 2015, CMS proposes to continue to set aside 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. It calculates the proposed fixed-dollar threshold using the same methodology that was used to set the threshold for 2014 and stipulates that the outlier threshold is met when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $3,100 fixed-dollar threshold. CMS proposes to maintain the outlier payment equal to 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the final fixed-dollar $3,100 threshold are met.

CMS also proposes to continue its long-standing policy that a portion of the 1.0 percent outlier pool, specifically 0.47 percent for 2015 (compared to 0.16 percent for 2014), be allocated to community mental health centers (CMHCs) for partial hospitalization program (PHP) outlier payments. This is the amount of estimated outlier payments that would result from the final CMHC outlier threshold as a proportion of total estimated outlier payments. CMS proposes to continue its policy that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services)) or APC 0173 (Level II Partial Hospitalization (4 or more services)), 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.

Hospitals that fail to report data required for the quality measures selected by the Secretary incur a 2.0 percentage point reduction to their OPPS annual payment update factor, resulting in reduced OPPS payments for most services. For hospitals that fail to satisfy the quality reporting requirements, CMS again proposes that a hospital's costs for the service will be compared to the reduced payment level for purposes of determining outlier eligibility and payment amount.

To model hospital outlier payments and set the outlier threshold for the proposed rule, CMS applied the overall CCRs from the April 2014 Outpatient Provider-Specific File (OPSF) after adjustment (using a proposed CCR inflation adjustment factor of 0.9813 to approximate 2015 CCRs) to charges on 2013 claims that were adjusted using a proposed charge inflation factor of 1.1146 to approximate 2015 charges. The inflation adjustments for CCRs and charges are the same as were used for the FY 2015 IPPS proposed rule.

CMS estimates that actual outlier payments in 2013 equal 1.2 percent of total OPPS payments and that actual outlier payments in 2014 will equal 0.9 percent of total payments, compared to the 1.0 percent set aside in both years.

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

This section provides step by step instructions for calculating an adjusted Medicare payment from the national unadjusted Medicare payment amounts shown in addenda A and B. The steps

show how to determine the APC payments that will be made under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1," "P," "Q1," "Q2," "Q3," "R," "S," "T," "U," or "V" (as defined in Addendum D1 of the final rule), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. CMS notes that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

I. Beneficiary Coinsurance

Medicare law proscribes that the maximum coinsurance rate for any service is 40 percent of the total OPPS payment to the hospital and the minimum is 20 percent. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,216 in 2014. The inpatient hospital deductible limit is applied to the *actual* co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate addenda of the proposed rule do not reflect application of the hospital deductible limit.

Although the last statutory reduction in the maximum coinsurance rate occurred in 2006, the methodology for calculating coinsurance rates ensures that beneficiary coinsurance amounts will continue to decrease gradually relative to the payment rates until all services have a coinsurance rate of 20 percent of the payment amount for the service.

For 2015, CMS proposes to determine copayment amounts for new and revised APCs using the methodology that was first implemented in 2004. CMS refers readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458) for a description of this methodology. Also, for 2015 as in prior years, CMS reduces the beneficiary co-payment proportionately to the two percentage point conversion factor reduction when services are rendered in a hospital that does not report the required quality measures, or that reported them unsatisfactorily.

For the proposed rule, CMS estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments for 2015 will be 20.1 percent, a decrease from the 21.7 percent share that beneficiary copayments were estimated to be for 2014 in the 2014 final rule.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New HCPCS and CPT Codes

Table 14 in the proposed rule (copied below) summarizes the CMS process for updatinG-codes through OPPS quarterly update Change Requests (CRs), seeking public comment, and finalizing their treatment under the OPPS.

TABLE 14: COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 1, 2014	Level II HCPCS Codes	April 1, 2014	2015 OPPS/ASC proposed rule	2015 OPPS/ASC final rule with comment period
July 1, 2014	Level II HCPCS Code	July 1, 2014	2015 OPPS/ASC proposed rule	2015 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2014	2015 OPPS/ASC proposed rule	2015 OPPS/ASC final rule with comment period
October 1, 2014	Level II HCPCS Codes	October 1, 2014	2015 OPPS/ASC final rule with comment period	2016 OPPS/ASC final rule with comment period
January 1, 2015	Level II HCPCS Codes	January 1, 2015	2015 OPPS/ASC final rule with comment period	2016 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2015	2015 OPPS/ASC final rule with comment period	2016 OPPS/ASC final rule with comment period

1. Proposed Treatment of New 2014 Level II HCPCS Codes and CPT Codes Effective April 1 and July 1, 2014 for which CMS Solicits Public Comments in the 2015 Proposed Rule

CMS made effective 4 new Level II HCPCS codes in the April 2014 OPPS quarterly update CR (see Table 15); the proposed payment rates, where applicable, can be found in Addendum B to this proposed rule. CMS made effective 4 new Level II HCPCS codes and 17 new Category III CPT codes effective in the July 2014 CRs. For the July 2014 update, there were no new Category I CPT vaccine codes. Tables 16 and 17 set out the codes and descriptors, the

proposed 2015 status indicators, the proposed APCs, and the proposed payment rates. Because CMS does not have sufficient time to incorporate the new Category III CPT and Level II HCPCS codes that became effective in July, they are not included in Addendum B to this proposed rule. CMS is proposing to incorporate these codes in Addendum B to the 2014 OPPS final rule.

2. Proposed Process for New Level II HCPCS Codes that Will Be Effective October 1, 2014 and New CPT and Level II HCPCS Codes that Will Be Effective January 1, 2015 for which CMS Solicits Public Comments in the 2015 Final Rule with Comment Period

CMS proposes to continue the practice of providing interim payment status indicators, APC assignments and payment rates, if applicable, for new Category I and Category III CPT codes implemented in January 2015 and new Level II HCPCS codes implemented in October 2014 or January 2015 in Addendum B to theS final rule. These codes will be flagged with comment indicator "NI" in Addendum B in the final rule with comment period, indicating that CMS has assigned the codes an interim OPPS payment status for 2015. CMS proposes that their status indicators and their APC assignments would be applicable in 2015 but that they would be open to public comment and would be finalized in the 2016 OPPS final rule.

3. Proposal to Modify the Current Process for Accepting Comments on New and Revised CPT Codes that Are Effective January 1

CMS notes that several stakeholders, including consultants, device manufacturers, drug manufacturers, as well as specialty societies and hospitals, have expressed concern with the process CMS uses to recognize new and revised CPT codes. Concern has been raised about the lack of the opportunity for public comment prior to the January 1 implementation date. CMS notes that similar concerns have been expressed about the process it uses for new and revised CPT codes in the Medicare Physician Fee Schedule (MPFS) and the 2015 MPFS proposed rule includes a proposed policy to address these concerns.

In conjunction with the proposals in the 2015 MPFS proposed rule to revise the process CMS uses to address new, revised, and potentially misvalued codes under the MPFS, for the OPPS proposed rule CMS is proposing to implement in 2016 a revised process:

- CMS would include in the OPPS proposed rule for a year proposed APC and status indicator assignments for new and revised codes that are effective January 1.
    - CMS would accept comments on the proposed assignments and assign the final APC and status indicators in the OPPS final rule.
    - For a code that describes a wholly new service (such as a new technology or new surgical procedure), CMS would continue to follow the current process of establishing interim APC and status indicator assignments in the OPPS final rule with comment. CMS notes it plans to make every effort to work with the AMA CPT Editorial Panel to ensure that codes are received in time to propose payment rates in the proposed rule.

- For new and revised CPT codes that are not received early enough in the CMS rate-setting process to propose APC and status assignments in the OPPS proposed rule for a year, CMS would create and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until CMS could include proposed assignments in the following year's proposed rule.
    - CMS provides the example of a single code separated into two codes that they did not receive until May 2015. Under the proposed process, CMS would assign each of the new codes to status indicator "B" (Non-allowed item or service for OPPS) and create a G-code with the same description as the single predecessor CPT code, and continue to use the same APC and status indicator assignments for that code during the year. CMS would propose status indicator and APC assignments for the two new CPT codes during rulemaking in 2016 for payment beginning in 2017.
    - CMS acknowledges that the use of HCPCS G-codes may place an administrative burden on providers billing for services under the OPPS & ASC payment system.

- For certain CPT codes that are revised in a manner that would not affect the cost of inputs, CMS would use the revised codes and would continue to assign those codes to their current APC.

CMS is specifically interested in comments on the following topics:

- Is this proposal preferable to the present process? Are there other alternatives it should consider?
- If this proposal were implemented, should it be implemented in 2016 or is more time needed?
- Are there alternatives to the use of HCPCS G-codes that would allow CMS to address the annual CPT code changes through notice and comment rulemaking rather than interim final rulemaking?
- Is the proposed process for wholly new codes appropriate? How should CMS define new services?
- Are there classes of services, other than new services, that should remain on the current process and have an assignment on the interim final schedule?

B. Proposed OPPS Changes – Variations within APCs

In accordance with section 1833(t)(2) of the Act, CMS annually reviews the items and services within an APC group to determine, with respect to comparability of the use of resources, if the median cost of the highest cost item or service within an APC group is more than 2 times greater than the median cost of the lowest cost item or service within that same group (known as the "2 times rule"). In making this determination, CMS considers only those HCPCS codes that are significant based on the number of claims. Specifically, CMS considers only those HCPCS codes that have more than 1,000 single major claims or codes that have both greater

than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant.

Section 1833(t)(9)(A) of the Act requires the Secretary to consult with an expert outside advisory panel composed of appropriate representatives of providers to review the clinical integrity of the APC groups and the relative payment weights and advise the Secretary about any issues. The Panel recommendations for specific services for the 2015 OPPS and CMS' responses are discussed throughout the proposed rule.

Addendum B to the proposed rule identifies with a comment indicator "CH" those HCPCS codes for which CMS is proposing a change to the APC assignment or status indicator. CMS states that in many cases, the proposed reassignments and associated APC reconfigurations for 2015 are related to changes in costs of services that were observed in the 2013 claims data used for 2015 rate setting. They also are proposing to change the status indicators for some codes because CMS thinks, based on proposed 2015 policies, another status indicator more accurately describes their payment status. In addition, CMS is proposing to rename existing APCs or create new clinical APCs to complement proposed HCPCS code reassignments.

CMS may make exceptions to the 2 times rule on the variation of costs within each APC group in unusual cases, such as low-volume items and services. CMS uses the following criteria to decide whether to propose exceptions: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for upcoding and code fragments. CMS notes that in cases in which a recommendation by the Panel appears to result in a violation of the 2 times rule, CMS generally accepts the Panel's recommendations because the Panel's recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 18 in the proposed rule lists the 9 APCs that CMS is proposing to exempt from the 2 times rule for 2015 based on established criteria and based on claims data from January 1, 2013, through December 31, 2013. For the final rule, CMS plans to use claims data for dates of service from January 1, 2013 and December 31, 2013 that were processed on or before June 30, 2014 and updated CCRs, if available.

C. Proposed OPPS APC-Specific Policies

1. Ophthalmic Procedures and Services

Based on CMS' evaluation of the available hospital outpatient claims data, they are proposing to restructure all of the ophthalmic-related APCs to better reflect the costs and clinical characteristics of the procedures within each APC. **The proposed restructuring results in 13 APCs for the 2015 OPPS update instead of the 24 APCs used for the 2014 OPPS update.** Table 19 shows the 2014 ophthalmology-related APCs and their status indicators and Table 20 shows the proposed 2015 ophthalmology-related APCs and their status indicators.

CMS notes that they intend to propose similar restructuring of the APC and procedure code assignments for other clinical areas in future rulemaking.

2. Female Reproductive Procedures (APCs 0188, 0192, 0193, and 0202)

At the Panel meeting in March 2014, a presenter raised several concerns related to female reproductive procedures. The presenter wanted the Panel to request that CMS revisit the packaging policy for APCs 0193 and 0195 and to reassign the procedures to better account for clinical complexity. The presenter also requested that CMS postpone converting APC 0202 into a comprehensive APC to allow for further study of the complexity of pelvic floor repair procedures. The Panel made no recommendations for any of the female reproductive APCs.

Based on CMS' evaluation of the available hospital outpatient claims data, they are proposing to restructure the female reproductive APCs to more appropriately reflect the resource and clinical characteristics of the procedures within each APC. **The proposed restructuring results in 5 APCs for the 2015 OPPS update instead of the 7 APCs used for the 2014 OPPS update.** Table 21 shows the 2014 female reproductive APCs and their status indicators and Table 22 shows the proposed 2015 female reproductive APCs and their status indicators. CMS notes that one of proposed 2015 APCs, APC 0202 (Level V Female Reproductive Procedures) is a comprehensive APC.

3. Image-Guided Breast Biopsy Procedures (APC 0005)

Effective January 1, 2014 the AMA CPT Editorial Panel deleted image-guided breast biopsy CPT codes 19102 and 19103 and replaced these specific procedure codes with six new CPT codes (19081 through 19086) that bundled the associated imaging service with the breast biopsy procedure. Table 23 shows how image-guided breast biopsies were reported prior to January 1, 2014 including the OPPS status indicators, the APC assignments and payment rates for the breast biopsy procedure codes, the localization devices used during the procedures and the specific image-guidance procedure codes describing the imaging service. For 2014, CMS assigned CPT codes 19081, 19083 and 19085 to APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow) and CPT codes 19082, 19084, and 19086, which describe add-on procedures, were packaged (see Table 24).

At the Panel meeting in March 2014, a presenter requested the reassignment of CPT codes 19081, 19083 and 19085 from APC 0005 with a 2014 payment rate of $702.08 to APC 0037 (Level IV Needle Biopsy/Aspiration Except Bone Marrow) with a 2014 payment rate of $1,223.25. According to the presenter, it was inappropriate to combine all of the new replacement CPT codes into one APC without consideration of the imaging modality or device used to perform the procedure and requested that CMS maintain the historic assignment of the predecessor CPT codes cost data. The Panel recommended the reassignment of CPT codes 19081, 19083, and 19085 from APC 0005 to APC 0037.

CMS evaluated the geometric mean costs associated with all of the existing four needle biopsy APCs (APCs 0004 (Level I), 0005 (Level II), 0685 (Level III) and 0037 (Level IV)). Based on evaluation of the available hospital outpatient claims data, CMS is proposing:

- Reassigning all of the procedures assigned to APCs 0685 and 00375 to either APC 0004 or APC 0005 based on clinical and resource homogeneity.
    - This reassignment results in increased payment rates for both APCs 0004 and 0005: the proposed 2015 payment rate for 0004 is approximately $494 (2014 payment rate is approximately $411) and the proposed payment rate for APC 0005 is approximately $1062 (2014 payment rate is approximately $702);
- Continuing to assign CPT codes 19081, 19083, and 19085 to APC 0005;
- Continuing to package payment for add-on CPT codes 19082, 19084, and 19086; and
- Deleting APCs 0685 and 0037.
    - This proposed revision would remove all procedures assigned to these APCs.

Table 24 shows the proposed 2015 OPPS status indicators, APC assignments, and payment rates for the image-guided breast biopsy CPT codes 19081 through 19086.

CMS notes that the proposed increase payment for APC 0005 is consistent with the Panel's recommendation to reassign CPT codes 19081, 19083, and 19085 to an appropriate APC based on resource utilization and clinical coherence.

4. Image-Guided Abscess Drainage Procedures (APC 0005 and 0007)

Effective January 1, 2014 the AMA CPT Editorial Panel established CPT code 10030 to report the bundled service of image-guided fluid collection drainage by catheter for percutaneous soft tissue and CPT code 49407 to report the image-guided fluid collection drainage by catheter for peritoneal, retroperitoneal, transvaginal or transrectal collection. For 2014, CPT code 10030 was assigned to APC 0006 with a payment rate of $159.66 and CPT code 49407 to APC 0685 with a payment rate of $757.76 (see Table 25).

At the Panel meeting in March 2014, a presenter requested the reassignment of both CPT codes to APC 0037, which has a 2014 payment rate of $1,223.25, and suggested that all image-guided fluid collection drainage procedures should be treated as one clinically cohesive group and should be assigned to APC 0037. The Panel recommended that CMS reassign CPT code 49407 to APC 0037 and that CPT code 10030 should be assigned to APC 0007.

CMS agrees with the Panel's recommendation for CPT code 10030 and for **2015 is proposing to reassign CPT code 10030 from APC 0006 to APC 0007**. As discussed above (section 3, Image-Guided Breast Biopsy Procedures), CMS evaluated the geometric mean costs associated with all of the existing four-needle biopsy APCs and proposed to reassign all of the procedures assigned to APC 0685 and 0037 to APCs 0004 or 0005. For 2015, **CMS is proposing to reassign CPT code 49407 from APC 0685 to APC 0005**. Table 25 shows proposed 2015 status indicators and APC assignments for CPT code 10030 and 49407. The proposed 2015 payment rates can be found in addendum B to this proposed rule.

5. Cystourethroscopy and Other Genitourinary Procedures (APCs 0160, 0161, 0162, and 0163)

Based on CMS' evaluation of the available hospital outpatient claims data, they are proposing to restructure all of the cystourethroscopy and other genitourinary procedures APCs to better reflect the costs and clinical characteristics of the procedures within each APC. **The proposed restructuring results in 4 APCs for the 2015 OPPS update instead of the 5 APCs used for the 2014 OPPS update** (See Tables 26 and 27).

