

Summary of Selected Provisions of the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule for Calendar Year 2015

On October 31, 2014, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system final rule for calendar year (CY) 2015 (the “Final Rule”). The Final Rule was published in the Federal Register on November 10, 2014,¹ and CMS will accept comments on certain provisions until December 30, 2014. The provisions in the rule generally will take effect on January 1, 2015.

CMS announced that the payment rates for 2015 will result in a 2.3 percent overall increase in OPPS payments to providers.² This reflects a 2.9 percent increase in the hospital operating market basket, a -0.5 percent multifactor productivity (MFP) adjustment, a 0.2 percentage point reduction required by the Affordable Care Act (ACA), and other payment changes, such as changes in estimated total outlier payments and pass-through payments. Hospitals that fail to meet the quality data reporting requirements will receive an update that is reduced by 2.0 percentage points.³ CMS expects that total Medicare payments to hospital outpatient departments (HOPDs) will be approximately \$56.1 billion and that total payments to ASCs will be \$4.147 billion in 2015.⁴

The addenda containing relative weights, payment rates, wage indices, and other payment information are available only on the CMS web site. Addenda relating to the OPPS are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. Addenda relating to the ASC payment system are available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html>.

1. Cost-to-Charge Ratios (CCRs) and Cost Centers

CMS finalized without modification its proposal for CY 2015 to calculate the OPPS relative payment weights using distinct CCRs for cardiac catheterization, computed tomography (CT) scans, magnetic resonance imaging (MRI), and implantable medical devices.⁵

CMS will continue its policy finalized in CY 2014 to remove claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the CT and MRI ambulatory payment classifications (APCs). In the Final Rule, CMS reiterates that the policy will sunset in four years, once the updated cost report data become available for ratesetting

¹ CMS, Medicare and Medicaid Programs: 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: CMS-Identified Overpayments Associated with Submitted Payment Data, Final Rule, CMS-1613-FC, 79 Fed. Reg. 66,769 (November 10, 2014), available at: <http://www.gpo.gov/fdsys/pkg/FR-2014-11-10/pdf/2014-26146.pdf>.

² *Id.* at 67028.

³ *Id.* at 66824-26.

⁴ *Id.* at 66776.

⁵ *Id.* at 66785.

purposes. Thus, beginning in CY 2018, CMS will estimate CT and MRI APC relative weights using cost data from all providers, regardless of the cost allocation statistic employed.⁶

Percentage Change in Estimated Cost for CT and MRI APCs when Excluding Claims from Providers Using “Square Feet” as the Cost Allocation Method

CY 2015 APC	CY 2015 APC Descriptor	Percentage Change
0283	Computed Tomography with Contrast	9.6%
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	4.0%
0331	Combined Abdomen and Pelvis CT without Contrast	12.1%
0332	Computed Tomography without Contrast	14.5%
0333	Computed Tomography without Contrast followed by Contrast	12.3%
0334	Combined Abdomen and Pelvis CT with Contrast	10.1%
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	7.5%
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast followed by Contrast	6.4%
0383	Cardiac Computed Tomographic Imaging	3.6%
0662	CT Angiography	10.3%
8005	CT and CTA without Contrast Composite	12.8%
8006	CT and CTA with Contrast Composite	9.4%
8007	MRI and MRA without Contrast Composite	6.7%
8008	MRI and MRA with Contrast Composite	6.9%

2. Establishment of Comprehensive APCs (C-APCs)

In the CY 2014 OPSS final rule, CMS finalized a policy with a delayed implementation date of CY 2015 under which certain covered outpatient services would be designated as “primary services” and assigned to C-APCs. CMS finalized its proposal for establishment of C-APCs in CY 2015 with some modifications. For CY 2015, CMS will define the services assigned to C-APCs as primary services and will define a C-APC as a classification for the provision of a primary service and all adjunctive services and supplies provided to support the delivery of the primary service. The C-APC payment bundle will include all hospital services reported on a claim that typically are covered under Medicare Part B, with the exception of excluded services or services requiring separate payment by statute, such as mammography services and ambulance services; brachytherapy seeds; pass-through drugs, biologicals, and devices; recurring therapy services; certain preventative services; and self-administered drugs that are not otherwise packaged as supplies. The use of C-APCs will result in a single prospective Medicare payment for the comprehensive service.⁷

As part of the C-APC, CMS will package payment for services that typically are integral, ancillary, supportive, dependent, or adjunctive to the primary service, and are provided during the delivery of comprehensive service. Such services include 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

⁶ *Id.* at 66785-86.

⁷ *Id.* at 66798-66810.

therapists or non-therapists as part of the comprehensive service; durable medical equipment (DME) as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by Healthcare Common Procedure Coding System (HCPCS) codes that are provided during the comprehensive services, with the exception of excluded services or services requiring separate payment by statute. Drugs, biologicals, and radiopharmaceuticals also are packaged for payment provided in conjunction with the primary service, with the exception of drugs with pass-through payment status and those that are usually self-administered, unless they function as packaged supplies.⁸ With regard to recurring services that are billed monthly, CMS clarifies that “in the event that a recurring service occurs on the same day as an acute service that falls within the span of the recurring service claim, hospitals should bill separately for recurring services on a monthly claim (repetitive billing) and submit a separate claim for the acute service.”⁹ This will ensure that the recurring services are paid separately from any C-APC for the acute service.

For CY 2015, CMS proposed a C-APC payment methodology that adheres to the same basic principles as those finalized in the CY 2014 OPPI final rule with comment period but which contains certain modifications, as discussed further below.¹⁰

- (1) CMS is reorganizing and consolidating several of the current device-dependent APCs and CY 2014 C-APCs.¹¹

As described below, CMS finalized its proposal to consolidate some of the current device-dependent APCs to improve both the resource and clinical homogeneity of these APCs.

- *Endovascular procedures*: CMS will combine C-APCs 0082, 0083, 0104, 0229, 0319, and 0656 to form three levels of comprehensive endovascular APCs and will rename this clinical family “Vascular Procedures.”
- *Automatic Implantable Cardiac Debrillators, Pacemakers, and Related Devices*: CMS will combine C-APCs 0089, 0090, 0106, 0654, 0655, and 0680 to form three levels of C-APCs within a broader series of APCs for pacemaker implantation and similar procedures.
- *Event Monitoring*: CMS will delete the clinical family for Event Monitoring, which had only one C-APC with a single Current Procedural Terminology (CPT®)¹² code 33282. CPT code 33282 will be reassigned to C-APC 0090.
- *Urogenital procedures*: CMS will use two levels instead of three levels for these procedures and reassign several codes from APC 0195 to C-APC 0202 (Level V Female Reproductive Procedures).
- *Arthroplasty procedures*: CMS will rename the arthroplasty family of APCs to Orthopedic Surgery and will reassign several codes from APC 0052 to C-APC 0425, which will be renamed “Level V Musculoskeletal Procedures Except Hand and Foot.”

⁸ *Id.* at 66800.

⁹ *Id.* at 66804.

¹⁰ *Id.* at 66809.

¹¹ *Id.*

¹² CPT copyright 2013 American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA.

- *Electrophysiologic Procedures:* CMS will use three levels of electrophysiologic procedures and rename APC 0086 “Level III Electrophysiologic Procedures.” CMS will also replace composite APC 8000 with C-APC 0086.
- *New clinical families:* CMS will create three new clinical families: Gastrointestinal Procedures (GIXXX) for gastrointestinal stents, Tube/Catheter Changes (CATHX) for insertion of various catheters, and Radiation Oncology (RADTX), which will include C-APC 0067.¹³

- (2) CMS is expanding the C-APC payment policy to include all device-dependent APCs except for APCs 0427 (Level II Tube or Catheter Changes or Repositioning), 0622 (Level II Vascular Access Procedures), and 0652 (Insertion of Intraperitoneal and Pleural Catheters);
- (3) CMS is creating two other new C-APCs (C-APC 0067 for single-session cranial stereotactic radiosurgery (SRS) and C-APC 0351 for Level V intraocular procedures) and will assign CPT codes 77424 and 77425 that describe intraoperative therapy treatment (IORT) to C-APC 0648 (Level IV Breast and Skin Surgery);
- (4) CMS will adjust C-APC assignments for complexity by assigning claims with certain combinations of services to a higher paying C-APC in the same clinical family. These adjustments will allow CMS to provide increased payment for certain comprehensive services. For CY 2015, CMS is establishing new complexity adjustment criteria that will require a frequency of 25 or more claims reporting the HCPCS code combination and violation of the “2 times” rule; and
- (5) CMS is establishing a policy to package all add-on codes furnished as part of a comprehensive service, though CMS will evaluate claims reporting a single primary service code reported in combination with an applicable add-on code for complexity adjustments.¹⁴

CMS finalized its proposal to define a clinical family of C-APCs as a set of clinically related C-APCs that represent different resource levels of clinically comparable services.¹⁵ Although CMS had proposed 28 C-APCs within 13 clinical families for CY 2015,¹⁶ CMS establishes in the Final Rule a total of only 25 C-APCs within 12 clinical families, as shown in the table below. CMS is accepting commenters’ recommendation not to convert APCs 0427, 0622, and 0652 to C-APCs for CY 2015 because, among other reasons, these APCs are not device-intensive APCs, meaning that the device offsets are not greater than 40 percent. Because CMS is not converting APC 0427 into a C-APC, CMS will not evaluate add-on CPT code 49435 for complexity adjustments.¹⁷

Clinical Family	CY 2015 C-APC	APC Title	CY 2015 Payment
Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices	0090	Level II Pacemaker and Similar Procedures	\$6,542.78
	0089	Level III Pacemaker and Similar Procedures	\$9,489.74
	0655	Level IV Pacemaker and Similar Procedures	\$16,400.98
	0107	Level I ICD and Similar Procedures	\$22,907.64
	0108	Level II ICD and Similar Procedures	\$30,806.39

¹³ 79 Fed. Reg. at 66803-04.

¹⁴ *Id.* at 66809.

¹⁵ *Id.*

¹⁶ 79 Fed. Reg. 40915, 40952 (July 14, 2014).

¹⁷ 79 Fed. Reg. 66769, 66805, 66809 (Nov. 10, 2014).