- CMS is proposing to reassign procedures that were previously assigned to APC 0429 to either APC 0161 (Level I Cystourethroscopy and Other Genitourinary Procedures) or APC 0163 (Level IV) for the 2015 OPPS update.
- CMS is proposing to delete APC 0169 (Lithotripsy) and reassign CPT code 50590 (Lithotripsy) to APC 0163 based on its assessment of resource costs and similarity to other procedures in APC 0163.

The proposed 2015 payment rates can be found in addendum B to this proposed rule.

6. Wound Treatments and Services (APCs 0015 and 0327)

a. Epidermal Autograft (APC 0327)

Based on CMS' evaluation of the available hospital outpatient claims data, the geometric mean costs for CPT code 15110 (Epidermal autograft, trunk, arms, legs; first 100 sq cm or less) was approximately $774 based on 90 single claims (out of 122 total claims). **CMS is proposing to reassign CPT code 15110 from APC 0329 to APC 0327, which has a geometric mean cost of approximately $451 (see Table 28).** CMS is also proposing to revise the APC titles for the four skin repair APCs from specific levels of skin repair to specific levels of skin procedures.

b. Negative Pressure Wound Therapy (NPWT) (APC 0015)

Based on CMS' evaluation of the available hospital outpatient claims data, the geometric mean cost of APC 0013 is close to the geometric mean cost of APC 0015**. CMS is proposing to combine these APCs by deleting APC 0013 and reassigning all the procedures from APC 0013 to APC 0015**. CMS is proposing to retitle APCs 0015, 0016, and 0017 to Level II, Level III and Level IV Debridement and Destruction respectively.

CMS is also proposing changes for the NPWT HCPCS codes G0456 and G0457. CMS found that the geometric mean costs for G0456 is approximately $152 based on 4,509 single claims (out of 5,722 total claims) and for G0457 approximately $193 based on 386 single claims (out of 591 total claims). In the 2014 OPPS, CMS assigned these codes to APC 0016, which has a payment rate of approximately $275. **CMS is proposing to reassign HCPCS codes G0456 and G0459 from APC 0016 to APC 0015, which has a geometric mean cost of approximately $148 (see Table 29).** The proposed 2015 payment rates for G0456 and G0457 can be found in Addendum B to this proposed rule.

7. Endoscopic Retrograde Cholangiopancreatography (ERCP) with Stent (APC 0384)

At the March 2014 meeting, the Panel recommended that CMS reassign CPT code 43274 and 43276 (ERCP CPT codes) to APC 0384 (GI Procedures with Stents). CMS agrees with the Panel's recommendation and for the 2015 OPPS update is **proposing to reassign CPT code 43274 and 43276 from APC 0151 to APC 0384** (see Table 30). CMS notes that for 2015 they have proposed APC 0384 as a comprehensive APC. The proposed 2015 payment rates for CPT codes 43274 and 43276 can be found in Addendum B to this proposed rule.

8. Radiation Therapy (APCs 0066, 0067, 0412, 0446, 0648, and 0667)

To correct a violation of the 2 times rule within APC 0064 (Level I Proton Beam Radiation Therapy), CMS is proposing:

- Reassigning CPT code 77520 (Proton treatment delivery, simple) from APC 0664 to APC 0412 (Level III Radiation Therapy);
- Reassigning CPT codes 77522, 77523 and 77525 (Proton treatment delivery, simple, with compensation, intermediate, and complex, respectively) to APC 0667 and rename APC 0667 to Level IV Radiation Therapy; and
- Deleting APC 0664

CMS is also proposing changes for Intraoperative Radiation Therapy (IORT), Magnetic Resonance-Guided Focus Ultrasound Surgery (MRgFUS) and Magnetoencephalography (MEG) services. CMS is **proposing to delete APC 0065 (IORT, MRgFUS, and MEG)** because they are proposing to reassign the services from this APC to more appropriate APCs based on clinical similarities and comparable geometric mean costs. Specifically CMS is proposing:

- Reassigning MEG CPT codes 95965 and 95966 from APC 0065 to APC 0446 (Level IV Nerve and Muscle Services);
- Reassigning IORT CPT codes 77424 and 77425 to comprehensive APC 0647 (Level IV Breast and Skin Surgery);
- Reassigning MRgFUS HCPCS codes C9734, 0071T, and 0072T from APC 0065 to APC 0066 and rename APC 0066 to Level V Radiation Therapy.
    - CMS acknowledges that MRgFUS services are not the same as radiation therapy, but this proposed assignment aligns with stereotactic radiosurgery services, HCPCS code G0339 and the successor CPT code 77373, that were grouped with MRgFUS services prior to 2014; and
- Renaming APC 0067 from Level II Stereotactic Radiosurgery to Single Session Cranial Stereotactic Radiosurgery, which CMS is proposing as a comprehensive APC.

IV. OPPS Payment for Devices

A. Proposed Pass-Through Payments for Devices

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

CMS follows the statutory requirements that a category of devices is eligible for transitional pass-through payments for at least 2, but not more than 3 years. CMS' established policy is to base the pass-through status expiration date for a device category on the date on which the pass-through payment is effective for the category, which is the first date on which pass-through payment may be made for any medical device. Further, except for brachytherapy sources, for devices that are no longer eligible for pass-through payments, CMS packages the costs of the devices into the procedures with which the devices are reported in the claims data used to set the payment rates. CMS proposes and finalizes the dates for expiration of pass-through status for device categories as part of the OPPS annual update.

CMS made effective for pass-through payments the device category described by HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) as of October 1, 2013. CMS is proposing an expiration date of December 31, 2015 for C1841. Effective January 1, 2016, C1841 would no longer be eligible for pass-through payment status and CMS is proposing to package the costs of C1841 into the costs related to the procedure with which it is reported in the claims data.

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

CMS follows the statutory requirements to set the amount of additional pass-through payments for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device) exceeds the portion of the otherwise applicable Medicare outpatient department fee schedule amount (the APC payment amount) associated with the device.

For 2015, CMS proposes to continue the following policies related to pass-through payment for devices:

- Treating implantable biologicals, which are surgically inserted or implanted (through a surgical incision or a natural orifice) and which are newly approved for pass-through status on or after January 1, 2010, as devices for purposes of the OPPS pass-through evaluation process and payment methodology;
- Including implantable biologicals in calculating the device APC offset amounts;
- 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
- Reducing device pass-through payments based on device costs already included in the associated procedural APCs when it is determined that device costs associated with the new category are already packaged into the existing APC structure.

CMS published a list of all procedural APCs with the 2014 portions of the APC payment amounts that it determines are associated with the cost of devices on the CMS web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. The dollar amounts are used as the device APC offset amounts. CMS is proposing to update this list with the final 2015 information and continue to publish this information on the CMS web site.

B. Proposed Adjustments to OPPS Payments for No Cost/Full Credit and Partial Credit Devices

In 2007, CMS implemented a policy to reduce the payment for specified device-dependent APCs by the estimated potion of the APC payment attributable to device costs (known as the device offset) when the hospital receives a specified device at no cost or full cost. In 2008, CMS expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Based on these policies, CMS reduced OPPS payments by 100 percent of the device offset amount when a hospital furnished a specific device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more of the cost for the specified amount.

In 2014, CMS modified its policy for reducing OPPS payment for specified APCs when a hospital furnishes a specified device without costs or with a full or partial credit. For 2014, CMS reduced OPPS payments by the full or partial credit a provider receives for a replaced device, for the applicable device-dependent APCs. Hospitals are required to report the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS also limits the total amount of the device offset when the "FD" value code appears on a claim

For 2015, CMS is proposing to continue the existing policy. CMS is proposing:

- Reducing the OPPS payments for the applicable APCs by the full or partial credit a provider receives for a replaced device; and
- Requiring hospitals to report the amount of credit in the amount portion for "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

CMS proposes to continue using three criteria when determining the APCs to which the policy should apply:

1. All procedures assigned to the selected APCs must involve implantable devices that would be reported if device replacements procedures were performed;
2. The required devices must be surgically inserted or be an implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
3. The device offset amount must be significant, which for purposes of this policy, is defined as exceeding 40 percent of the APC cost.

CMS also proposes to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure the adjustment would not be triggered by the implantation of an inexpensive device whose costs would not constitute a significant portion of the total payment rate for an APC.

Table 31 lists the proposed APCs to which the proposed payment adjustment policy for no cost/full credit and partial credit devices would apply in 2015. Table 32 lists the proposed devices to which the proposed payment adjustment policy for no cost/full credit and partial credit devices would apply in 2015. Based on the final 2013 claims data available for the 2015 final rule, CMS will update these lists.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

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

1. Drugs and Biologicals with Expiring Pass-Through Status in 2015

Effective January 1, 2015, CMS proposes to terminate the pass-through status of the 9 drugs and biologicals listed in Table 33 (copied below) of the proposed rule. By that date, all of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years. These items were approved for pass-through status on or before January 1, 2013. Except for so-called policy-packaged drugs, which are drugs and biologicals that are always packaged when they do not have pass-through status, CMS would continue to make a separate payment if the product's estimated per day cost exceeds the OPPS drug packaging threshold, which is estimated to be $90 in 2015 at the time of this proposed rule. CMS designates these products as "policy-packaged drugs": diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure (e.g., skin subsitutes). Table 33 indicates that 5 of the 9 drugs losing pass-through status would qualify for separate payment; CMS proposes that the remaining 4 products with pass-through status ending December 31, 2014 would be packaged.

TABLE 33—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WILL EXPIRE DECEMBER 31, 2014

Proposed 2015 HCPCS Code	Proposed 2015 Long Descriptor	Proposed 2015 SI	Proposed 2015 APC
C9290	Injection, bupivicaine liposome, 1 mg	N	N/A
C9293	Injection, glucarpidase, 10 units	K	9293
J0178	Injection, aflibercept, 1 mg vial	K	1420
J0716	Injection, centruroides (scorpion) immune f(ab)2, up to 120 milligrams	K	1431

Proposed 2015 HCPCS Code	Proposed 2015 Long Descriptor	Proposed 2015 SI	Proposed 2015 APC
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9306	Injection, pertuzumab, 1 mg	K	1471
Q4131	EpiFix, per square centimeter	N	N/A
Q4132	Grafix core, per square centimeter	N	N/A
Q4133	Grafix prime, per square centimeter	N	N/A

2. Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in 2015

CMS proposes to continue pass-through status in 2015 for 22 drugs, biologicals and radiopharmaceuticals. 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, 2014. These items, which were approved for pass-through status between January 1, 2013 and July 1, 2014, are listed in Table 34 (copied below) of the proposed rule. Pass-through drugs and biologicals are identified by status indicator "G" in Addenda A and B.

TABLE 34—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN 2015

Proposed 2015 HCPCS Code	2015 Long Descriptor	Proposed 2015 SI	Proposed 2015 APC
A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
C9021	Injection, obinutuzumab, 10 mg	G	1476
C9022	Injection, elosulfase alfa, 1mg	G	1480
C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activity	G	9132
C9133	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
C9134	Injection, Factor XIII A-subunit, (recombinant), per 10 i.u.	G	1481
C9441	Injection, ferric carboxymaltose, 1 mg	G	9441
C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1446	Injection, tbo-filgrastim, 5 micrograms	G	1447
J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
J3060	Injection, taliglucerase alfa, 10 units	G	9294
J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J7316	Injection, Ocriplasmin, 0.125mg	G	9298
J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465

Proposed 2015 HCPCS Code	2015 Long Descriptor	Proposed 2015 SI	Proposed 2015 APC
J9047	Injection, carfilzomib, 1 mg	G	9295
J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
J9400	Injection, Ziv-Aflibercept, 1 mg	G	9296
Q4121	Theraskin, per square centimeter	G	1479
Q4122	Dermacell, per square centimeter	G	1419
Q4127	Talymed, per square centimeter	G	1449

Note: Because the payment rates associated with these codes effective July 1, 2014 were not available to CMS in time for incorporation into the Addenda to the proposed rule, the Level II HCPCS codes and the Category III CPT codes implemented through the July 2014 OPPS quarterly update change request (CR) could not be included in Addendum B to the rule.

For 2015, CMS would continue to pay for drugs and biologicals with pass-through status at average sales price plus 6 percent (ASP+6). For purposes of pass-through payment, CMS considers radiopharmaceuticals to be drugs under the OPPS and therefore also would set payment for them at ASP+6; if ASP data are not available for a radiopharmaceutical, CMS would provide pass-through payment at WAC+6 percent, the same payment provided to pass-through drugs and biologicals without ASP information, and if WAC information also is not available, payment would be made at 95 percent of the most recent AWP.

CMS will update the list of pass-through drugs on a quarterly basis on the CMS website during 2015 to reflect newly approved pass-through drugs and biologicals as well as to adjust payment rates for pass-through drugs as necessary based on later quarter ASP submissions (or more recent WAC or AWP information, as applicable).

The pass-through payment portion of the total payment is the difference between the 2015 payment rate that CMS sets for nonpass-through, separately payable drugs and the pass-through payment rate of ASP+6 percent. Except for the policy-packaged drugs, the pass-through portion is zero since CMS will pay both pass-through and nonpass-through drugs at ASP+6 percent. For policy-packaged drugs, the pass-through payment portion of the payment is the full payment, which equals ASP+6 percent less, any "policy-packaged" drug offset (described in the next subsection) because, if not for pass-through status, payment for these products would be packaged into the associated procedures. Determining the pass-through portion of a drug's payment is important, in part, because this is the portion that is counted in calculating total pass-through payments for the purpose of the conversion factor offset.

The statute sets the amount of copayment associated with pass-through items equal to the amount of copayment that would be applicable if the pass-through adjustment was not applied. Therefore, as it did in 2014, CMS proposes to set the copayment amount for all pass-through policy-packaged products equal to zero for 2015.

3. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups

Payment Offset Policy for Diagnostic Radiopharmaceuticals
There currently is one diagnostic radiopharmaceutical with pass-through status under the OPPS: HCPCS code A9520 (Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries), which was granted pass-through status beginning October 1, 2013. The established radiopharmaceutical payment offset policy is currently applied to pass-through payment for this product.

For 2015, CMS would continue current policies for the "policy-packaged" drug offset. It deducts from the payment for pass-through radiopharmaceuticals an amount that reflects the portion of the APC payment associated with predecessor radiopharmaceuticals in order to ensure no duplicate radiopharmaceutical payment is made. In 2009, CMS established a policy to estimate the portion of each APC payment rate that could reasonably be attributed to the cost of predecessor diagnostic radiopharmaceuticals. Specifically, CMS uses the policy-packaged drug offset fraction for APCs containing nuclear medicine procedures, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC.

To determine the actual APC offset amount for pass-through diagnostic radiopharmaceuticals that takes into consideration the otherwise applicable OPPS payment amount, CMS: 1) multiplies the "policy-packaged" drug offset fraction by the APC payment amount for the nuclear medicine procedure with which the pass-through diagnostic radiopharmaceutical is used and 2) reduces the separate OPPS payment for the pass-through diagnostic radiopharmaceutical by this amount.

Table 35 in the proposed rule (pages 326-327 of display copy) lists the APCs to which nuclear medicine procedures are assigned in 2015 and for which an APC offset could be applicable in the case of diagnostic radiopharmaceuticals with pass-through status.

Payment Offset Policy for Contrast Agents
There are currently no contrast agents with pass-through status under the OPPS.

For 2015, CMS proposes to continue to deduct from the OPPS payment for pass-through contrast agents an amount that reflects the portion of the APC payment associated with predecessor contrast agents in order to ensure no duplicate contrast agent payment is made. To determine and apply the APC offset amount, CMS uses the same methodology that is applicable to radiopharmaceuticals, as described above. CMS proposes to identify procedural APCs for which it expects a pass-through contrast agent offset could be applicable in the case of a pass-through contrast agent as any procedural APC with a "policy-packaged" drug amount greater than $20 that is not a nuclear medicine APC (listed in Table 35 of the proposed rule) and that is included in the APCs to which a contrast agent may be applicable (Table 36 of the proposed rule).

Payment Offset for Products Packaged According to the Policy to Package Drugs, Biologicals, and Radiopharmaceuticals that Function as Supplies When Used in a Diagnostic Test or Procedure and Drugs and Biologicals that Function as Supplies or Services When Used in a Surgical Procedure

As part of the new policy effective in 2014 to package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies or services when used in a surgical procedure, the 2014 OPPS final rule packaged skin substitutes and stress agents used in myocardial perfusion imaging (MPI). In 2014, CMS employed its standard offset methodology to identify the offset portion and to deduct from the payment for applicable pass-through drugs, biological, and radiopharmaceuticals an amount that reflects the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made.