Clinical Family	CY 2015 C-APC	APC Title	CY 2015 Payment
(AICDP)			
Breast Surgery	0648	Level IV Breast and Skin Surgery	\$7,461.40
ENTXX Procedures	0259	Level VII ENT Procedures	\$29,706.85
Cardiac Electrophysiology (EPHYS)	0084	Level I Electrophysiologic Procedures	\$872.92
	0085	Level II Electrophysiologic Procedures	\$4,633.33
	0086	Level III Electrophysiologic Procedures	\$14,356.62
Ophthalmic Surgery (EYEXX)	0293	Level IV Intraocular Procedures	\$8,446.54
	0351	Level V Intraocular Procedures	\$23,075.30
Gastrointestinal Procedures	0384	GI Procedures with Stents	\$3,173.83
Neurostimulators (NSTIM)	0061	Level II Neurostimulator & Related Procedures	\$5,288.58
	0039	Level III Neurostimulator & Related Procedures	\$17,099.35
	0318	Level IV Neurostimulator & Related Procedures	\$26,152.16
Orthopedic Surgery	0425	Level V Musculoskeletal Procedures Except Hand and Foot	\$10,220.00
Implantable Drug Delivery Systems	0227	Implantation of Drug Infusion Device	\$15,566.34
Radiation Oncology	0067	Single Session Cranial Stereotactic Radiosurgery	\$9,765.40
Urogenital Procedures (UROGN)	0202	Level V Gynecologic Procedures	\$3,977.63
	0385	Level I Urogenital Procedures	\$6,822.35
	0386	Level II Urogenital Procedures	\$13,967.97
Vascular Procedures (VASCX)	0083	Level I Endovascular Procedures	\$4,537.45
	0229	Level II Endovascular Procedures	\$9,624.10
	0319	Level III Endovascular Procedures	\$14,840.64

3. Device-Dependent APCs

Historically, device-dependent APCs have been populated by HCPCS codes that usually, but not always, require that a device be implanted or used to perform the procedure. In the CY 2014 OPPS final rule with comment period, CMS finalized a policy to create 29 C-APCs for 29 device-dependent services, where the cost of the device is large compared to other costs that contribute to the cost of delivering the primary service. CMS delayed implementation of this policy until CY 2015.

For CY 2015, CMS proposed that it would consolidate and restructure the 39 current device-dependent APCs into 26 of the total 28 proposed C-APCs, and that device-dependent APCs would no longer exist because these APCs all will have been converted to C-APCs. However, in the Final Rule, CMS adopts a comprehensive APC policy under which 3 of the current 39 device-dependent APCs will remain in the CY 2015 OPPS. Thus, for CY 2015, CMS finalized the C-APC policy as proposed for 25 out of the proposed 28 C-APCs. All of the remaining device-dependent APCs were either deleted due to the consolidation and restructuring of these APCs or they were converted to C-APCs.

For CY 2014, CMS proposed but did not finalize a policy to reduce the burden on hospitals and the Medicare program by no longer implementing procedure-to-device edits and device-to-procedure edits for any APCs. CMS finalized its proposal to implement this policy for CY 2015 because the agency believes that hospitals now have more experience in coding and reporting these claims fully and, for the most costly devices, the C-APCs will reliably reflect the cost of the device if it is included anywhere on the claim. Although hospitals still would be expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable, claims no longer would be returned to providers when specific procedure and device code pairings do not appear on a claim.

In response to stakeholder concerns about the costs of devices being reported and captured, however, CMS also finalized its proposal 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 of the current device-dependent APCs (that remain after the consolidation and restructuring of these APCs) are reported on the claim to ensure that device costs are captured by hospitals. Although CMS has opted not to recognize APCs 0427, 0622, and 0652 as C-APCs for CY 2015, CMS’s finalized device edit policy still will apply to these three APCs. The term “device-dependent APC” no longer will be employed beginning in CY 2015. Instead, CMS will refer to APCs with a device offset of more than 40 percent as “device-intensive” APCs.

In the Final Rule, CMS reiterates that it expects hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place. CMS also continues to expect that hospitals would use an appropriate device code consistent with correct coding in order to ensure that device costs always are reported on the claim so that costs are captured appropriately in claims that CMS uses for ratesetting. CMS will monitor the claims data to ensure that hospitals continue reporting appropriate device codes on the claims for the formerly device-dependent APCs.¹⁸

APCs That Will 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 Electrophysiologic Procedures
0085	Level II Electrophysiologic Procedures
0086	Level III Electrophysiologic Procedures
0089	Level III Pacemaker
0090	Level II Pacemaker
0107	Level I Implantation of Cardioverter-Defibrillators (ICDs)
0108	Level II Implantation of Cardioverter-Defibrillators (ICDs)
0202	Level V Female Reproductive
0227	Implantation of Drug Infusion
0229	Level II Endovascular

¹⁸ *Id.* at 66793-95.

APCs That Will Require a Device Code to Be Reported on a Claim When a Procedure Assigned to One of These APCs is Reported	
APC	APC Title
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 Intraperitoneal/Pleural Catheters
0655	Level IV Pacemaker

4. Changes to Packaged Items and Services

CMS believes that packaging payment for multiple interrelated items and services into a single payment encourages hospitals to furnish services efficiently, manage their resources with maximum flexibility, and negotiate effectively with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements. CMS also believes that packaging payments promotes the predictability and accuracy of payment for services over time and may reduce the importance of refining service-specific payment.

As part of its effort to make OPSS payments for all services paid under the OPSS more consistent with those of a prospective payment system and less like those of a per service fee schedule, CMS examined the HCPCS code definitions to determine whether there were categories of codes for which packaging would be appropriate according to existing OPSS packaging policies or a logical expansion of those existing OPSS packaging policies. CMS proposed for CY 2015 to package the costs of selected HCPCS codes into payment for services reported with other HCPCS codes where CMS believes that one code reported an item or service that was integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by another HCPCS code. The new categories and classes of items and services that CMS packages for CY 2015 are discussed further below.¹⁹

a. Revisions to Packaging Policy Established in CY 2014 – Procedures Described by Add-On Codes

For CY 2014, CMS packaged add-on codes, with the exception of add-on codes describing drug administration services. CMS also adopted a C-APC policy for which implementation would be delayed until CY 2015. Under the policy, CMS would continue to pay separately for only those add-

¹⁹ *Id.* at 66817.

on codes (except for drug administration add-on codes) that were assigned to device-dependent APCs in CY 2014, but that, after CY 2014, these device-dependent add-on codes would be paid under the C-APC policy. CMS is instead adopting its proposal to package all of the procedures described by add-on codes that currently are assigned to device-dependent APCs, which will be replaced by C-APCs. The device-dependent add-on codes that are separately paid in CY 2014 that CMS will package in CY 2015 are listed in the table below.²⁰

CY 2015 Add-on Code	Short Descriptor
19297	Place breast cath for rad
33225	L ventric pacing lead add-on
37222	Iliac revasc add-on
37223	Iliac revasc w/stent add-on
37232	Tib/per revasc add-on
37233	Tib/per revasc w/ather add-on
37234	Revasc opn/prq tib/pero stent
37235	Tib/per revasc stnt & ather
37237	Open/perq place stent ea add
37239	Open/perq place stent ea add
49435	Insert subq exten to ip cath
92921	Prq cardiac angio addl art
92925	Prq card angio/athrect addl
92929	Prq card stent w/angio addl
92934	Prq card stent/ath/angio
92938	Prq card revasc byp graft addl
92944	Prq card revasc chronic addl
92998	Pul art balloon repr precut
C9601	Perc drug-el cor stent bran
C9603	Perc d-e cor stent ather br
C9605	Perc d-e cor revasc t cabg b
C9608	Perc d-e cor revasc chro add

b. Packaging Policies for CY 2015

(i) *Ancillary Services*

CMS pays separately for certain ancillary services in the OPSS. In the CY 2014 final rule, CMS stated that ancillary services should be packaged when they are performed with another service but should continue to be paid separately when performed alone. CMS did not finalize the ancillary packaging policy proposed for CY 2014 because CMS believed that further evaluation was needed, however.

For CY 2015, CMS finalized its proposal to conditionally package certain ancillary services. CMS will limit the initial set of APCs that contain conditionally packaged services to those ancillary service APCs with a geometric mean cost of less than or equal to \$100 (prior to application of the conditional packaging status indicator).

²⁰ *Id.* at 66817-18.

CMS will limit the initial set of packaged ancillary service APCs as a result of concerns expressed in public comments that certain low volume but relatively costly ancillary services would have been packaged into high volume but relatively inexpensive primary services. CMS notes that this limit is not intended as a threshold above which ancillary services will not be packaged but rather is intended to be used as the methodology for selecting the initial set of conditionally packaged ancillary service APCs under the packaging policy. CMS notes that it may in the future package ancillary services assigned to APCs with geometric mean costs higher than \$100 and explains that a change in the geometric mean cost of any of the APCs to above \$100 in future years would not change the conditionally packaged status of services assigned to the APCs selected in 2015 in a future year. CMS intends to review the conditionally packaged status of ancillary services annually. CMS will exclude from this policy certain psychiatry and counseling-related services as well as certain low cost drug administration services. CMS also will exclude certain preventative services from this policy. The excluded preventative services are listed in the table below.

Preventative 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 also finalized its proposal to delete status indicator “X” (ancillary services) because the majority of the services assigned to status indicator “X” will be assigned to status indicator “Q1” (STV-Packaged Codes). Services currently assigned status indicator “X” that will not be conditionally packaged under this policy will be assigned to status indicator “S,” specifying separate payment and indicating that the services are not subject to the multiple procedure reduction.²¹

The APCs that CMS will conditionally package as ancillary services in CY 2015 are listed in the table below.²²

APC	Final CY 2015 OPSS SI	Group Title	CY 2015 OPSS Geometric Mean Cost
0012	Q1	Level I Debridement & Destruction	\$102.18
0060	Q1	Manipulation Therapy	\$25.57
0077	Q1	Level I Pulmonary Treatment	\$170.77
0099	Q1	Electrocardiograms/Cardiography	\$81.40
0215	Q1	Level I Nerve and Muscle Services	\$98.52

²¹ *Id.* at 66819-22.

²² *Id.* at 66822.