For 2015, CMS proposes to continue its 2014 policies, including these:

- For pass-through skin substitutes, CMS will utilize the policy-packaged drug offset fraction for skin substitute procedural APCs, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs divided by the cost from single procedure claims in the APC.
- Because policy-packaged radiopharmaceuticals are also included in the drug offset fraction for the APC to which MPI procedures are assigned, for pass-through stress agents CMS is utilizing the policy-packaged drug offset fraction for the procedural APC, calculated as 1 minus the following: the cost from single procedure claims in the APC after removing the cost for policy-packaged drugs excluding policy-packaged diagnostic radiopharmaceuticals divided by the cost from single procedure claims in the APC.
- To determine the actual APC offset amount for pass-through skin substitutes and pass-through stress agents that take into consideration the otherwise applicable OPPS payment amount, CMS multiplies the policy-packaged drug offset fraction by the APC amount for the procedure with which the pass-through skin substitute or pass-through stress agent is used and reduces the separate OPPS payment for the pass-through skin substitute or pass-through stress agent by this amount.

There are currently six skin substitutes (HCPCS codes Q4121, Q4122, Q4127, Q4131, Q4132, and Q4133) with pass-through status under the OPPS. CMS currently applies the established skin substitute payment offset policy to pass-through payment for these products. Table 37 in the proposed rule lists the APCs to which skin substitute procedures are assigned in 2015 and for which CMS expects that an APC offset could be applicable in the case of a skin substitute with pass-through status. Table 38 shows the 2015 APC for MPI procedures for which CMS expects that an APC offset could be applicable in the case of a stress agent with pass-through status.

CMS will continue to post annually on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html a file that contains the APC offset amounts that will be used for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals and for establishing any appropriate APC offset amounts.

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

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

CMS currently pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged into the payment for the associated service; or separate payment (individual APCs). Hospitals do not receive a separate payment for packaged items and hospitals may not bill beneficiaries separately for any packaged items whose costs are recognized and paid within the OPPS payment rate for the associated procedure or service.

Cost Threshold for Packaging of "Threshold-Packaged Drugs"
"Threshold-packaged drugs" under OPPS are drugs, non-implantable biologicals and therapeutic radiopharmaceuticals whose packaging status is determined by the packaging threshold. If a drug's average cost per day exceeds the packaging threshold, it is separately payable and if not, it is packaged. For 2014, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that were not new and did not have pass-through status is $90. For 2015, CMS proposes to set the packaging threshold at $90. In calculating this amount, CMS used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics (BLS) series code WPUSI07003) from CMS' Office of the Actuary (OACT) to trend the $50 threshold forward from the third quarter of 2005 to the third quarter of 2015 and rounded the resulting dollar amount ($91.46) to the nearest $5 increment.

For the 2015 proposed rule, CMS calculated the per day cost of all threshold-packaged drugs on a HCPCS code-specific basis (with the exception of those drugs and biologicals with multiple HCPCS codes described below) to determine their proposed 2015 packaging status. To calculate the per day costs, CMS used an estimated payment rate of ASP+6 percent (the payment rate that CMS proposes for separately payable drugs and non-implantable biologicals in 2015, as discussed below) for each drug and non-implantable biological HCPCS code. CMS used the manufacturer-submitted ASP data from the fourth quarter of 2013 (data that were used for payment purposes in the physician's office setting, effective April 1, 2014) to determine per day cost for the proposed rule. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, CMS used their mean unit cost derived from the 2013 hospital claims data to determine their per day cost. Items with a per day cost of less than or equal to $90 are proposed to be packaged and items with a per day cost greater than $90 are proposed to be separately payable.

CMS proposes to use quarterly ASP updates as follows:

- 4th quarter of 2013: budget neutrality estimates, packaging determinations, impact analyses, and Addenda A and B for the 2015 OPPS proposed rule;
- 1st quarter of 2014: budget neutrality estimates, packaging determinations, and impact analyses for the 2015 OPPS final rule;

- 2nd quarter of 2014: payment rates for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B to the 2015 OPPS final rule;
- 3rd quarter of 2014: payment rates effective January 1, 2015 for HCPCS codes for separately payable drugs and non-implantable biologicals included in Addenda A and B; these are the same ASP data used to calculate payment rates effective January 1, 2015 for drugs and biologicals furnished in the physician office setting.

ASP-based payment rates for both the OPPS and physician office settings would continue to be updated quarterly using quarterly reported ASP data with a two-quarter lag. CMS proposes to continue its policy of making an annual packaging determination for a HCPCS code for the OPPS final rule and not updating that code's packaging status during the year. Only HCPCS codes which are identified as separately payable in the final rule would be subject to quarterly updates.

As for past years, CMS proposes to apply the following policies to determine the 2015 final rule packaging status of a threshold-packaged drug when the drug's calculated final rule packaging status differs from its status in the proposed rule based on more current data.

- HCPCS codes that were separately payable in 2014 and were proposed for separate payment in 2015 would continue to be separately payable in 2015 even if the updated data used for the 2015 final rule were to indicate per day costs equal to or less than $90.
- HCPCS codes that were packaged in 2014, proposed for separate payment in 2015, and then have per day costs equal to or less than $90 based on the updated data used for the 2015 final rule would be packaged in 2015.
- HCPCS codes for which CMS proposed packaged payment in 2015 but then have per day costs greater than $90 based on the updated data used for the 2015 final rule would be separately payable in 2015.

Proposed High/Low Cost Threshold for Packaged Skin Substitutes
In the 2014 OPPS final rule, CMS unconditionally packaged skin substitute products into their associated surgical procedures as part of its policy to package drugs and biologicals that function as supplies when used in a surgical procedure. The final rule also established a methodology to divide the skin substitutes into a high cost group and a low cost group for packaging purposes. Skin substitutes that had a July 2013 ASP + 6 percent amount above $32 per cm^2 were classified in the high cost group and those with a July 2013 ASP + 6 percent amount at or below $32 per cm^2 were classified in the low cost group. The final rule also included separate, parallel APC assignments for the respective groups.

For 2015, CMS proposes to revise the methodology for making the high cost/low cost group division based on concerns raised by manufacturers after publication of the 2014 final rule. The proposed new policy would maintain the high/low cost APC structure for skin substitute procedures in 2015 but change the methodology used to establish the high/low cost threshold. CMS would establish the high/low cost threshold based on the weighted average mean unit cost (MUC) for all skin substitute products from claims data. The proposed MUC threshold would be $27 per cm^2. Skin substitutes with a MUC above $27 per cm^2 using 2013 claims are proposed to be classified in the high cost group and those with a MUC at or below $27 per cm^2 would be

classified in the low cost group. Table 39 below shows the high/low cost status for each skin substitute product in 2014 and the proposed 2015 high/low cost status based on the weighted average MUC threshold of $27.

Skin substitutes with pricing information but without claims data to calculate a MUC would be assigned to either the high or low cost category based on the product's ASP + 6 percent payment rate. If ASP is not available, CMS would use WAC + 6 percent or 95 percent of AWP to assign a product to either the high or low cost category. CMS further proposes that any new skin substitute without pricing information be assigned to the low cost category until pricing information is available to compare to the proposed $27 per cm^2 threshold for 2015. CMS would continue the current policy that skin substitutes with pass-through status are assigned to the high cost category.

CMS believes the revised methodology may provide more stable high/low cost categories, addressing a concern that as new high priced pass-through skin substitutes gain market share, the weighted average ASP high/low cost threshold could escalate rapidly resulting in a shift in the assignment of many skin substitutes from the high cost category to the low cost category. Also, because the revised threshold would be based on costs from outpatient claims data rather than manufacturer reported sales prices, which include both inpatient and outpatient sales, the data would not include the larger product sizes, and their lower per cm^2 prices, used primarily for inpatient burn cases.

TABLE 39.—PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS

2014 HCPCS Code	2014 Short Descriptor	Proposed 2015 SI	2014 High/Low Status Based on Weighted ASP	Proposed 2015 High/Low Status Based on Weighted MUC
C9358	SurgiMend, fetal	N	Low	Low
C9360	SurgiMend, neonatal	N	Low	Low
C9363	Integra Meshed Bil Wound Mat	N	Low	High
Q4101	Apligraf	N	High	High
Q4102	Oasis wound matrix	N	Low	Low
Q4103	Oasis burn matrix	N	Low	Low
Q4104	Integra BMWD	N	Low	High
Q4105	Integra DRT	N	Low	High
Q4106	Dermagraft	N	High	High
Q4107	Graftjacket	N	High	High
Q4108	Integra matrix	N	Low	High

2014 HCPCS Code	2014 Short Descriptor	Proposed 2015 SI	2014 High/Low Status Based on Weighted ASP	Proposed 2015 High/Low Status Based on Weighted MUC
Q4110	Primatrix	N	High	High
Q4111	Gammagraft	N	Low	Low
Q4115	Alloskin	N	Low	Low
Q4116	Alloderm	N	High	High
Q4117	Hyalomatrix	N	Low	Low
Q4119	Matristem wound matrix	N	Low	Low
Q4120	Matristem burn matrix	N	Low	Low
Q4121	Theraskin	G	High	High
Q4122	Dermacell	G	High	High
Q4123	Alloskin	N	Low	Low
Q4124	Oasis tri-layer wound matrix	N	Low	Low
Q4125	Arthroflex	N	High	High
Q4126	Memoderm/derma/tranz/integup	N	High	High
Q4127	Talymed	G	High	High
Q4128	Flexhd/Allopatchhd/matrixhd	N	Low	High
Q4129	Unite biomatrix	N	Low	Low
Q4131	Epifix	N	High	High
Q4132	Grafix core	N	High	High
Q4133	Grafix prime	N	High	High
Q4134	hMatrix	N	High	High
Q4135	Mediskin	N	Low	High
Q4136	EZderm	N	Low	Low
Q4137	Amnioexcel or biodexcel, 1cm	N	Low	Low
Q4138	BioDfence DryFlex, 1cm	N	Low	Low
Q4140	Biodfence 1cm	N	Low	Low
Q4141	Alloskin ac, 1 cm	N	Low	Low
Q4142	Xcm biologic tiss matrix 1cm	N	Low	Low
Q4143	Repriza, 1cm	N	Low	Low
Q4146	Tensix, 1cm	N	Low	Low
Q4147	Architect ecm, 1cm	N	High	High
Q4148	Neox 1k, 1cm	N	High	High

Proposed Pass-Through Evaluation Process for Skin Substitutes
Since 2001, skin substitutes have been evaluated for pass-through status through the drug, biological, and radiopharmaceutical pass-through process. Effective 2015, CMS proposes that applications for pass-through payment for skin substitutes be evaluated using the medical device pass-through process and payment methodology. The last skin substitute pass-through applications evaluated using the drug and biological pass-through evaluation process would be those with an application deadline of September 1, 2014, and an earliest effective date of January 1, 2015.

CMS also proposes to change the December 1, 2014 pass-through application deadline (for an earliest effective date of April 1, 2015) for both drugs and biologicals and devices to January 15, 2015, in order to provide sufficient time for applicants to adjust to the new policies and procedures in effect as of January 1, 2015.

The proposed change would conform the pass-through application process of skin substitutes to the pass-through application process for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice). In 2010, CMS finalized a policy to evaluate implantable biological pass-through applications through the medical device pass-through evaluation process. The proposed rule also notes that implantable devices are considered supplies in the OPPS and that in the 2014 OPPS final rule, CMS finalized a packaging policy to consider skin substitutes a type of surgical supply.

Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages
For 2015, CMS proposes to continue its policy of making packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for HCPCS codes describing the same drug or biological but with different dosages. The codes to which this policy apply, and their packaging status, are listed in Table 41 of the proposed rule (pages 351-352 of display copy).

2. Payment for Drugs and Biologicals without Pass-Through Status that Are Not Packaged

For 2015, CMS proposes to continue the 2015 policy and pay for separately payable drugs and biologicals at ASP+6 percent. This payment represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. CMS would continue to include payments for separately payable drugs and biologicals in determining budget neutrality adjustments (i.e., the budget neutral weight scaler) although the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals due to the statutory requirement to base their payments on acquisition costs.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For 2015, CMS would pay for all nonpass-through, separately payable therapeutic radiopharmaceuticals under the same ASP methodology that is adopted for separately payable drugs and biologicals, i.e. ASP+6 percent, when all manufacturers of a product submit the

necessary ASP information for a "patient ready" dose. The payment rate would be updated quarterly using the most recently available ASP data reported by manufacturers. Reporting ASP information remains optional for manufacturers. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS would determine payment rates based on 2013 geometric mean unit cost data derived from 2013 hospital claims data.

4. Payment for Blood Clotting Factors

For 2015, CMS proposes to continue to pay for blood clotting factors using the same methodology that is used to pay other nonpass-through separately payable drugs and biologicals under the OPPS, which is proposed to be ASP+6 percent. CMS would update the 2014 furnishing fee ($0.192 per unit) based on the percentage increase in the Consumer Price Index (CPI) for medical care following the same methodology it has used since 2008. For 2015, the updated amount will be based on the percentage increase in the CPI for medical care for the 12-month period ending in June 2014. Because this information will not be available when the final rule is scheduled to be published, CMS will announce the actual fee through program instructions and posting on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html. When blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee also is applied to the payment.

5. Payment for New Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes, but without OPPS Hospital Claims Data

For 2015, CMS would continue its policy of paying for new 2015 drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the proposed 2015 payment methodology for other separately payable products. Similarly, CMS would continue its policy of packaging payment for all new nonpass-through policy-packaged products (diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) with HCPCS codes but without claims data (i.e., those new 2015 HCPCS codes that do not crosswalk to predecessor HCPCS codes). This is consistent with the proposed policy packaging of existing similar products.

In the absence of ASP data, CMS would continue for 2015 the policy first implemented in 2005 of using WACs to establish the initial payment rate for new nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals which have HCPCS codes and are separately payable. If the WAC also is unavailable, CMS would pay at 95 percent of the product's most recent AWP. Once ASP data become available in later quarter submissions, payment rates under the OPPS would be adjusted based on the ASP methodology using the ASP+6 payment amount.

The new 2015 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available for the proposed rule. They will, however, be included in Addendum B to the 2015 OPPS final rule and will be assigned comment indicator "NI" to reflect that their interim final OPPS treatment is open to public comment.

CMS also would continue its existing methodology for determining the 2015 packaging status of nonpass-through drugs and biologicals that were payable in 2013 and/or 2014 but for which CMS does not have 2013 hospital claims data. If CMS has pricing information available for the ASP methodology, it proposes to calculate the per day cost of the drug or biological by multiplying the payment rate for each product based on ASP+6 percent by an estimated average number of units of each product that would typically be furnished to a patient during one administration in the hospital outpatient setting. The proposed rule packages items with an estimated per administration cost of less than or equal to $90. These products, their estimated units per day, status indicators, and proposed APCs/packaging status in 2015 are listed in Table 42 of the proposed rule (page 367 of display copy).

CMS would continue to assign status indicator "E" to drugs and biologicals that were payable in 2014 but for which it lacks both 2013 claims data and pricing information for the ASP methodology. The 35 products that fall into this category are listed in Table 43 of the proposed rule (pages 368-369 of display copy). If pricing information were to become available for these products, CMS would assign the products status indicator "K" and pay for them separately for the remainder of 2015.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

CMS' proposed estimate for total pass-through spending for drug and device pass-through payments during 2015 will equal about $15.5 million, or 0.03 percent of total OPPS projected payments for 2015, which is less than the proposed applicable pass-through payment percentage limit of 2.0 percent.

Beginning in 2015, CMS proposes that applications for pass-through payment for skin substitutes and similar products would be evaluated using the medical device pass-through evaluation process and payment methodology. This means that the last skin substitute pass-through applications evaluated using the drugs and biologicals pass-through evaluation process and payment methodology would have a deadline of September 1, 2014 (with an earliest effective date of January 1, 2015). CMS would change the December 1, 2014 pass-through application deadline to January 15, 2015 (for an earliest effective date of April 1, 2015) for both drugs and biologicals and medical devices. Should CMS finalize this proposal, it would include skin substitutes in its device pass-through payment estimates beginning in 2015.

A. Devices

Using its established methodology, CMS projects $10.5 million in pass-through spending attributable to device categories in 2015. The proposed estimate for the first group of items (i.e., those device categories that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in 2015) is $500,000[5]. CMS proposes an estimate of $10 million for the second group of device categories which consists of those device

[5] There is one device category: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) first eligible for pass-through payment as of October 1, 2013 that will continue to be eligible in 2015.

categories CMS knows or projects may be approved for pass-through status in 2015 as of the development of the proposed rule, and includes contingent projections for new device categories in the second through fourth quarters of 2015. CMS includes implantable biologicals newly eligible for pass-through payment in the estimate for the second group.

B. Drugs and Biologicals

CMS projects $5 million in pass-through spending attributable to drugs and nonimplantable biologicals in both groups in 2015. CMS considers radiopharmaceuticals as drugs for pass-through purposes and includes them in their estimates for drugs and biologicals.

The proposed estimate for the first group of drugs and nonimplantable biologicals is $2.8 million. The first group consists of drugs and biologicals recently eligible for pass-through payments that would continue for 2015. CMS proposes to project utilization based on physician office data, information in pass-through applications, historical hospital claims data, as well as other data sources.