APC	Final CY 2015 OPPS SI	Group Title	CY 2015 OPPS Geometric Mean Cost
0230	Q1	Level I Eye Tests & Treatments	\$54.01
0260	Q1	Level I Plain Film Including Bone Density Measurement	\$61.59
0261	Q1	Level II Plain Film Including Bone Density Measurement	\$98.56
0265	Q1	Level I Diagnostic and Screening Ultrasound	\$95.12
0340	Q1	Level II Minor Procedures	\$54.33
0342	Q1	Level I Pathology	\$56.31
0345	Q1	Level I Transfusion Laboratory Procedures	\$78.91
0364	Q1	Level I Audiometry	\$44.94
0365	Q1	Level II Audiometry	\$122.36
0367	Q1	Level I Pulmonary Tests	\$167.31
0420	Q1	Level III Minor Procedures	\$136.66
0433	Q1	Level II Pathology	\$190.55
0450	Q1	Level I Minor Procedures	\$30.33
0624	Q1	Phlebotomy and Minor Vascular Access Device Procedures	\$81.76
0690	Q1	Level I Electronic Analysis of Devices	\$36.47
0698	Q1	Level II Eye Tests & Treatments	\$104.61

SI = Status indicator

(ii) *Prosthetic Supplies*

Implantable prosthetic devices are packaged in the OPPS under 42 C.F.R. § 419.2(b)(11). It is common for implantable prosthetic devices to be provided as a part of a device system, which includes nonimplantable prosthetic supplies that are integral to the functioning of the medical device.

Because these supplies are integral to the overall function of the implanted prosthetic and in light of CMS's goal of packaging items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service, CMS finalized its proposal to package the payment of prosthetic supplies (along with the implantable prosthetic device) into the surgical procedure that implants the prosthetic device. Payment for patients requiring replacement supplies at a later time than the initial surgical procedure and outside of the hospital would be made under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule.

CMS also finalized its proposal to package and change the status indicator from "A" to "N" for all DMEPOS prosthetic supplies, thereby packaging all these medical and surgical supplies in the OPPS. In addition, CMS finalized its proposal to delete "prosthetic supplies" from the regulations at 42 C.F.R. § 419.22(j) because prosthetic supplies are packaged covered outpatient department services in the OPPS for CY 2015. Prosthetic supplies provided in the hospital outpatient department will be included in the packaged category of "medical and surgical supplies" under 42 C.F.R. § 419.2(b)(4).²³

²³ *Id.* at 66822-23.

5. OPSS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

CMS finalized its proposal to use the same methodology and policies to establish payment for drugs, biologicals, and radiopharmaceuticals with pass-through status in CY 2015 as the agency used in 2014; these products will continue to be reimbursed at average sales price (ASP) plus six percent, as required by statute.²⁴ CMS also finalized its proposal to pay for separately payable drugs and biologicals at ASP+6 percent.²⁵ Although CMS proposed for CY 2015 to keep the packaging threshold the same at \$90, CMS establishes in the Final Rule a packaging threshold for CY 2015 of \$95.²⁶ CMS also establishes the high/low cost threshold for skin substitute products based on the weighted average mean unit cost (MUC) for these products from CY 2013 claims data, which will be \$25 per cm² for CY 2015.²⁷

a. Pass-through Payment for Drugs and Biologicals

For CY 2015, 35 drugs and biologicals will continue to have pass-through payment status or have been granted pass-through status. Eligible products, listed in the chart below, will continue to be paid at ASP+6 percent, with quarterly updates. Policy packaged drugs (including contrast agents; diagnostic radiopharmaceuticals; 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) are eligible to receive pass-through status, and, if it is granted, they will be reimbursed at ASP+6 percent for two to three years.²⁸ This reimbursement rate is equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2015.

Drugs and Biologicals with Pass-Through Payment Status in CY 2015

CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 Long Descriptor	Final CY 2015 SI	Final CY 2015 APC
A9520	A9520	Technetium Tc 99m tilmanocept, diagnostic, up to 0.5 millicuries	G	1463
N/A	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	1664
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476
C9022	J1322	Injection, elosulfase alfa, 1mg	G	1480
C9023	J3145	Injection, testosterone undecanoate, 1 mg	G	1487
C9025	C9025	Injection, ramucirumab, 5 mg	G	1488
C9026	C9026	Injection, vedolizumab, 1 mg	G	1489
N/A	C9027	Injection, pembrolizumab, 1 mg	G	1490
C9132	C9132	Prothrombin complex concentrate (human), Kcentra, per i.u. of Factor IX activit	G	9132
C9133	J7200	Factor ix (antihemophilic factor, recombinant), Rixubus, per i.u.	G	1467
C9134	J7181	Injection, Factor XIII A-subunit, (recombinant), per 10 i.u.	G	1746

²⁴ *Id.* at 66876.

²⁵ *Id.* at 66891.

²⁶ *Id.* at 66881.

²⁷ *Id.* at 66884.

²⁸ *Id.* at 66875-77.

CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 Long Descriptor	Final CY 2015 SI	Final CY 2015 APC
C9135	J7201	Injection, factor ix, fc fusion protein (recombinant), per i.u.	G	1486
N/A	C9136	Injection, factor viii, fc fusion protein (recombinant) per i.u.	G	1656
C9441	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441
N/A	C9349	FortaDerm, and FortaDerm Antimicrobial, any type, per square centimeter	G	1657
N/A	C9442	Injection, belinostat, 10 mg	G	1658
N/A	C9443	Injection, dalbavancin, 10 mg	G	1659
N/A	C9444	Injection, oritavancin, 10 mg	G	1660
N/A	C9446	Injection, tedizolid phosphate ,1 mg	G	1662
N/A	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	1663
C9497	C9497	Loxapine, inhalation powder, 10 mg	G	9497
J1446	J1446	Injection, tbo-filgrastim, 5 micrograms	G	1447
J1556	J1556	Injection, immune globulin (Bivigam), 500 mg	G	9130
J3060	J3060	Injection, taliglucerase alfa, 10 units	G	9294
J7315	J7315	Mitomycin, ophthalmic, 0.2 mg	G	1448
J7316	J7316	Injection, Ocriplasmin, 0.125mg	G	9298
J7508	J7508	Tacrolimus, Extended Release, Oral, 0.1 mg	G	1465
J9047	J9047	Injection, carfilzomib, 1 mg	G	9295
J9262	J9262	Injection, omacetaxine mepesuccinate, 0.01 mg	G	9297
J9354	J9354	Injection, ado-trastuzumab emtansine, 1 mg	G	9131
J9371	J9371	Injection, Vincristine Sulfate Liposome, 1 mg	G	1466
J9400	J9400	Injection, Ziv-Aflibercept, 1 mg	G	9296
Q4121	Q4121	Theraskin, per square centimeter	G	1479
Q4122	Q4122	Dermacell, per square centimeter	G	1419
Q4127	Q4127	Talymed, per square centimeter	G	1449

CMS finalized its proposal that the pass-through status of nine drugs and biologicals, listed below, will expire on December 31, 2014.²⁹

Drugs and Biologicals with Expiring Pass-Through Status in CY 2014

CY 2015 HCPCS Code	CY 2015 Long Descriptor	Final CY 2015 SI	Final CY 2015 APC
C9290	Injection, bupivacaine 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 (ab)2, up to 120 milligrams	K	1431
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

²⁹ *Id.* at 66875.

b. Pass-through Payment for Diagnostic and Therapeutic Radiopharmaceuticals

Consistent with its CY 2014 policy for diagnostic and therapeutic radiopharmaceuticals, CMS finalizes its proposal to pay for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through status based on the ASP methodology. For purposes of pass-through payment, CMS considers radiopharmaceuticals to be drugs under the OPPI. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through status during CY 2015, CMS will follow the standard ASP methodology to determine the pass-through payment rate that drugs receive, resulting in a payment rate of ASP+6 percent. If ASP data are not available for a radiopharmaceutical, CMS will provide pass-through payment at Wholesale Acquisition Cost (WAC) plus six percent, the equivalent payment provided to pass-through drugs and biologicals without ASP information. If WAC is not available, payment will be based on 95 percent of the radiopharmaceutical's most recent Average Wholesale Price (AWP).³⁰

c. 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. In CY 2014, CMS packaged nonpass-through skin substitutes under the policy that packages all drugs and biologicals that function as supplies when used in a surgical procedure because CMS considers skin substitutes to be a type of surgical supply in the hospital outpatient department.

CMS believes that the similarities between implantable biologicals and skin substitutes support similar treatment under the OPPI device pass-through process, which has been the evaluation methodology for implantable biologicals since 2010. CMS finalized its proposal that applications seeking pass-through payment for skin substitutes and similar wound healing products effective April 1, 2015 be evaluated using the medical device pass-through process, rather than through the drug, biological, and radiopharmaceutical pass-through process. The policy takes effect on January 1, 2015, and the regular December 1, 2014 application deadline will be extended to January 15, 2015 for this cycle.³¹

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

i. Threshold-Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS finalized its proposal to continue indexing the packaging threshold using its historical methodology. In the CY 2015 OPPI/ASC proposed rule, CMS proposed that the packaging threshold for drugs and biologicals would be \$90 per day – the same threshold that was used in CY 2014. However, using more recently available data for the Final Rule, CMS finalized a packaging threshold for CY 2015 of \$95 per day. Drugs and biologicals with a per day cost greater than \$95 are separately payable, except for policy-packaged items such as 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, which CMS proposes to package regardless of cost.

³⁰ *Id.* at 66876.

³¹ *Id.* at 66885-88.