The proposed estimate for the second group of drugs and nonimplantable biologicals is $2.2 million. The second group consists of those drugs and biologicals CMS knows or projects could be approved for pass-through status in 2015, and includes contingent projections for new drugs and nonimplantable biologicals that could initially be eligible in the second through fourth quarters of 2015. CMS proposes to project utilization for this group from pass-through applicants, pharmaceutical industry data, clinical information, recent trend in per unit ASPs of hospital outpatient drugs, and projected changes in service volume and intensity. CMS also proposes to consider recent OPPS experience in approving new pass-through drugs and biologicals.

Because CMS proposes to pay for most nonpass-through separately payable drugs and biologicals and all pass-through drugs and biologicals at the same rate (ASP+6 percent), its estimates for this group of items is zero. However, the estimate of pass-through payment amounts for diagnostic radiopharmaceuticals and contrast agents with pass-through status approved before 2015 is not zero because they would be paid at ASP+6 percent in lieu of being packaged into associated procedures as is the case for nonpass-through radiopharmaceuticals and contrast agents. Additionally, as noted earlier, if CMS determines that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, it proposes to offset the amount of pass-through payment for the policy-packaged drug or biological and also proposes to provide for a corresponding reduction in the estimate of pass-through payments for those drugs or biologicals.

VII. Proposed OPPS Payment for Hospital Outpatient Visits

A. Proposed Payment for Clinic Visits and Emergency Department Visits

For 2015, CMS proposes to continue the policy it adopted in the 2014 OPPS final rule of using HCPCS code G0463 (assigned to APC 0634) for hospital use only to represent any and all clinic

visits under the OPPS. CMS proposes to use 2013 claims data to develop payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes currently recognized for clinic visits (HCPCS codes 99201-99205 and 99211-99215). CMS notes that it no longer recognizes distinctions between new and established patients.

For Type A and Type B Emergency Department (ED) visits, CMS indicated in the 2014 OPPS final rule that additional study was required to determine the "most suitable payment structure" which would include a number of visit levels that "would not underrepresent resources required to treat the most complex patients." CMS did not make any change in ED visit coding in the 2014 OPPS final rule. Similarly, in this proposed rule, CMS does not propose any change in ED visit coding, citing the continued need for additional study. Thus CMS proposes to continue to recognize the existing CPT codes for Type A ED visits as well as the five HCPCS codes that apply to Type B ED visits; it also proposes to set the 2015 proposed OPPS payment rates using the established standard process.

B. Critical Care Services

For 2015, CMS proposes to continue its 2011 methodology for calculating payment rates for critical care services, which includes packaged payment of ancillary services. CMS continues to find, using 2013 claims data, that both the mean line item costs and charges (for CPT code 99291) increased as compared to the 2012 hospital claims data. CMS believes this continues to suggest that many hospitals did not change billing practices for CPT code 99291, and it continues to find separate payment for these ancillary services inappropriate. It proposes to continue to implement claims processing edits that conditionally package payment for ancillary services furnished on the same date of service as critical care services, and will continue to monitor claims data for CPT code 99291 for potential revisions to this policy.

VIII. Proposed Payment for Partial Hospitalization Program (PHP) Services

A. Proposed PHP APC Update for 2015

For 2015, CMS proposes to calculate the payment rates for the four PHP APCs (Level I and Level II partial hospitalization services computed separately for Community Mental Health Center (CMHC)-based PHPs and hospital-based PHPs) based on geometric mean per diem costs using the most recent claims data for each provider type. The proposed rates are contained in Table 44 of the proposed rule and are reproduced below:

Proposed 2015 Geometric Mean Per Diem Costs for PHP Services, Based on 2013 Claims Data				
Category	**CMHC PHPs**		**Hospital-Based PHPs**	
Level I (days with 3 services)	APC 0172	$97.43	APC 0175	$177.32
Level II (days with 4 or more services)	APC 0173	$114.93	APC 0176	$190.21

CMS notes that under the geometric mean methodology using only 2013 data, the proposed per diem costs for hospital-based PHPs are lower (by approximately $14 for Level I and $24 for Level II PHP services) than the final 2014 rates calculated under geometric mean methodology using 2012 data. For CMHCs, CMS notes that the rates would remain relatively constant, with a

decrease of roughly $2 for Level I PHP services and an increase of approximately $3 for Level II PHP services. The proposed geometric mean per diem costs continue to be substantially lower for CMHCs than for hospitals. CMS invites comments on its proposals.

B. Separate Threshold for Outlier Payments to CMHCs

For 2015, CMS proposes to designate 0.47 percent of the estimated 1.0 outlier target amount specifically for CMHCs for PHP outliers. CMS again proposes to set the outlier threshold for CMHCs for 2015 at 3.40 times the highest CMHC PHP APC payment rate (APC 0173 Level II Partial Hospitalization), and to pay 50 percent of CMHC per diem costs over the threshold. Specifically, CMS will calculate a CMHC outlier payment equal to 50 percent of the difference between the CMHC's cost for the services and the product of 3.40 times the APC 0173 payment rate. CMS does not propose to set a dollar threshold for CHMC outlier payments as it proposes to apply to other OPPS outlier payments. CMS invites comments on its proposals.

C. Regulatory Impact

CMS estimates that payments to CMHCs will decline by 1.6 percent, due to the continuation of the four-separate-APC method of payment calculation (based on cost report and claims data submitted by CMHCs) and other adjustments.

IX. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

CMS proposes to continue to use the same methodology to review the inpatient list. Under that methodology, CMS does not identify any procedures for removal from the inpatient list.

After the annual review of APCs and code assignments (required under section 1833(t)(9) of the Act), CMS proposes to add CPT code 22222 (Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic) to the 2015 inpatient list.

Addendum E to the proposed rule contains the 2015 complete list of codes that CMS proposes to be paid only as inpatient procedures.

X. Proposed Nonrecurring Policy Changes: Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

CMS continues to be concerned by hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS seeks to better understand the impact of these acquisitions on beneficiaries, who may have increased copayments, and on the program, which incurs additional hospital facility payments, through the collection of information to analyze frequency, type and payment for services furnished in those provider-based departments. MedPAC also questions the appropriateness of increased payment and beneficiary cost-sharing when physician offices become hospital outpatient departments and recommends that CMS pay selected hospital outpatient services at MPFS rates.

In the 2014 OPPS rulemaking cycle, CMS sought public comment on the best means to collect this information. While many comments were submitted, and there was no consensus approach, CMS believes the most efficient and equitable way to collect this information is to create a HCPCS modifier to be reported on both the CMS-1500 claim form and the UB-04 form (CMS Form 1450) with every code for physicians' services and outpatient hospital services furnished in an off-campus provider-based department of a hospital

CMS also notes that section 220(a) of the PAMA (Pub. L. 113-93) grants CMS authority to collect data to support valuation of services paid under the MPFS. CMS would use this authority to seek more information on the frequency and type of services furnished in provider-based departments to improve the accuracy of practice expense payments under the MPFS for services furnished in off-campus provider-based departments[6]. It proposes to collect information on physicians' services and hospital outpatient services furnished in off-campus provider-based departments of hospitals through the use of the HCPCS modifier described above. CMS seeks comment on whether the use of a modifier code is the best manner in which to collect this service-level data in the hospital outpatient department.

XI. OPPS Payment Status and Comment Indicators

Proposed 2015 OPPS Payment Status Indicator Definitions. In the 2014 OPPS final rule CMS created a payment status indicator "J1" to identify HCPCS codes paid under a comprehensive APC, but it delayed the effective date of payment status indicator "J1" because the new comprehensive APC policy was delayed until 2015. Thus beginning in 2015, claims with payment status indicator "J1" will trigger a comprehensive APC payment.

For 2015, CMS proposes to delete payment status indicator "X"; ancillary services currently assigned to status indicator "X" would be assigned either to payment status indicator "Q1" or "S". Additionally, the definition of payment status indicator "Q1" would be revised by removing payment status indicator "X" from the packaging criteria; thus codes assigned payment status indicator "Q1" would be designated as STV-packaged (not STVX-packaged).

CMS proposes to revise the definition of payment status indicator "E" to clarify that it applies to items, codes, and services—

1. For which pricing is not available (for drugs and biologicals assigned a HCPCS code but with no available pricing information, i.e., WAC);
2. Not covered by any Medicare outpatient benefit category;
3. Statutorily excluded by Medicare; and
4. Not reasonable and necessary.

CMS proposes to update the definition of status indicator "A" by—

1. Removing "EPO for ESRD Patients" from the list of examples; and
2. By adding "separately payable" to "nonimplantable prosthetic and orthotic devices".

[6] See HPA summary of the 105 MPFS proposed rule.

The complete list of proposed 2015 status indicator assignments for APCs and HCPCS codes (displayed in Addendum A and Addendum B, respectively) and of proposed 2015 status indicators and their definitions (displayed in Addendum D1) is available from the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Proposed Comment Indicator Definitions. For 2015, CMS proposes to use the same two comment indicators that are in effect for the 2014 OPPS:

- "CH" – Active HCPCS codes in current and next calendar year; status indicator and/or APC assignment have changed or active HCPCS code that will be discontinued at the end of the current calendar year.
- "NI" – New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

Use of the "CH" indicator in the proposed rule identifies:

- Proposed changes in status indicator and/or APC assignment for a HCPCS code for 2015 compared to its assignment as of June 30, 2014.
- For composite APC indicators, the configuration of the composite APC is proposed to be changed in the 2015 OPPS/ASC final rule with comment period.

CMS proposes to use the "CH" indicator in the 2015 OPPS/ASC final rule with comment period to indicate HCPCS codes for which the status indicator, APC assignment, or both, would change in 2015 compared to their assignment as of December 31, 2014.

CMS proposes that existing HCPCS codes with substantial revisions to the code descriptors for 2015 (as compared to the 2014 descriptors) would be labeled with the comment indicator "NI" in Addendum B to the OPPS final rule. CMS notes that use of the comment indicator "NI" is for a significant revision to the code descriptor—meaning that the new code descriptor describes a new service or procedure for which OPPS treatment may change. CMS proposes to continue to assign the comment indicator "NI" to those codes to allow for comment on the proposed payment for substantially revised codes, and CMS will respond to those comments and finalize their OPPS treatment in the 2015 OPPS final rule.

CMS is not proposing any changes to the 2014 definitions of the OPPS comment indicators for 2015 which are listed in Addendum D2 on the CMS Web site found at the link above.

XII. Updates to the Ambulatory Surgical Center Payment System

Summary

Selected key elements of proposed ASC payment rates for 2015		
	ASCs reporting quality data	**ASCs not reporting quality data**
2014 ASC Conversion Factor	$43.471	
Proposed 2015 Update		
CPI-U update	1.7%	
Multi-factor productivity adjustment (MFP)	-0.5%	
Net MFP adjusted update	1.2%	
Penalty for not reporting quality data	0.0%	-2.0%
Net MFP and quality adjusted update	1.2%	-0.8%
Budget neutrality wage adjustment	0.9983	
Proposed 2015 ASC Conversion Factor	$43.918	$43.050

CMS notes that the projections may be updated in the final rule based on more recent data.

A. Background

CMS reviews the legislative history and regulatory policies regarding changes to the lists of codes and payment rates for ASC covered surgical procedures and covered ancillary services. In brief:

- Covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS and that would not be expected to:
  - Pose a significant risk to beneficiary safety when performed in an ASC; or
  - Require an "overnight stay": active medical monitoring and care at midnight following the procedure

- Separate ASC payments are made for selected ancillary items and services when they are provided integral to ASC covered procedures. Payment for ancillary items and services that are not paid separately are packaged into the ASC payment.
- ASC payments are based on the OPPS payment policies.
- CMS provides quarterly update change requests (CRs) for ASC services throughout the year and makes new codes effective outside the formal rulemaking process via these quarterly updates. The annual rulemaking process is used to solicit comments and finalize these decisions.

B. Proposed Treatment of New Codes

CMS continues to recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures;
- Category III CPT codes, which describe new and emerging technologies, services and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CMS continues a policy adopted in the final rule for 2008 to evaluate all new Category I and III CPT codes and Level II HCPCS codes that describe surgical procedures in order to make preliminary determinations during the annual rulemaking process about whether they meet the criteria for payment in an ASC setting, and if so, whether they are office-based procedures. CMS also identifies new codes as ASC covered ancillary services based on the final payment policies in the revised ASC payment system.

CMS sets out proposals for new codes in two categories as it has in prior years: proposed treatment of codes previously identified during the year in the quarterly update process and on which it is seeking comments in this proposed rule; and a process for new codes for which it will be seeking comments in the final rule with comment period.

Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2014 for Which CMS is Soliciting Public Comments in this Proposed Rule: CMS in April and July of 2014 change requests (CRs) made effective seven new Level II HCPCS codes and four new Category III CPT Codes describing covered ASC services that were not included in the 2014 OPPS final rule. Tables 45-47 in the proposed rule set out the codes and descriptors, the proposed 2015 payment indicators and the proposed payment rates. CMS solicits comments on these proposals.

Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which CMS will be Soliciting Public Comments in the 2015 OPPS/ASC Final Rule with Comment Period: CMS proposes to include in Addenda AA and BB to the 2015 OPPS/ASC final rule with comment period:

- New Category I and III CPT codes effective January 1, 2015 that would be incorporated in the January 2015 ASC quarterly update CR; and
- New level II HCPCS codes, effective October 1, 2014 or January 1, 2015 that would be released in the October 2014 or January 2015 quarterly CRs.

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

Proposed Additions to the List of ASC Covered Surgical Procedures: CMS conducted its annual review of procedures paid under the OPPS but not included on the list of covered ASC procedures, and proposes to add 10 new procedures to the list of covered surgical procedures.

CMS determined that these 10 procedures that are currently excluded could meet the standards for inclusion – that is, they could be safely performed in the ASC setting and would not require an overnight stay. The 10 proposed additions are provided in Table 48.

Proposed Surgical Procedures Designated as Office-Based: CMS annually reviews volume and utilization data to identify "office-based" procedures that are added to the ASC list of covered surgical procedures and are performed more than 50 percent of the time in physicians' offices and that CMS' medical advisors believe are of a level of complexity consistent with other procedures performed routinely in physicians' offices. Based on its review of 2013 data, CMS proposes to permanently identify two additional procedures as office-based, and invites public comment. Table 49 lists the procedures and proposed 2015 ASC payment indicators.

CMS also reviewed information for the eight procedures finalized for temporary office-based status in last year's final rule. Table 50 in the proposed rule lists the procedures and CMS' proposal for payment indicators for 2015.

Proposed Changes to ASC Covered Surgical Procedures Designated as Device-Intensive for 2015: Current rules provide a modified payment methodology for ASC covered procedures eligible for payment according to the device- intensive procedure payment methodology for the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost. That policy is in place to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in these procedures.

CMS is proposing in the OPPS section of the proposed rule to create 28 comprehensive APCs to replace the current device-dependent APCs (and several non-device dependent APCs) under the OPPS (see section II.A.6 of this summary). Because a comprehensive APC would treat all individually reported codes as components of the comprehensive service, the OPPS proposal would make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service.

CMS notes that the OPPS claims processing system can be configured to make a single payment for the comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim. The ASC claims processing system does not allow for this.

Therefore, CMS proposes that all separately paid ancillary services provided integral to surgical procedures that map to a comprehensive APC would continue to be separately paid under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS. The ASC payment rates for these comprehensive APCs would be based on the 2015 OPPS relative payment rates calculated using the standard APC rate-setting methodology for the primary service instead of the relative payment weights based on the comprehensive bundled service under the OPPS. CMS also proposes to use the standard OPPS APC rate-setting methodology to calculate the device offset percentage for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs.

Since it is proposing to eliminate device-dependent APCs under the OPPS, CMS needs to define ASC device-intensive procedures for 2015. It proposes to define an ASC device-intensive procedure as one that is assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC rate setting methodology. CMS notes that its proposal to lower the offset threshold from greater than 50 percent to greater than 40 percent better aligns with the OPPS device credit policy finalized for 2014 that applies to procedures with a significant device offset amount, which is also defined as exceeding 40 percent of the APC cost.

CMS proposes to update the list of ASC covered surgical procedures eligible for payment consistent with this modified definition of device-intensive procedures. Table 51 lists, for comment, the procedures that CMS proposes to identify as device-intensive. CMS invites public comment on these proposals.

Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices: CMS refers readers to the 2009 OPPS final rule for a full discussion of the ASC policy, which adopts OPPS policy, for payment when a specified device is furnished without cost or with full or partial credit from the manufacturer for the cost of the device.

CMS finalized a modification in payment for devices furnished with full or partial credit under the OPPS in the 2014 final rule, but there is no mechanism in the ASC claims processing system for ASCs to submit the actual amount received when furnishing a device without cost or with full or partial credit. As a result, CMS continued current policy for ASCs, and proposes to continue that policy this year:

- When the device is furnished at no cost or with full credit from the manufacturer, the contractor would reduce payment to the ASC by 100 percent of the device offset amount, which is the amount that CMS estimates as the cost of the device.
- When the device is furnished with partial credit of 50 percent or more of the cost of the new device, CMS proposes that the contractor would reduce payments to the ASC by 50 percent of the device offset amount.