In light of the difference between the proposed packaging threshold and the finalized packaging threshold for CY 2015, CMS implemented the following policies for CY 2015:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2014 and that were proposed for separate payment in CY 2015 and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on updated ASPs and hospital claims data used for the CY 2015 final rule, will continue to receive separate payment in CY 2015.
- HCPCS codes for drugs and biologicals that were packaged in CY 2014 and that were proposed for separate payment in CY 2015 and that then have per day costs equal to or less than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, will remain packaged in CY 2015.
- HCPCS codes for drugs and biologicals for which CMS proposed packaged payment in CY 2015 and then have per day costs greater than the CY 2015 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2015 final rule, will receive separate payment in CY 2015.³²

ii. High/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS final rule, CMS unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package drugs and biologicals that function as supplies when used in a surgical procedure. CMS divided the skin substitutes into a high cost group and a low cost group for packaging purposes. For CY 2014, assignment to the high cost or low cost skin substitute group depended upon a comparison of the July 2013 ASP+6 percent payment amount for each skin substitute to the weighted average payment per unit for all skin substitutes (which, for CY 2014, is \$32 per cm²). Stakeholders subsequently expressed concerns that using ASP to determine a product's placement in the high or low cost category may unfairly disadvantage the limited number of skin substitute products sold in large sizes and that using a weighted average ASP to establish the high/low cost categories, combined with the drug pass-through policy, would lead to unstable high/low cost skin substitute categories in the future.

In response to these comments, CMS finalized its proposal to maintain the high/low cost APC structure for skin substitute procedures in CY 2015 but to revise the current methodology used to establish the high/low cost threshold. For CY 2015, CMS finalized its proposal to establish the high/low cost threshold based on the weighted average mean unit cost for all skin substitute products from CY 2013 claims data. CMS proposed that the CY 2015 threshold would be \$27 per cm², but in the Final Rule, CMS finalized the CY 2015 weighted average MUC threshold at \$25. The final threshold decreased slightly from the proposed threshold due to updated claims data.

Skin substitutes with a MUC above \$25 per cm² using CY 2013 claims will be classified in the high cost group and those with a MUC at or below \$25 per cm² will be classified in the low cost group. CMS finalized its proposal to continue the current policy that skin substitutes with pass-through status will be assigned to the high cost category for CY 2015. Skin substitutes with pricing information but without claims data to calculate a MUC will be assigned to either the high or low cost category based on the product's ASP+6 percent or, if not available, based on WAC+6 percent or 95

³² *Id.* at 66880-82.

percent of AWP. CMS also finalized its proposal that any new skin substitute without pricing information will be assigned to the low cost category until pricing becomes available to compare to the CY 2015 threshold. New skin substitute manufacturers must submit pricing information to CMS no later than the 15th of the third month prior to the effective date of the next OPPS quarterly update.

For 2014, there are 16 high cost skin substitutes and 27 low cost skin substitutes. For 2015, there are 30 high cost skin substitutes; 24 low cost skin substitutes; 7 powdered, liquid, or micronized skin substitutes; and 1 miscellaneous skin substitute code. The chart below shows the current 2014 high/low cost status for each skin substitute product as well as the 2015 high/low cost status for each product.³³

Skin Substitutes Assignments to High Cost and Low Cost Groups				
CY 2015 HCPCS Code	CY 2015 Short Description	CY 2015 SI	CY 2014 High/Low Status Based on Weighted ASP	CY 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
Q4100	Skin substitute, NOS	N	Low	Low
Q4101	Apligraf	N	High	High
Q4102	Oasis wound matrix	N	Low	Low
Q4103	Oasis burn matrix	N	Low	Low
Q4104	Integra BMWWD	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
Q4110	Primatrix	N	High	High
Q4111	Gammagraft	N	Low	Low
Q4112	Cymetra injectable	N	N/A	N/A
Q4113	GraftJacket Xpress	N	N/A	N/A
Q4114	Integra Flowable Wound Matrix	N	N/A	N/A
Q4115	Alloskin	N	Low	Low
Q4116	Alloderm	N	High	High
Q4117	Hyalomatrix	N	Low	Low
Q4118	Matristem Micromatrix	N	N/A	N/A
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	High
Q4124	Oasis tri-layer wound matrix	N	Low	Low
Q4125	Arthroflex	N	High	High
Q4126	Memoderm/derma/tranz/integup	N	High	High

³³ *Id.* at 66882-84.

Skin Substitutes Assignments to High Cost and Low Cost Groups				
CY 2015 HCPCS Code	CY 2015 Short Description	CY 2015 SI	CY 2014 High/Low Status Based on Weighted ASP	CY 2015 High/Low Status Based on Weighted MUC
Q4127	Talymed	G	High	High
Q4128	Flexhd/Allopatchhd/matrixhd	N	Low	High
Q4129	Unite biomatrix	N	Low	High
Q4131	Epifix	N	High	High
A4132	Grafix core	N	High	High
Q4133	Grafix prime	N	High	High
Q4134	HMatrix	N	High	High
Q4135	Mediskin	N	Low	Low
Q4136	EZderm	N	Low	Low
Q4137	Amnioexcel or biodexcel, 1cm	N	Low	High
Q4138	BioDfence DryFlex, 1cm	N	Low	High
Q4139	Amniomatrix or Biodmatrix, 1 cc	N	N/A	N/A
Q4140	Biodfence 1cm	N	Low	High
Q4141	Alloskin ac, 1 cm	N	Low	Low
Q4142	Xcm biologic tiss matrix 1cm	N	Low	Low
Q4143	Repriza, 1cm	N	Low	Low
Q4145	Epifix, 1 mg	N	N/A	N/A
Q4146	Tensix, 1cm	N	Low	Low
Q4147	Architect ecm px fx 1 sq cm	N	High	High
Q4148	Neox 1k, 1cm	N	High	High
Q4149	Excellagen, 0.1 cc	N	N/A	N/A
Q4150	Allowrap DS or Dry 1 sq cm	N	N/A	Low
Q4151	AmnioBand, Guardian 1 sq cm	N	N/A	Low
Q4152	Dermapure 1 square cm	N	N/A	Low
Q4153	Dermavest 1 square cm	N	N/A	Low
Q4154	Biovance 1 square cm	N	N/A	High
Q4155	NeoxFlo or ClarixFlo 1 mg	N	N/A	N/A
Q4156	Neox 100 1 square cm	N	N/A	High
Q4157	Revitalon 1 square cm	N	N/A	Low
Q4158	MariGen 1 square cm	N	N/A	Low
Q4159	Affinity 1 square cm	N	N/A	Low
Q4160	NuShield 1 square cm	N	N/A	High
C9349	Fortaderm, fortaderm antimic	G	N/A	High