CMS proposes to apply the full credit/partial credit policy to all device-intensive procedures in 2015, rather than limiting it to devices received at no cost/full credit or partial credit due to a recall or warranty situation. CMS notes that ASCs can also receive a device at full or partial credit due to being part of an investigational device trial, and believes that the payment policy should cover any situation in which an ASC may receive a device at no cost/full credit or partial credit. Table 51, listing ASC covered procedures, includes the proposed device offset percentages. CMS solicits comments on these proposals.

ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient Only List for 2015: There are no procedures proposed for removal from the OPPS inpatient list for 2015, so CMS is not proposing any procedures for possible inclusion on the ASC list of covered surgical procedures.

Covered Ancillary Services: CMS notes again that it is proposing to package certain Categories of ancillary or adjunctive services under the OPPS for 2015. To maintain consistency with the OPPS, CMS proposes that these services would also be packaged under the ASC payment system.

ASC covered ancillary services and their proposed payment indicators for 2015, including those proposed for change as a result of the proposed OPPS and resulting ASC packaging, are included in Addendum BB. Tables 46 and 47 provide the information for the proposed new Level II HCPCS codes and Category III CPT codes discussed earlier.

D. Proposed ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

Proposed Payment for Covered Surgical Procedures; Proposed Update to ASC Covered Surgical Procedure Payment Rates for 2015: CMS proposes to update ASC payment rates using its previously established methodologies, and seeks comments.

CMS proposes to update payments for office-based procedures and device-intensive procedures using its previously established methodology, and using its proposed modified definition for device-intensive procedures. That means that CMS would make payment for office-based procedures at the lesser of the proposed 2015 MPFS nonfacility PE RVU-based amount, or the proposed 2015 ASC payment amount calculated according to the standard methodology.

Waiver of Coinsurance and Deductibles for Certain Preventive Services: CMS refers readers to the 2011 OPPS final rule for its policies and list of preventive services for which the coinsurance and deductible are waived. CMS is not proposing any changes to its policies or the list of services for 2015. The preventive services are flagged in Addenda AA and BB.

Payment for Cardiac Resynchronization Therapy (CRT) Composite: CMS refers readers to the 2012 OPPS final rule for a discussion of the policy. CMS proposes for 2015 that CPT code 33249 (Insertion or replacement of permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber) continue to be assigned to APC code 0108, and payment for CPT code 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator) be packaged under the primary covered surgical procedure (for example, CPT code 33249). CMS invites comments.

Proposed Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite: CMS proposes no changes in ASC payment for LDR prostate brachytherapy services for 2015.

Proposed Payment for Covered Ancillary Services: CMS proposes to update the payments and make changes necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services. CMS proposes to continue to set payment methodologies for brachytherapy services and separately payable

drugs and biologicals equal to the proposed 2015 OPPS rates.

CMS proposes to continue to base payment for separately payable covered radiology services on the lower of the 2015 MPFS nonfacility PE RVU-based amounts and the proposed 2015 ASC rate calculated under standard rate-setting methodology (except in the case of nuclear medicine procedures and services that use contrast agents). If the radiology service is packaged or conditionally packaged under the OPPS, payment for the radiology service would be packaged into the payment for the ASC. Addendum BB indicates the payment status for each radiology service.

In the case of nuclear medicine procedures designated as radiology services paid separately when provided integral to a surgical procedure on the ASC list, CMS proposes to continue to set payments based on the OPPS relative payment weights. In the case of radiology services that use contrast agents, CMS proposes to continue to set payment based on the OPPS relative payment rate, and will, therefore, include the cost of the contrast agent.

CMS proposes one change in policy. Currently, certain non-imaging diagnostic tests can have payment made under the OPPS but not when provided in an ASC setting. CMS believes that such tests should be considered covered ancillary services and separately paid when the tests are required for the successful performance of a surgery and are performed in the ASC on the same day as a covered surgical procedure. CMS proposes that, beginning in 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS be covered ancillary services when they are integral to an ASC covered surgical procedure. It proposes to pay for the tests at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard rate-setting methodology.

CMS notes that this payment methodology is similar to that for covered ancillary services that are radiology services, and proposes a related change to the definition of payment indicators "Z2" and "Z3" to incorporate these diagnostic services: the new definitions would be a "Radiology *or diagnostic* service paid separately when provided integral to a surgical procedure on the ASC list…"

CMS has identified one diagnostic test within the medicine range of CPT codes and for which separate payment is allowed under the OPPS: CPT code 91035 (Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation). CMS proposes to add this code to the list of covered ASC ancillary services with separate ASC payment beginning in 2015 when the test is integral to an ASC covered surgical procedure.

CMS invites comments on the proposals.

E. New Technology Intraocular Lenses (NTIOL)

CMS did not receive any requests for review to establish a new NTIOL class for 2015 by the March 3, 2014 deadline. CMS is not proposing any change to its payment adjustment of $50

per lens for a 5-year period from the implementation date of a new NTIOL class.

F. Proposed ASC Payment and Comment Indicators

CMS is not proposing any changes to the definitions in the ASC payment and comment indicators for 2015 (note that there is a proposed change to the definitions of payment indicators "Z2" and "Z3" described above). Addenda DD1 and DD2 list the ASC payment and comment indicators for
2014.

G. Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

Updating the ASC Relative Payment Rates for 2015 and Future Years: CMS proposes to continue to update relative weights using the national OPPS relative weights and the MPFS nonfacility PE RVU-based amounts when applicable.

CMS proposes to scale the relative weights as under prior policy. Holding ASC use and mix of services constant from 2013, CMS computes the ratio of:

- Total payments using the 2014 relative payment rates, to
- Total payments using the 2015 relative payment rates.

The resulting ratio, 0.9142, is the proposed weight scaler for 2015. The scaler would apply to the payment for covered surgical procedures and covered radiology services for which the ASC payments are based on OPPS relative weights. The scaler would not apply to ASC payments for separately payable covered ancillary services that have a predetermined national payment amount and are not based on OPPS relative payment weights. That includes drugs and biologicals that are separately paid, and services that are contractor-priced or paid at reasonable cost in ASCs.

Proposed Transition to New OMB Delineations for ASC Wage Index. CMS proposes that the ASC wage indices continue to adopt the pre-floor and pre-reclassified IPPS hospital wage index. For 2015, CMS will adopt the Office of Management and Budget's February 28, 2013 revisions to the delineation of revised Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. CMS proposes a one-year transition similar to that proposed for the IPPS: that is a 1-year blended wage index for all ASCs that would experience any decrease in their wage index exclusively due to the implementation of the new OMB delineations. The blend would be 50 percent of the ASC wage index based on the new OMB revisions, and 50 percent of the wage index based on the prior OMB delineations.

Updating the ASC Conversion Factor: CMS proposes to compute the budget neutrality adjustment factor for changes in wage index values as under prior policy. Holding constant ASC use and mix of services in 2013 and the proposed 2015 national payment rates after application of the weight scalar, CMS proposes to compute the ratio of:

- ASC payments using the 2014 ASC wage indices, to
- ASC payments using the 2015 ASC wage indices.

The resulting ratio, 0.9983, is the proposed wage index budget neutrality adjustment for 2015.

CMS proposes to continue its policy of updating the conversion factor by the CPI-U estimated for the 12-month period ending with the mid-point for 2015. CMS uses the IHS Global Insight (IGI) 2014 first quarter forecast, which yields a projected CPI-U update of 1.7 percent and a multifactor productivity adjustment of -0.5 percent. That yields a proposed update of 1.2 percent.

CMS notes that, as in prior years, it proposes to revise the update if more current CPI-U or MFP data are available when the final rule is issued.

The 2012 and 2013 OPPS/ACS final rules established a policy that ASCs begin submitting data on quality measures for services beginning October 1, 2012 for the 2014 payment determination, with the conversion factor reduced by 2.0 percentage points for ASCs that fail to meet their quality reporting requirements (see section XIV of this summary for detail on the ASC quality reporting requirements). CMS notes that the 2.0 percent reduction may result in an update of less than zero. As a result, CMS proposes the following updates:

- Facilities reporting quality data would receive the 1.2 percent update for 2015;
- Facilities not reporting quality data would receive 1.2 percent minus 2.0 percent, or a -0.8 percent update for 2015 (a 0.992 update factor).

The resulting 2015 ASC conversion factor proposed by CMS is $43.918 for ASCs reporting quality data, and $43.050 for those that do not, computed as follows:

	ASC reporting quality data	ASC not reporting quality data
2014 ASC conversion factor:	$43.471	$43.471
Wage adjustment for budget neutrality	x 0.9983	x 0.9983
Net MFP-adjusted update	x 1.012	x 0.992
Proposed 2015 ASC conversion factor	$43.918	$43.050

Impact

CMS sets out estimated increases by surgical specialty group in Table 53 of the proposed rule, replicated below, which assumes the same mix of services as reflected in 2013 claims data.

The eye and ocular adnexa group remains the largest source of payments, but with a 2 percent decline attributable to the proposed payment changes in 2015. The second largest group, digestive system, is estimated to see a 6 percent increase, which CMS notes is likely due to an

increase in the ASC payment weight for some of the high volume procedures. CMS notes the separate estimate for separately payable covered ancillary items and services, with no change in aggregate payments estimated. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services.

Table 53: **Estimated Impact of the Proposed 2015 Update to the ASC Payment System on Aggregate 2015 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group**

Surgical Specialty Group	Estimated 2014 ACS Payments (in Millions)	Estimated 2015 Percent Change
Total	**$3,819**	**1%**
Eye and ocular adnexa	$1,556	-2%
Digestive system	$780	6%
Nervous system	$572	1%
Musculoskeletal system	$474	2%
Genitourinary system	$167	3%
Integumentary system	$137	3%
Respiratory system	$54	1%
Cardiovascular system	$35	-3%
Ancillary items and services	$24	0%
Auditory system	$14	0%
Hematologic & lymphatic systems	$6	12%

CMS sets out estimated increases for 30 selected procedures in Table 54 in the proposed rule; the top 10 procedures are replicated below. CPT code 66984 (Cataract surgery with intraocular lens, 1 stage) is the largest aggregate payment procedure by far, and is estimated to see a 2 percent reduction.

Excerpt from Table 54: Estimated Impact of the Proposed 2015 Update to the ASC Payment System on Aggregate Payments for Selected Procedures

CPT/ HCPS Code	Short Descriptor	Estimated 2014 ACS Payments (in Millions)	Estimated 2015 Percent Change
66984	Cataract surg w/iol, 1 stage	$1,132	-2%
43239	Upper GI endoscopy, biopsy	$170	9%
45380	Colonoscopy and biopsy	$168	6%
45385	Lesion removal colonoscopy	$107	6%
66982	Cataract surgery, complex	$93	-2%
64483	Inj foramen epidural l/s	$90	0%
62311	Inject spine l/s (cd)	$79	0%
45378	Diagnostic colonoscopy	$72	6%
66821	After cataract laser surgery	$63	2%
64493	Inj paravert f jnt 1/s 1 lev	$47	0%
See Table 54 for full list of 30 procedures.			

Addenda tables available only on the website provide additional details.
http://www.cms.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS-1613-P-CY-2015-NPRM-ASC-addenda.zip

- AA -- Proposed List of ASC Covered Surgical Procedures for 2015 (Including surgical procedures for which payment is packaged as well as those paid separately)
- BB -- Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for 2015 (Including Ancillary Services for Which Payment is Packaged)
- DD1 -- Proposed ASC Payment Indicators for 2015 used in Addenda AA and BB
- DD2 -- Proposed ASC Comment Indicators for 2015
- EE -- Surgical Procedures Proposed to be Excluded from Payment in ASCs for 2015

XIII. Hospital Outpatient Quality Reporting Program Updates

CMS proposes changes to the Hospital Outpatient Quality Reporting (OQR) Program beginning with the 2017 payment determination, including removal of three previously adopted measures, the conversion of one previously adopted measure to voluntary reporting only, and the addition of a new claims-based measure. Changes are also proposed to the data validation process for chart-abstracted measures reported by hospitals under the OQR Program. A table at the end of this section shows previously adopted OQR Program measures and those proposed for the 2017 payment determination.

A. Background

CMS reviews the history of the various quality reporting programs currently in place and discusses its goal of aligning clinical quality measures across these programs, including the OQR Program. The process for OQR Program measure updates and the display of hospital quality measure data on the *Hospital Compare* website are described, with no changes proposed. As established under the CY2013 OPPS final rule, once a measure is adopted for the Hospital OQR Program for a payment determination year it will automatically be adopted for subsequent years until CMS proposes to remove, suspend or replace it.

B. Removal of Measures from the Hospital OQR Program

CMS proposes specific criteria for removal of a "topped out" measure from the OQR Program; the same proposal was made in the FY 2015 IPPS/LTCH proposed rule with respect to the Hospital Value Based Purchasing and Inpatient Quality Reporting programs (79 FR 28219). (As discussed in section XIV.B below this policy is also proposed in this rule with respect to the ASC Quality Reporting Program.) Topped out measures are those for which performance among hospitals is so uniformly high that meaningful distinctions in performance can no longer be made. The proposed rule would specifically define a topped out measure as one that meets two criteria: 1) statistically indistinguishable performance at the 75th and 90th percentiles; and 2) A truncated coefficient of variation (CV) less than or equal to 0.10. In addition to the proposal regarding topped out measures, various other previously adopted criteria and considerations for

removal of measures from the program are discussed, including taking into account the views of the Measure Applications Partnership (MAP).

CMS further proposes to remove three measures from the OQR Program beginning with the 2017 payment determination because they are topped out (under both the current definition and the proposed specific criteria.) These measures are:

- OP-4: Aspirin at Arrival (NQF # 0286);
- OP-6: Timing of Antibiotic Prophylaxis; and
- OP-7: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528).

CMS indicates that if it subsequently determines that hospital adherence to these practices has unacceptably declined, the measures would be re-proposed in future rulemaking.

C. Changes to Previously Adopted Measures

Previously, CMS adopted 27 measures for the 2016 payment determination, and, as noted above, these measures are automatically continued for future years unless CMS proposes to suspend or remove them. In addition to the proposed removal of three topped out measures discussed above, CMS proposes to exclude a previously adopted measure regarding cataract surgery from the 2016 payment determination and make reporting on it voluntary only for 2017. In addition, CMS discusses previously announced changes including a delay in the reporting period for two measures and changes to reporting requirements for a third.

Treatment of OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery. It involves physician-conducted pre- and post- surgery patient questionnaires, and was adopted in the 2014 OPPS final rule with an initial reporting period of calendar year 2014. Subsequent to publication of that final rule, CMS has twice issued guidance to delay implementation of this measure. In December 2013 CMS announced that the initial reporting period would be delayed by three months, to begin April 1, 2014. On April 2, 2014 CMS announced a further nine-month delay, making calendar year 2015 the initial data collection period for this measure. Two reasons were offered for these delays. First, CMS has come to believe that it will be difficult for hospitals to collect and report this measure, which requires the hospital to have knowledge of a patient's visual function before and after surgery. Second, CMS is concerned that the measure specifications allow for use of any validated survey for this purpose, which may lead to inconsistent survey results.

In this rule, CMS proposes that while OP-31 would still be included in the OQR Program measure set, it would be excluded from the 2016 payment determination. In addition, reporting on this measure beginning with the 2017 payment determination would be voluntary only. CMS believes that this measure addresses an area of care that is not adequately addressed in the current measure set and that it provides an opportunity for HOPDs to partner with physicians for the purpose of coordinating care.

Under the voluntary reporting proposal, hospitals would not be subject to any payment reduction in 2017 for failure to report data on this measure for the calendar year 2015 reporting period. For hospitals choosing to voluntarily submit data, CMS requests that they use the procedures and timelines finalized for this measure in the 2014 OPPS final rule period (78 FR 75112 through 75113). Data submitted voluntarily on OP-31 would be publicly reported.

In addition, CMS corrects its response to public comments in the 2014 OPPS final rule regarding the OP-31 cataract measure. Specifically, CMS indicates that in addressing comments on all three then-proposed measures it "inadvertently misstated" that the OP-31 measure had been field tested in the hospital outpatient setting, and "we are clarifying here that this measure has not been field-tested in that setting."

Previously Announced Delays in Data Collection. In the 2014 OPPS final rule period, CMS added, beginning with the 2016 payment determination, two chart-abstracted endoscopy/polyp surveillance measures: OP-29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF # 0658) and OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps –Avoidance of Inappropriate Use (NQF # 0659). Hospitals were to submit initial aggregate data on these measures via the QualityNet website between July 1, 2015 and November 1, 2015 for encounters occurring during calendar year 2014. Subsequent to publication of the final rule (on December 31, 2013), CMS issued guidance delaying the implementation of OP-29 and OP-30 for 3 months for the 2016 payment determination. Instead of beginning January 1, 2014 the initial encounter period will begin April 1, 2014, still ending December 31, 2014. The July through October data submission window was unchanged.

Reporting Requirements for OP-27: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). CMS discusses the reporting requirements for this previously adopted measure of influenza vaccination of healthcare personnel. These changes were also discussed in the IPPS/LTCH proposed rule for FY 2015. Specifically, hospital reporting for this measure will be submitted by CMS Certification Number (CCN) rather than by requiring separate reporting by inpatient or outpatient setting. This is in response to public comment expressing concern about the burdens of separate reporting by setting. In addition, CMS notes that the 2014 OPPS final rule included a typographical error regarding the first deadline for hospitals to submit health care personnel influenza vaccination summary reporting data, which is May 15, 2015 with respect to the October 1, 2014 through March 31, 2015 encounter period. The CDC has produced an Operational Guidance document regarding reporting for this measure: http://www.cdc.gov/nhsn/PDFs/HCP/Operational-Guidance-ACH-HCP-Flu.pdf

D. New Measure for 2017

CMS proposes the addition of one new claims-based measure to begin with the 2017 payment determination: Facility Seven Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, proposed as measure number OP-32. The measure was submitted for National Quality Forum (NQF) endorsement in February 2014.

The proposed measure would be calculated as all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within seven days of an outpatient colonoscopy procedure. The measure score, also referred to as the facility level risk-standardized hospital visit rate, is a ratio multiplied by the "crude rate", or national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy. The ratio numerator for a facility is the number post-colonoscopy unplanned hospital visits within seven days as predicted by the facility's case mix. The facility's ratio denominator is the number of unplanned hospital visits expected based on national performance with the facility's case-mix. Colonoscopies for patients undergoing concomitant high-risk upper GI endoscopy are excluded, as are patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy. CMS states that the statistical risk adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following colonoscopy. Specifications for the proposed measure are available under "Hospital Outpatient Colonoscopy" at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

CMS discusses the adverse outcomes associated with this common procedure that may lead to an unexpected hospital visit and concludes from the literature that most of these visits occur within seven days after the procedure. While stating that some related hospital visits do occur later and would be missed, CMS believes that a seven-day time interval captures most visits associated with the procedure while minimizing the inclusion of unrelated hospital visits. CMS believes that providers are often unaware of complications following colonoscopy for which patients visit the hospital, and that the proposed measure would provide feedback to facilities and physicians, as well as transparency for patients on rates across facilities of unplanned hospital visits after colonoscopy.

The MAP conditionally supported this measure, stating that it needs to be further developed and gain NQF endorsement. The MAP also indicated that the endorsement process should resolve questions of the measure's reliability and validity and raised the issue of how the measure attributes colonoscopies to HOPDs in light of the IPPS 3-day window policy (which captures as inpatient services those HOPD services provided during the three days prior to inpatient admission). CMS states that it has addressed the issues raised by the MAP, indicating that the measure meets reliability and validity tests. Regarding concern about the attribution of claims, CMS indicates that it identified physician claims for colonoscopy in the HOPD setting from the Medicare Part B Standard Analytical Files for which there is an inpatient admission within three days and no corresponding HOPD facility claim. The identified colonoscopies are attributed to the appropriate HOPD facility using the facility provider ID from the inpatient claim. CMS believes that this measure meets statutory requirements regarding the use of measures that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by national consensus building entities.

The data collection timeline for this measure would be the same as the timeline previously adopted for other OQR Program claims-based measures (78 FR 75111). That is, to calculate this measure CMS would use paid Medicare FFS claims from a 12-month period from July 1st of the 3 years before the payment determination through June 30th of the following year. For example,

for the 2017 payment determination, the claims period would be July 1, 2014 through June 30, 2015.

In total, CMS proposes 24 mandatory measures for the 2017 payment determination. The table below shows the proposed measures along with OQR measures previously adopted for payment determinations from 2011 through 2016. Specifications for adopted measures are available on the QualityNet.org website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244

Hospital OQR Program Measure Sets Previously Finalized and Proposed for 2017							
	Payment Determination Year						
	2011	2012	2013	2014	2015	2016	2017-P
OP-1: Median Time to Fibrinolysis	X	X	X	X	X	X	X
OP-2: Fibrinolytic Therapy Received Within 30 Minutes	X	X	X	X	X	X	X
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X	X	X
OP-4: Aspirin at Arrival	X	X	X	X	X	X	Proposed removal
OP-5: Median Time to ECG	X	X	X	X	X	X	X
OP-6: Timing of Antibiotic Prophylaxis	X	X	X	X	X	X	Proposed removal
OP-7: Prophylactic Antibiotic Selection for Surgical Patients	X	X	X	X	X	X	Proposed removal
OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X	X
OP-9: Mammography Follow-up Rates	X	X	X	X	X	X	X
OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X	X	X
OP-11: Thorax CT – Use of Contrast Material	X	X	X	X	X	X	X
OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data		X	X	X	X	X	X
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery		X	X	X	X	X	X
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)		X	X	X	X	X	X

Hospital OQR Program Measure Sets Previously Finalized and Proposed for 2017							
	Payment Determination Year						
	2011	2012	2013	2014	2015	2016	2017-P
OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache		Adopted, but public reporting deferred					X, with deferred public reporting continued
OP-17: Tracking Clinical Results between Visits			X	X	X	X	X
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients			X	X	X	X	X
OP-19: Transition Record with Specified Elements Received by Discharged Patients			Adopted, but data collection suspended		Removed		
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional			X	X	X	X	X
OP-21: ED- Median Time to Pain Management for Long Bone Fracture			X	X	X	X	X
OP-22: ED- Patient Left Without Being Seen			X	X	X	X	X
OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival			X	X	X		X
OP-24: Cardiac Rehabilitation Patient Referral From an Outpatient Setting				Adopted, but data collection deferred	Removed		
OP-25: Safe Surgery Checklist Use				X	X	X	X
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (see note below)				X	X	X	X
OP-27: Influenza Vaccination Coverage among Healthcare Personnel						X	X
OP-29: Endoscopy/Poly Surveillance: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients						X	X
OP-30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of						X	X

Hospital OQR Program Measure Sets Previously Finalized and Proposed for 2017							
	Payment Determination Year						
	2011	2012	2013	2014	2015	2016	2017-P
Inappropriate Use							
OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery						X (proposed for exclusion)	Voluntary
Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy							X
Note: For OP-26, specific surgical procedure codes for which volume data must be reported are identified by organ system (gastrointestinal, eye, nervous system, musculoskeletal, skin, genitourinary, cardiovascular, respiratory and other) and procedure category. These can be found in the measure specifications available at QualityNet.org.							

E. Possible Hospital OQR Program Measure Topics for Future Consideration

With respect to possible future measures, CMS indicates that it is exploring four areas:

1. Electronic Clinical Quality Measures. CMS discusses its activities aimed at accelerating health information exchange through electronic health records (EHRs) and other information technologies (IT). Part of this goal is to accept electronic clinical quality measures, which CMS believes will reduce the administrative burden created by hospital reporting of chart-abstracted measures in the OQR Program. CMS recognizes that much work remains to reach this point by measure owners and IT developers, including developing electronic specifications, pilot testing, reliability and validity testing, and implementing measures in certified EHR technology.

2. Partial Hospitalization. CMS seeks public comment on the three measures below regarding partial hospitalization programs (PHPs) as potential future OQR Program measures. These claims-based measures were submitted to the MAP for consideration in the 2014 pre-rulemaking report. All three measures are included in the PHP Program for Evaluating Payment Patterns Electronic Reports developed under the Comprehensive Error Rate Testing Program. Further information is available at: http://www.pepperresources.org/LinkClick.aspx?fileticket=stK9uUmQWlM%3d&tabid=148

- 30-Day Readmission
- Group Therapy
- No Individual Therapy

CMS also invites public comment on other potential PHP measures and on the utility of including PHP measures in the OQR Program given the decline in PHP utilization.

3. Behavioral Measures. CMS is also considering other measures specific to behavioral health in the outpatient setting, such as measures involving depression and alcohol abuse, and cites data on the prevalence of these conditions among older individuals. In addition, CMS indicates that depression, along with other serious mental health conditions, has the second highest Medicare inpatient readmission rate, behind heart failure.

4. National Quality Strategy Domains. In considering future measures, CMS is focused on the National Quality Strategy and CMS Quality Strategy domains, which it describes as: make care safer, strengthen person and family engagement, promote effective communication and coordination of care, promote effective prevention and treatment, work with communities to promote best practices of healthy living, and make care affordable.

F. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the 2015 Payment Update

CMS proposes to continue for the 2015 update the existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements. The proposed reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio", is 0.98. It is calculated by dividing the proposed reduced conversion factor of $72.692 by the proposed full conversion factor of $74.176. Continuing previous policies, when applicable the reporting ratio would be applied to all services calculated using the OPPS conversion factor. It would be applied to all HCPCS codes to which CMS has assigned status indicators P, Q1, Q2, Q3, R, S, T, V, and U, excluding services paid under the New Technology APCs to which CMS has assigned status indicators S and T. (CMS notes that elsewhere in this rule, it proposes to delete current status indicator 'X' and to develop a status indicator 'J1' under the proposed comprehensive APC policy, and to apply the reporting ratio to the comprehensive APCs.) The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services, all other applicable standard adjustments to the OPPS national unadjusted payment rates would apply, and OPPS outlier eligibility and outlier payment would be based on the reduced payment rates.

In 2014, 64 were subject to the update reduction for failure to meet OQR Program requirements (46 of these hospitals chose not to participate in the quality reporting program and 18 hospitals participated but did not fully satisfy program requirements and thus were also subject to the reduction).

G. Requirements for Reporting of Hospital OQR Program Data for the 2017 Payment Determination and Subsequent Years

CMS proposes no changes to the OQR Program data submission requirements for the 2017 payment determination. (One technical correction to the regulatory text is proposed to correct a typographical error.) No changes are proposed to the reconsideration and appeals process or to the extraordinary circumstances extension or exceptions process, except that the latter was

formerly referred to as the extraordinary circumstances extensions or waivers process, and CMS proposes technical changes to the regulatory text to reflect the name change.

Deferred Public Reporting of OP-15. With respect to the claims-based measure OP-15: Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache, CMS notes that public reporting of this measure was deferred in previous rulemaking, and no change in this policy is proposed. The measure remains in the OQR Program measure set.

Review and Corrections of Chart-Abstracted Measures. CMS proposes to formalize the existing quarterly data submission time periods as the review and corrections period for chart-abstracted data for the Hospital OQR Program. The period begins on the first discharge day of the reporting quarter and generally ends 4 months after the end of the reporting quarter (unless an extension or exception is granted). Under the proposal, as now, during this entire time frame hospitals could enter, review, and correct data submitted directly to CMS. After the submission deadline, however, hospitals would not be allowed to change these data. CMS encourages hospitals to submit data early in the submission schedule so that they can identify errors and resubmit data before the quarterly submission deadline.

Data Validation. CMS proposes three changes to OQR Program data validation procedures. First, the eligibility requirements for hospitals to be selected for validation would be changed. Currently, a hospital is eligible for inclusion in the validation sample for a payment determination if it is coded as "open" in the CASPER system at the time of selection and it has submitted at least 10 encounters to the OPPS Clinical Warehouse during the relevant data collection period. Under the proposal, a hospital would be eligible if it submits at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data. The quarter containing the most recently available data would be based on when the random sample is drawn. CMS offers the example of a sample drawn in December 2014, for which the most recent data available would be that from the second quarter of 2014, which ends June 2014, because the submission deadline for second quarter data would be November 1, 2014. CMS believes the change is necessary to increase the probability that selected hospitals have current data in the Warehouse to be validated.

Under the second proposed change to validation procedures, hospitals would be given the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation. CMS notes that a similar policy has been finalized for the IQR program, which allows hospitals to submit electronic records through the mail on a CD, DVD, or flash drive. In the FY 2015 IPPS/LTCH proposed rule CMS would expand this policy to also allow hospitals to submit patient charts using a Secure File Transfer Portal on the QualityNet website. For the OQR Program, CMS proposes that all these options would be available beginning with the 2017 payment determination. Detailed information on submission using the Secure File Transfer Portal is available on QualityNet: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598

The third proposed change relates to ensuring that the validation contractor has the necessary contact information to request records. Current procedures require the validation contractor to

request medical documentation from each hospital selected for validation via certified mail or other trackable method. This request is sent to the hospital's medical records staff identified by the hospital to the state Quality Improvement Organization (QIO). CMS proposes to modify this to require that the hospital identify to the designated CMS contractor the medical record staff responsible for submission of records under the Hospital OQR Program. The designated contractor may or may not be the state QIO.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

In this section of the proposed rule, CMS proposes changes to the ASCQR program measures that parallel the changes proposed for the OQR Program, and discussed in section XIII above. These proposed changes involve addition of one new claims-based measure beginning with the 2017 payment determination, and making reporting voluntary only for one measure previously adopted for 2016 payment determination voluntary. CMS also proposes a policy for removal of adopted measures and discusses delays in the reporting period for two additional measures previously adopted for the 2016 payment determination.

A. Background

In the 2012 OPPS/ASC final rule, CMS finalized the implementation of an ASC Quality Reporting (ASCQR) Program beginning with the 2014 payment determination. That rule finalized measures for the 2014, 2015 and 2016 payment determinations. In several subsequent rules, additional program requirements were finalized and additional measures were adopted for 2016.

B. Removal of Adopted Measures

CMS proposes a process for removing adopted measures from the ASCQR program that parallels the process used in other quality reporting programs. The proposal includes a process for immediate removal and criteria for proposing removal during rulemaking. CMS proposes to immediately remove an ASCQR program measure when there is evidence that its continued use as specified raises patient safety concerns. ASCs and the public would be notified of the removal and the reasons for it through the ASCQR program ListServ and the ASCQR Program QualityNet website. Removal would be confirmed in the next OPPS/ASC rule. As is the case for other quality reporting programs, proposed criteria for proposing removal of a measure during rulemaking with public comment are: (1) a measure is "topped out; 2) alternative measures with a stronger relationship to patient outcomes are available 3) a measure does not align with current clinical guidelines or practice; (4) availability of more broadly applicable measures on the topic; (5) availability of a measure that is more proximal in time to desired patient outcomes; (6) the availability of a measure that is more strongly associated with desired patient outcomes; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

The proposed definition of "topped out" measure is identical to that proposed for the OQR Program and described above in section XIII.B.

C. ASCQR Program Quality Measures for the 2017 Payment Determination and Subsequent Years

CMS proposes to add one new measure to the ASCQR program for the 2017 payment determination: ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. This measure is also proposed for addition to the OQR Program for that year, and is discussed in detail in section XIII.D above. The MAP conditionally supported this measure for the ASCQR Program, noting that it is promising but needs further development, and should be submitted for and receive NQF endorsement. CMS believes it has addressed specific concerns raised by the MAP, and that the measure meets statutory requirements regarding the use of measures that reflect consensus among affected parties and, to the extent feasible and practicable, that include measures set forth by national consensus building entities.

Previously adopted measures would be continued for 2017, although as discussed in section XIV.E below, reporting on the measure regarding complications from cataract surgery would be made voluntary. The table below shows previously adopted ASCQR measures for 2014-2016 and proposed measures for 2017. Specifications for adopted measures are available on the QualityNet.org website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754

ASCQR Program Measure Sets Adopted for the 2014-2016 Payment Determinations and Proposed Measure Set for 2017				
	2014	**2015**	**2016**	**2017-P**
ASC-1: Patient Burn (NQF #0263)	X	X	X	X
ASC-2: Patient Fall (NQF #0266)	X	X	X	X
ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267)	X	X	X	X
ASC-4: Hospital Transfer/Admission (NQF #0265)	X	X	X	X
ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing (NQF #0264)	X	X	X	X
ASC-6: Safe Surgery Checklist Use		X	X	X
ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures (see below)		X	X	X
ASC-8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)			X	X
ASC-9 Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)			X	X
ASC-10 Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659)			X	X

ASCQR Program Measure Sets Adopted for the 2014-2016 Payment Determinations and Proposed Measure Set for 2017				
	2014	**2015**	**2016**	**2017-P**
ASC-11 Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)			X, Proposed for exclusion	Voluntary
ASC-12 Facility Seven Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy				X
Note: For ASC-7, specific surgical procedure codes for which volume data must be reported are identified by organ system (gastrointestinal, eye, nervous system, musculoskeletal, skin, genitourinary, cardiovascular, respiratory and other) and procedure category. These are available in the measure specifications at QualityNet.org.				

D. ASCQR Program Measures for Future Consideration

CMS indicates that in considering future ASCQR Program measures it is focused on the following National Quality Strategy and CMS Quality Strategy domains: Make care safer; strengthen person and family engagement; promote effective communication and coordination of care; promote effective prevention and treatment; work with communities to promote best practices of healthy living; and make care affordable.

E. Reporting Requirements and Procedures

CMS proposes to maintain existing policies and procedures for the ASCQR program. No changes are proposed with respect to public reporting, administrative requirements, data collection procedures and completeness requirements for measures submitted through quality data codes (QDCs), procedures for reporting on certain measures through a web-based tool, or the information reconsideration process. The previously finalized extraordinary circumstances extension or waiver process is maintained but will be referred to as extraordinary circumstances extensions or exemptions. No data validation process has been adopted for the ASCQR Program and none is proposed in this rule.

Several changes are proposed with respect to reporting specific measures. For the most part these proposals parallel those made with respect to these same measures in the OQR Program, as discussed above in section XIII.C.

Proposed Reporting Changes for ASC-11 (Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery). This measure was finalized for inclusion in the ASCQR Program measure set beginning with the 2016 payment determination as part of last year's rulemaking. Subsequently, CMS has come to believe that it may be operationally difficult for ASCs to collect and report this measure, which requires physicians to share results of pre-and post-surgery patient surveys with the ASC. In addition CMS is concerned that the use of different validation patient survey instruments might lead to inconsistent results. As a result,

CMS has twice issued guidance delaying the initial data collection period for this measure from calendar year 2014 to calendar year 2015.

In this rule, CMS proposes to 1) exclude this measure from the 2016 payment determination measure set and 2) make reporting on this measure voluntary for the 2017 payment determination and subsequent years. ASCs would not be subject to an update reduction for failing to report on this measure during the period of voluntary reporting. If an ASC chooses to voluntarily report, CMS requests that this be done using the process and timelines finalized for this measure in the 2014 OPPS/ASC final rule (78 FR 75138 to 75139). Data reported voluntarily will be publicly reported.

Previously Announced Delays in Data Collection for ASC-9 and ASC-10 (Endoscopy/Polyp Surveillance Measures). Subsequent to publication of the 2014 OPPS/ASC final rule, CMS issued guidance to delay the implementation period for two measures finalized in that rule: ASC-9: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659). ASCs were originally required to submit initial aggregate data on these measures via the QualityNet website between January 1, 2015 and August 15, 2015 for encounters occurring during calendar year 2014. Instead of beginning January 1, 2014 the initial encounter period was changed to April 1, 2014, still ending December 31, 2014. The data submission window (January – August 2015) was unchanged.

Data Collection Timeline and Data Submission Deadline for ASC-8 (Influenza Vaccination Coverage Among Healthcare Personnel). CMS proposes to adopt a data collection period policy for this measure, which was added to the ASCQR measure set beginning with the 2016 payment determination. In that rule a data collection period for the 2016 payment determination was finalized to be October 1, 2014 through March 31, 2015. For the 2017 payment determination and later, CMS now proposes that ASCs similarly collect data for the period from October 1 of the year 2 years prior to the payment determination year through March 31 of the year prior to the payment determination year. For example, for the 2017 payment determination the data collection period would be October 1, 2015 through March 31, 2016.

No data submission deadline was finalized for this measure in last year's rulemaking, and CMS in this rule proposes that ASCs submit data on this measure by May 15 of the year prior to the payment determination year (e.g., May 15, 2015 for the 2016 payment determination). CMS notes that this is the same deadline used for reporting this measure in the IQR and OQR programs.

Timeline for Proposed New Claims-Based Measure. For the proposed new claims-based measure ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy, CMS proposes to use paid Medicare FFS claims from a 12 month period from July 1 of the year 3 years prior to the payment determination to June 30 of the following year. For example, for the 2017 payment determination, CMS would use claims from July 1, 2014 through June 30, 2015 to calculate this measure. This period aligns with the data submission requirements for claims-based measures that were adopted for the OQR Program in the 2014 OPPS/ASC final rule.

XV. Changes to the Rural Provider and Hospital Ownership Exceptions to the Physician Self-Referral Law

A. Background

Among the exceptions to the physician self-referral law created under statute and regulations, section 1877(d)(2) of the Act excepts ownership and investment interests in rural providers[7], and section 1877(d)(3) of the Act provides the hospital ownership exception[8].

Section 6001 of the ACA added restrictions to these exceptions. First, the term "physician owner or investor" now means a physician or immediate family member who has a direct or indirect ownership or investment interest in a hospital; CMS refers to hospitals with these ownership or investment interests as "physician-owned hospitals." Second, the ACA imposed limits on expansion of facility capacity of physician-owned hospitals beyond the number of operating rooms, procedure rooms and beds for which the hospital was licensed as of March 23, 2010, unless CMS grants an exception (referred to as the "expansion exception process"). CMS has implemented the ACA requirements for these exceptions[9]. For example, CMS uses data from the CMS Healthcare Cost Report Information System (HCRIS) to determine whether the hospital meets the requisite criteria, such as inpatient Medicaid admissions, bed capacity and bed occupancy criteria. Stakeholders have identified potential limitations of HCRIS data.

B. Limitations Regarding Required Use of HCRIS Data

Stakeholders note that completed hospital cost reports do not include Medicaid managed care admissions or discharges. Because those data are not available in HCRIS, stakeholders believe this precludes them from qualifying for an exception under the expansion exception process. Additionally, a hospital that does not have filed cost report discharge data for each of the 3 most recent fiscal years for which data are available because it was not a Medicare provider during the entire period would be precluded from seeking an expansion exception even if it had treated Medicaid patients during that 3-year period.

CMS agrees with stakeholders and proposes a change to the process whereby physician-owned hospitals may use data from the HCRIS (i.e., filed hospital cost report data) as well as from "supplemental data sources" (i.e., data from certain internal or external data sources) to estimate the required percentages.

[7] To qualify for the exception, the designated health services must be furnished in a rural area, and substantially all of those designated health services must be furnished to individuals residing in the rural area.
[8] Known as the "whole hospital exception, this exception applies to ownership and investment interests in a hospital (outside Puerto Rico) where the physician is authorized to perform services at the hospital and the interest is in the hospital itself (rather than merely a subdivision of the hospital).
[9] See e.g., 42 CFR 411.362(b)(2) for the prohibition on expansion; 42 CFR 411.362(c)(2) for the expansion exception rules generally; and 42 CFR 411.362(c)(3) for the expansion exception rules for high Medicaid facilities.

C. Proposed Changes to Permit Supplemental Data Sources

CMS proposes to allow physician-owned hospitals to use data from certain internal or external data sources to estimate the percentages of inpatient Medicaid admissions and to determine the bed capacity and bed occupancy criteria. CMS proposes that internal data sources are those sources generated, maintained or under the control of the Department, such as the Healthcare Cost and Utilization Project (HCUP), Medicaid Statistical Information System (MSIS), and Medicaid Analytic Extract (MAX). CMS proposes that external data sources would be data sources generated, maintained, or under the control of a State Medicaid agency. CMS seeks comments that recommend other internal and external data sources for purposes of the expansion exception process.

CMS proposes to define internal and external data sources for purposes of the expansion exception process.

- "Internal data source" would include only those non-HCRIS data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable.
- "External data source" would include only data sources that are reliable and transparent, and that maintain or generate data that are accurate, complete, and objectively verifiable.

CMS notes that supplemental data sources would have to meet all the following requirements. They should:

1. Be transparent regarding what comprises the data, where the data originated, and the manner and method by which the data source received the data;
2. Be maintained on a secure database that prevents distortion or corruption of data and that ensures the accuracy of the data;
3. Contain sufficient information to enable accurate estimates of the percentages of inpatient Medicaid admissions, and accurate determinations of bed capacities and bed occupancy rates;
4. Contain sufficient information to enable the comparisons required by §§ 411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) for the fiscal year(s) at issue; and
5. Contain sufficiently clear and detailed data that will enable multiple users to produce consistent results and outcomes when using the same data set.

Recognizing that a physician-owned hospital using supplemental data sources may have to make additional estimates or determinations to those required under regulations, CMS proposes to permit such a hospital to make its own estimates and determinations, such as:

1. The hospital's annual percentage of inpatient Medicaid admissions.
2. The average percentage of inpatient Medicaid admissions for all hospitals located in the county.
3. The State and national average bed capacities.
4. The hospital's and the State average bed occupancy rates.
5. The hospital's annual percentage of total inpatient Medicaid admissions for each of the 3 most recent fiscal years for which data are available.
6. The annual percentages of total inpatient Medicaid admissions for every other hospital located in the county for those fiscal years.

In implementing the requirement for data from the 3 most recent fiscal years for which data are available for applicable hospitals and high Medicaid facilities in regulations, CMS currently considers the most recent fiscal year to be the most recent year for which the HCRIS contains data from at least 6,100 hospitals. CMS proposes to revise this standard to the year for which the data source(s) contain sufficient data to perform the comparisons under §§411.362(c)(2)(ii), (c)(2)(iv), (c)(2)(v), and (c)(3)(ii) (described immediately above). Sufficient data would mean all data from the requesting hospital and each hospital to which the requesting hospital must compare itself as well as data necessary to determine State and national average bed capacity as well as the State average bed occupancy rate. CMS also proposes that the data used be from the same fiscal year. CMS seeks comment on these proposals.

CMS proposes to require a requesting hospital to notify in writing those hospitals whose data are part of the comparisons with the requesting hospital seeking the exception. CMS also proposes to substantially extend the period for the community input and hospital rebuttal process where supplemental data sources are used. Under the proposal, the expansion exception request using supplemental data sources would be deemed complete no later than:

1. 180 days after the end of the 30-day comment period if no written comments from the community are received; and
2. 180 days after the end of the 30-day rebuttal period if written comments from the community are received, regardless of whether the physician-owned hospital submitting the request submits a rebuttal statement.

CMS also seeks comment on the following:

- Whether the use of supplemental data sources would significantly affect the outcomes for any of the estimates or determinations required in regulations.
- Whether the use of supplemental data sources would materially affect a physician-owned hospital's ability to request an exception or CMS' determination on an exception request.
- The length of time necessary to obtain or generate the required data from a specific data source.
- Whether and when data will be available and accessible per fiscal year.
- Whether the data will be available and accessible in a format that allows the requesting hospital to perform the necessary comparisons.
- How supplemental data sources should be prioritized, such as rankings related to accuracy or reliability.
- How data from a particular data source could be used in the expansion exception process.
- The cost to industry stakeholders, State governments, and the Federal government for obtaining or generating data from any potential data source.
- Any additional burdens that would affect the quality of care for beneficiaries as a result of additional costs borne by a requesting hospital.

D. Impact

Given the voluntary nature of the expansion exception process, CMS believes the impact of its proposals on affected hospitals would be minimal, including the requirement to notify hospitals

whose data are part of the comparison. CMS notes that there are 265 physician-owned hospitals and that each year as many as four may apply for an exception. CMS also states that it has no data or projections to estimate the number of physicians who would be affected as a result of their ownership interests in hospitals. CMS solicits comments on its impact estimates, especially from State governments with respect to the proposed external data sources.

XVI. Proposed Revision of the Requirements for Physician Certification of Hospital Inpatient Services

With respect to the certification requirement under the statute for an inpatient hospital stay, CMS maintains that its interpretation that the certification requirement applies to more than just long-stay cases, or indeed all inpatient admissions, is permissible.

CMS believes that a physician's or other qualified practitioner's order is required for all inpatient admissions since the order is the means by which a beneficiary becomes a hospital inpatient triggering the requirement for payment under Part A. CMS also believes that the order must be present in the medical record and be supported by the physician ad mission and progress notes.

Upon reflection, CMS believes that in the majority of cases the benefits of a formal physician certification (e.g., program safeguards) may not outweigh the associated administrative burden. While not changing its conclusion that its interpretation of the statutory requirement for the physician certification requirement is permissible, CMS nonetheless proposes to only require physician certification for long-stay cases and outlier cases. CMS believes the appropriate minimum threshold for physician certification is cases with stays of 20 days or longer, with certification required no later than 20 days into the hospital stay.

Additionally, CMS proposes to remove the requirement of the physician order for inpatient admission as an element of the physician certification and to require it instead under its general rulemaking authority under section 1871 of the Act. Thus, the physician order (while still necessary) would no longer be a required component of physician certification of medical necessity.

CMS is not proposing any changes to the certification requirements for inpatient psychiatric hospital services or to the admission requirements for inpatient rehabilitation facilities. CMS invites comments on these proposals.

XVII. CMS-Identified Overpayments Associated with Payment Data Submitted by Medicare Advantage (MA) Organizations and Medicare Part D

CMS believes that it must establish a formal process to recoup overpayments that result from the submission of erroneous payment data by a Medicare Advantage organization (MAO) or Part D sponsor when the organization or sponsor fails to correct those data after notice by CMS. Erroneous payment data refers to data submitted by MAOs or Part D sponsors that are inaccurate or that are inconsistent with Medicare Part C and Part D requirements.

CMS states that the new process would neither replace established recovery and appeals processes (i.e., the Risk Adjustment Data Validation (RADV) audit dispute and appeal process or the Part D payment appeals process) nor constitute a change to existing Part C or D payment methodologies. Rather it is intended to address errors and payment adjustments not addressed by existing processes. For example, if an MAO or Part D sponsor self-identified an overpayment, it would report and return the overpayment pursuant to section 1128J(d) of the Act and regulations at §§422.326 and 423.360. CMS invites comment on its proposal.

Definitions (Proposed §§422.330(a); 423.352(a)).

CMS proposes definitions for two key terms: "payment data" and "applicable reconciliation date" which are very similar to the definitions used under other Part C and D overpayment audit and appeals processes.

- Payment data would mean data controlled and submitted by an MAO or Part D sponsor to CMS that is used for payment purposes (e.g., Part C enrollment and risk adjustment data, and for Part D data on enrollment, risk adjustment, and cost, data for retroactive adjustments and reconciliations, reinsurance and risk corridor costs). It does not include data submitted by entities like the Social Security Administration.
- The applicable reconciliation date would mean—
  - For MAOs under Part C, the date of the annual final risk adjustment data submission deadline under §422.310(g)(2)(ii).
  - For Part D sponsors, the later of (i) the annual deadline for submitting PDE data for the annual Part D payment reconciliations under §423.343(c) and (d) [i.e., the last Federal business day before June 30 of the year after the coverage year]; or (ii) the annual deadline for submitting direct and indirect remuneration (DIR) data [i.e., generally the last business day in June of the year after the coverage year].

Request for Corrections of Payment Data (Proposed §§422.330(b); 423.352(b)).

Should CMS identify a payment data error that would result in an overpayment, CMS would request that the MAO or Part D sponsor correct the payment data error through a data corrections notice that would identify the erroneous payment data and the timeframe in which the organization or sponsor must correct the data. CMS proposes to apply the same look-back period of 6 years for which CMS would request corrections to erroneous payment data as applies under the process for correction of plan-identified overpayments. CMS would explain the timeframes for correcting the data under this process through procedural rules and guidance which would be the same as existing timeframes for correcting data (e.g., 90 days from data of discovery of an error to correct prescription drug event (PDE) data).

Payment Offset (Proposed §§422.330(c); 423.352(c)).

Upon receipt of a request to correct payment data, an MAO or Part D sponsor may submit the corrected data (which would trigger reconciliation in the payment system under established procedures) or fail to correct the data in which case CMS proposes to offset the payment error from plan payments. CMS would use a payment algorithm to calculate what the correct payment

should have been for the year involved using corrected payment data, but would differ for payments under Part C and Part D due to the different payment rules under those Parts. CMS proposes to calculate the payment with and then without the corrected data as of a specified date.

If erroneous payment data is subsequently corrected through the CMS payment system, CMS proposes to reverse the payment offset amount and update the payment to the MAO or Part D sponsor through the routine payment process. CMS would also be able to reverse an original offset amount and recalculate the offset using more recent data (such as data in the most recent payment reconciliation or reopening).

Payment Offset Notification (Proposed §§422.330(d); 423.352(d)).

CMS proposes to provide a payment offset notice to the MAO or Part D sponsor involved which would include the offset dollar amount, an explanation of how the erroneous data were identified and how the offset amount was calculated, and the organization's or sponsor's appeal rights.

Appeals Process (Proposed §§422.330(e) and (f); 423.352(e) and (f)).

CMS proposes an appeals process for a notice of payment offset with three levels of review: reconsideration, informal hearing and Administrator review. The grounds for appeal would be limited to whether CMS' findings of erroneous payment data were incorrect or otherwise inconsistent with applicable program requirements.

A request for reconsideration would have to be made within 30 days of the payment offset notice and would have to include the finding(s) or issue(s) with respect to which there is disagreement, the reasons for that disagreement, and any documentary evidence (which must be submitted with the reconsideration request). The MAO or Part D sponsor would have to establish by a preponderance of the evidence that CMS' findings of erroneous payment data were incorrect or otherwise inconsistent with applicable program requirements. A CMS reconsideration official would review the underlying data and the evidence submitted with the request and would inform the MAO or Part D sponsor of its decision, which would be final and binding absent a timely filing for an informal hearing.

A request for an informal hearing would have to be made within 30 days of the reconsideration decision and would have to specify the finding(s) or issue(s) with respect to which there is disagreement and the reasons for that disagreement. CMS would have to give 10 days prior notice of the time and place of the informal hearing which would be conducted by a CMS hearing official. The review would be limited to the record for the reconsideration decision; no new documentation or evidence could be submitted. The reconsideration decision would not be reversed unless the MAO or Part D sponsor could establish that the decision was clearly erroneous based on the evidence in the record. A CMS hearing official would send a written decision to the MAO or Part D sponsor that would be final and binding absent a timely filing for Administrator review.

A request for review by the CMS Administrator would have to be made within 30 days of the decision of the informal hearing. The Administrator could grant or decline review. If the

Administrator declines to review the hearing official's decision, that decision would be final and binding. If the Administrator grants review, the MAO or sponsor would be allowed to submit written arguments which the Administrator would review along with the hearing official's decision and the record. The Administrator could uphold, reverse, or modify the hearing official's decision, and the Administrator's determination would be final and binding.

Proposed Effective Date.

CMS proposes to make the appeals process effective on the effective date of any final rule implementing the appeals process, but it notes that requests to correct payment data and any associated payment offsets would apply to any payment year within the six-year look-back period described above.

Impact.

CMS believes it is highly unlikely that more than 10 cases per year would be subject to the proposed offset and appeals regulation, and also notes that the decision to appeal an offset notice would be made by the MAO or Part D sponsor. CMS estimates a total annual cost for appeals requests at all three levels at $11,000. This is based on an hourly rate of $62.93 for 5 hours to prepare a reconsideration request and 2 additional hours for each of the subsequent two levels of appeal for each case.

XVIII. Files Available to the Public via the Internet

CMS adds a new Addendum J to the proposed rule which lists the HCPCS code pairs for which it proposes complexity adjustments for 2015, by clinical family; the HCPCS codes proposed for exclusion from the comprehensive APC payment bundle; and the relevant cost statistics. To view this addendum and all other addenda to the proposed rule, CMS instructs readers to go the following CMS website and select "1613-P" from the list of regulations: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html. For addenda related to 2015 ASC payments, please see http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html and select 1613-P from the list of regulations.

XIX. Collection of Information Requirements

CMS provides estimates of the burden associated with various collection of information requirements specified in the regulation text as well as those not discussed in regulation text. For the former, CMS addresses its proposal to expand the exception process for the rural provider and hospital ownership exceptions to the physician self-referral law and finds that the policy proposal is exempt from the PRA because it would not impact 10 or more persons in a 12-month period. For the latter, CMS discusses burdens associated with the hospital OQR program and the ASCQR program. CMS invites comment on its burden estimates for the collection of information requirements.

XX. Response to Comments

CMS notes that it will consider all comments timely received and respond to those comments (though not individually) in the preamble of a subsequent document.

APPENDICES: SELECTED TABLES REPRODUCED FROM THE PROPOSED RULE

TABLE 52.—ESTIMATED IMPACT OF THE PROPOSED 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

ADDENDUM J: 2015 COMPLEXITY ADJUSTMENT APC ASSIGNMENTS OF COMBINATIONS OF COMPREHENSIVE HCPCS CODES

TABLE 52.—ESTIMATED IMPACT OF THE PROPOSED 2015 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Budget Neutral Changes and Proposed Update (Column 4) with Proposed Frontier Wage Index Adjustment**	**All Proposed Changes**
ALL FACILITIES *	3,947	0.0	0.0	2.1	2.2	2.2
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,814	0.0	0.0	2.1	2.2	2.2
URBAN HOSPITALS	2,953	-0.1	0.0	2.1	2.2	2.2
LARGE URBAN	1,616	-0.1	0.1	2.2	2.2	2.3
(GT 1 MILL.)						
OTHER URBAN	1,337	-0.1	-0.1	1.9	2.2	2.1
(LE 1 MILL.)						
RURAL HOSPITALS	861	0.5	-0.2	2.4	2.7	2.5
SOLE COMMUNITY	377	0.7	-0.1	2.6	3.0	2.7
OTHER RURAL	484	0.3	-0.3	2.2	2.3	2.2
BEDS (URBAN)						
0 - 99 BEDS	1,008	0.1	0.1	2.4	2.6	2.5
100-199 BEDS	856	0.2	0.0	2.3	2.4	2.4
200-299 BEDS	462	-0.2	0.1	2.0	2.2	2.2
300-499 BEDS	412	-0.3	0.0	1.8	2.0	2.0
500 + BEDS	215	0.1	0.0	2.1	2.1	2.3
BEDS (RURAL)						
0 - 49 BEDS	338	0.9	0.0	3.0	3.2	3.0
50- 100 BEDS	319	1.2	-0.2	3.0	3.3	3.1
101- 149 BEDS	117	0.3	-0.1	2.3	2.6	2.4
150- 199 BEDS	47	0.0	-0.5	1.6	2.3	1.7
200 + BEDS	40	-0.6	-0.2	1.3	1.3	1.4

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Budget Neutral Changes and Proposed Update (Column 4) with Proposed Frontier Wage Index Adjustment**	**All Proposed Changes**
VOLUME (URBAN)						
LT 5,000 Lines	500	-2.6	-0.2	-0.8	-0.6	-0.7
5,000 - 10,999 Lines	138	-2.7	-0.1	-0.7	-0.1	-0.5
11,000 - 20,999 Lines	120	-2.4	0.0	-0.3	-0.1	-0.1
21,000 - 42,999 Lines	237	-0.4	0.1	1.8	1.8	1.9
42,999 - 89,999 Lines	540	-0.2	0.0	1.9	1.9	2.0
GT 89,999 Lines	1,418	0.0	0.0	2.1	2.2	2.3
VOLUME (RURAL)						
LT 5,000 Lines	35	-5.1	-0.1	-3.1	-0.3	-3.1
5,000 - 10,999 Lines	27	-4.1	0.1	-1.9	-0.7	-1.9
11,000 - 20,999 Lines	50	-0.2	-0.4	1.5	1.7	1.5
21,000 - 42,999 Lines	162	1.0	-0.1	3.0	3.5	3.0
GT 42,999 Lines	587	0.5	-0.2	2.4	2.6	2.5
REGION (URBAN)						
NEW ENGLAND	151	1.3	-0.1	3.3	3.3	3.4
MIDDLE ATLANTIC	357	0.5	0.5	3.1	3.1	3.2
SOUTH ATLANTIC	468	-0.2	-0.2	1.6	1.6	1.8
EAST NORTH CENT.	465	0.1	-0.3	1.9	1.9	2.1
EAST SOUTH CENT.	175	-1.0	-0.5	0.6	0.6	0.8
WEST NORTH CENT.	192	-0.1	0.0	2.0	3.2	2.1
WEST SOUTH CENT.	509	-1.1	-0.2	0.8	0.8	1.0
MOUNTAIN	199	0.0	0.0	2.1	2.5	2.3
PACIFIC	390	-0.1	1.0	3.1	3.1	3.2
PUERTO RICO	47	1.0	0.5	3.6	3.6	3.6
REGION (RURAL)						
NEW ENGLAND	23	2.0	-0.1	4.0	4.0	4.1
MIDDLE ATLANTIC	58	1.4	0.4	3.9	3.9	4.0
SOUTH ATLANTIC	130	-0.3	-0.5	1.3	1.3	1.4
EAST NORTH CENT.	120	0.7	0.0	2.8	2.8	2.9

	(1)	(2)	(3)	(4)	(5)	(6)
	Number of Hospitals	**APC Recalibration (all proposed changes)**	**Proposed New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2,3) with Proposed Market Basket Update**	**All Proposed Budget Neutral Changes and Proposed Update (Column 4) with Proposed Frontier Wage Index Adjustment**	**All Proposed Changes**
EAST SOUTH CENT.	165	-0.2	-0.4	1.5	1.5	1.6
WEST NORTH CENT.	99	0.7	-0.2	2.6	3.8	2.6
WEST SOUTH CENT.	181	0.1	-0.6	1.6	1.6	1.7
MOUNTAIN	61	0.9	-0.5	2.6	4.3	2.8
PACIFIC	24	1.4	0.9	4.4	4.4	4.4
TEACHING STATUS						
NON-TEACHING	2,793	-0.1	0.0	2.0	2.1	2.1
MINOR	699	-0.3	-0.1	1.7	1.9	1.8
MAJOR	322	0.6	0.1	2.8	2.8	2.9
DSH PATIENT PERCENT						
0	15	0.2	0.5	2.8	3.2	2.8
GT 0 - 0.10	334	0.3	0.2	2.6	2.8	2.7
0.10 - 0.16	317	0.3	-0.1	2.4	2.5	2.4
0.16 - 0.23	681	0.2	-0.1	2.3	2.4	2.4
0.23 - 0.35	1,095	0.0	0.0	2.1	2.3	2.2
GE 0.35	811	-0.2	0.0	1.9	1.9	2.1
DSH NOT AVAILABLE **	561	-6.6	0.1	-4.4	-4.4	-4.5
URBAN TEACHING/DSH						
TEACHING & DSH	928	0.1	0.0	2.2	2.3	2.3
NO TEACHING/DSH	1,482	-0.2	0.1	2.0	2.1	2.1
NO TEACHING/NO DSH	13	0.2	0.5	2.9	2.9	2.9
DSH NOT AVAILABLE**	530	-6.1	0.2	-3.8	-3.8	-3.9
TYPE OF OWNERSHIP						
VOLUNTARY	2,007	0.1	0.0	2.2	2.4	2.4
PROPRIETARY	1,255	-0.5	0.0	1.6	1.7	1.7
GOVERNMENT	552	0.0	-0.1	2.1	2.1	2.2
CMHCs	72	-4.0	-0.1	-2.0	-2.0	-1.6

Column (1) shows total hospitals and/or CMHCs.
Column (2) includes all proposed 2015 OPPS policies and compares those to the 2014 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2015 hospital inpatient wage index, including all proposed hold harmless policies and transitional wages. The proposed rural adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the proposed cancer hospital adjustment is 1.000 because the payment-to-cost ratio target remains the same as in 2014.
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.1 percent OPD fee schedule update factor (2.7 percent reduced by 0.4 percentage points for the final productivity adjustment and further reduced by 0.2 percentage point in order to satisfy statutory requirements set forth in the Affordable Care Act).
Column (5) shows the non-budget neutral impact of applying the frontier State wage adjustment in 2015.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, adding estimated outlier payments, and applying payment wage indexes.

*These 3,947 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

ADDENDUM J: 2015 COMPLEXITY ADJUSTMENT APC ASSIGNMENTS OF COMBINATIONS OF COMPREHENSIVE HCPCS CODES

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary or Device Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted APC Assignment	Combination Frequency	Combination Geometric Mean Cost	Primary Comprehensive Family
33207	Insert heart pm ventricular	J1	0089	33225	L ventric pacing lead add-on	N		0655	239	20,157.58	AICDP
33208	Insrt heart pm atrial & vent	J1	0089	33224	Insert pacing lead & connect	J1	0089	0655	44	17,580.09	AICDP
33208	Insrt heart pm atrial & vent	J1	0089	33225	L ventric pacing lead add-on	N		0655	817	20,067.87	AICDP
33208	Insrt heart pm atrial & vent	J1	0089	93600	Bundle of his recording	J1	0085	0655	54	17,481.61	AICDP
33208	Insrt heart pm atrial & vent	J1	0089	C9600	Perc drug-el cor stent sing	J1	0229	0655	43	21,914.02	AICDP
33224	Insert pacing lead & connect	J1	0089	33216	Insert 1 electrode pm-defib	J1	0090	0655	36	17,656.04	AICDP
33228	Remv&replc pm gen dual lead	J1	0089	33225	L ventric pacing lead add-on	N		0655	94	17,602.68	AICDP
33282	Implant pat-active ht record	J1	0090	93620	Electrophysiology evaluation	J1	0085	0089	777	10,616.76	AICDP
35011	Repair defect of artery	J1	0622	36558	Insert tunneled cv cath	J1	0622	0083	45	6,103.85	VASCX
36558	Insert tunneled cv cath	J1	0622	36558	Insert tunneled cv cath	J1	0622	0083	321	4,785.46	VASCX
36561	Insert tunneled cv cath	J1	0622	37197	Remove intrvas foreign body	J1	0622	0083	28	4,511.61	VASCX
36595	Mech remov tunneled cv cath	J1	0622	36558	Insert tunneled cv cath	J1	0622	0083	57	4,209.60	VASCX
36870	Percut thrombect av fistula	J1	0622	36558	Insert tunneled cv cath	J1	0622	0083	418	4,965.78	VASCX
36870	Percut thrombect av fistula	J1	0622	36581	Replace tunneled cv cath	J1	0622	0083	25	6,595.71	VASCX
36870	Percut thrombect av fistula	J1	0622	36870	Percut thrombect av fistula	J1	0622	0083	33	5,567.32	VASCX
37191	Ins endovas vena cava filtr	J1	0622	37191	Ins endovas vena cava filtr	J1	0622	0083	32	5,357.14	VASCX
37205	Transcath iv stent percut	D	0229	37205	Transcath iv stent percut	D	0229	0319	166	17,895.60	VASCX
37221	Iliac revasc w/stent	J1	0229	37204	Transcatheter occlusion	D	0229	0319	32	16,493.37	VASCX
37221	Iliac revasc w/stent	J1	0229	37205	Transcath iv stent percut	D	0229	0319	222	14,991.34	VASCX
37221	Iliac revasc w/stent	J1	0229	C9600	Perc drug-el cor stent sing	J1	0229	0319	92	16,889.07	VASCX
37224	Fem/popl revas w/tla	J1	0083	35476	Repair venous blockage	J1	0083	0229	162	10,550.46	VASCX
37225	Fem/popl revas w/ather	J1	0229	37205	Transcath iv stent percut	D	0229	0319	41	18,143.76	VASCX
37225	Fem/popl revas w/ather	J1	0229	37221	Iliac revasc w/stent	J1	0229	0319	749	17,599.65	VASCX

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary or Device Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted APC Assignment	Combination Frequency	Combination Geometric Mean Cost	Primary Comprehensive Family
37225	Fem/popl revas w/ather	J1	0229	37225	Fem/popl revas w/ather	J1	0229	0319	108	15,103.07	VASCX
37225	Fem/popl revas w/ather	J1	0229	37226	Fem/popl revasc w/stent	J1	0229	0319	35	17,971.93	VASCX
37226	Fem/popl revasc w/stent	J1	0229	37205	Transcath iv stent percut	D	0229	0319	91	16,108.59	VASCX
37226	Fem/popl revasc w/stent	J1	0229	37221	Iliac revasc w/stent	J1	0229	0319	1,540	16,271.84	VASCX
37226	Fem/popl revasc w/stent	J1	0229	37226	Fem/popl revasc w/stent	J1	0229	0319	217	16,491.00	VASCX
49423	Exchange drainage catheter	J1	0427	49423	Exchange drainage catheter	J1	0427	0652	49	3,060.36	CATHX
57282	Colpopexy extraperitoneal	J1	0202	57288	Repair bladder defect	J1	0202	0385	1,480	7,480.66	UROGN
57283	Colpopexy intraperitoneal	J1	0202	57288	Repair bladder defect	J1	0202	0385	389	7,487.95	UROGN
57285	Repair paravag defect vag	J1	0202	57288	Repair bladder defect	J1	0202	0385	230	6,976.96	UROGN
61885	Insrt/redo neurostim 1 array	J1	0039	61885	Insrt/redo neurostim 1 array	J1	0039	0318	629	24,797.89	NSTIM
61885	Insrt/redo neurostim 1 array	J1	0039	64553	Implant neuroelectrodes	J1	0061	0318	45	22,665.56	NSTIM
61885	Insrt/redo neurostim 1 array	J1	0039	64569	Revise/repl vagus n eltrd	J1	0061	0318	38	28,179.80	NSTIM
64555	Implant neuroelectrodes	J1	0061	63650	Implant neuroelectrodes	J1	0061	0039	70	13,143.61	NSTIM
64581	Implant neuroelectrodes	J1	0061	64581	Implant neuroelectrodes	J1	0061	0039	53	9,998.82	NSTIM
64590	Insrt/redo pn/gastr stimul	J1	0039	64555	Implant neuroelectrodes	J1	0061	0318	118	28,566.32	NSTIM
64590	Insrt/redo pn/gastr stimul	J1	0039	64575	Implant neuroelectrodes	J1	0061	0318	174	27,971.81	NSTIM
64590	Insrt/redo pn/gastr stimul	J1	0039	64590	Insrt/redo pn/gastr stimul	J1	0039	0318	42	33,293.76	NSTIM
92924	Prq card angio/athrect 1 art	J1	0229	C9600	Perc drug-el cor stent sing	J1	0229	0319	42	19,124.54	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	33210	Insert electrd/pm cath sngl	J1	0090	0319	64	14,973.18	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	37205	Transcath iv stent percut	D	0229	0319	108	16,702.31	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	92929	Prq card stent w/angio addl	N		0319	124	14,636.96	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	92943	Prq card revasc chronic 1vsl	J1	0229	0319	57	14,905.01	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	C9600	Perc drug-el cor stent sing	J1	0229	0319	5,855	16,390.83	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	C9601	Perc drug-el cor stent bran	N		0319	4,214	15,748.11	VASCX
C9600	Perc drug-el cor stent sing	J1	0229	C9605	Perc d-e cor revasc t cabg b	N		0319	35	16,488.39	VASCX
C9604	Perc d-e cor revasc t cabg s	J1	0229	C9600	Perc drug-el cor stent sing	J1	0229	0319	620	17,248.19	VASCX
C9604	Perc d-e cor revasc t cabg s	J1	0229	C9601	Perc drug-el cor stent bran	N		0319	37	16,127.97	VASCX

Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary or Device Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted APC Assignment	Combination Frequency	Combination Geometric Mean Cost	Primary Comprehensive Family
C9604	Perc d-e cor revasc t cabg s	J1	0229	C9604	Perc d-e cor revasc t cabg s	J1	0229	0319	169	17,940.12	VASCX
C9604	Perc d-e cor revasc t cabg s	J1	0229	C9605	Perc d-e cor revasc t cabg b	N		0319	134	16,375.15	VASCX