iii. Separately Payable Drugs and Biologicals

For CY 2015, CMS finalized its proposal to continue paying for separately payable drugs and biologicals at ASP+6 percent, the statutory default amount, as provided in §1833(t)(14)(A)(iii)(II) of

the Social Security Act (SSA). This reimbursement rate is equivalent to the rate provided for drugs administered in the physician's office setting in CY 2015.³⁴

iv. Separately Payable Therapeutic Radiopharmaceuticals

CMS finalized its proposal to continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. Therefore, for CY 2015, CMS will pay for all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in §1833(t)(14)(A)(iii)(II) of the SSA.

If ASP information is unavailable for a therapeutic radiopharmaceutical, CMS will rely on mean unit cost data derived from hospital claims data to set the payment rates. CMS will update the payment rates for separately payable therapeutic radiopharmaceuticals, according to the agency's usual process for updating the payment rates for separately payable drugs and biologicals, on a quarterly basis if updated ASP information is available.³⁵

v. Payment for Blood Clotting Factors

For CY 2015, CMS finalized its proposal to pay for blood clotting factors at ASP+6 percent, consistent with its payment policy for other nonpass-through separately payable drugs and biologicals, and to continue its policy of updating the furnishing fee. The furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. The furnishing fee per unit for CY 2014 is \$0.192 per unit. For CY 2015, the furnishing fee will be announced on the following CMS website: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/ClotFactorFurnishFee.html>.³⁶

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

For CY 2015, CMS finalized its proposal to provide payment for new drugs, biologicals, and therapeutic radiopharmaceuticals that do not have pass-through status at ASP+6 percent, consistent with the CY 2015 payment methodology for other separately payable nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals.

For CY 2015, CMS finalized its proposal to package 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.

³⁴ *Id.* at 66891.

³⁵ *Id.* at 66891-92.

³⁶ *Id.* at 66892-93. At the time this summary was prepared, the CY 2015 furnishing fee had not yet been posted to the CMS website.

In the absence of ASP data, CMS also finalized its proposal to continue its policy of using the WAC to establish the initial payment rate for new nonpass-through drugs and biologicals with HCPCS codes, but which do not have OPPS claims data. If the WAC also is unavailable, CMS will continue its policy of making payment at 95 percent of the product's most recent AWP.

With respect to the new, nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals for which CMS does not have ASP data, CMS finalized its proposal that once their ASP data become available in later quarterly submissions, their payment rates under the OPPS will be adjusted so that the rates would be based on the ASP methodology and set to the proposed ASP-based amount for items that have not been granted pass-through status.

CMS also finalized its proposal to continue to base the initial payment for new therapeutic radiopharmaceuticals with HCPCS codes, but which do not have pass-through status and are without claims data, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals are not available. If the WACs also are unavailable, CMS will make payment for new therapeutic radiopharmaceuticals at 95 percent of the products' most recent AWP.³⁷

vii. Blood and Blood Products

For CY 2015, CMS finalized its proposal to continue to establish payment rates for blood and blood products using the agency's blood-specific CCR methodology, using actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been CMS's standard rate-setting methodology for blood and blood products since CY 2005.

As discussed above, CMS is establishing C-APCs that will provide all-inclusive payments for certain device-dependent procedures. Under this policy, CMS included the costs of blood and blood products when calculating the overall costs of these C-APCs and will continue to apply the blood-specific CCR methodology when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products are reflected in the overall costs of the C-APCs, however, CMS finalized its proposal not to make separate payments for blood and blood products when they appear on the same claims as services assigned to C-APCs.³⁸

viii. Brachytherapy Sources

Although commenters expressed a number of concerns regarding CMS's outpatient hospital claims data used to set prospective payment rates for brachytherapy sources, CMS finalized its proposal to continue to set the payment rates for brachytherapy sources using its established prospective payment methodology, based on geometric mean costs. CMS invites hospitals and other parties to submit recommendations to CMS for new HCPCS codes that describe new brachytherapy sources consisting of a radioactive isotope.³⁹

³⁷ *Id.* at 66893-94.

³⁸ *Id.* at 66795-96.

³⁹ *Id.* at 66796-98.

6. Pass-Through Payments for Devices

There is currently one device category eligible for pass-through payments: HCPCS code C1841 (Retinal prosthesis, includes all internal and external components), which CMS made effective for pass-through payment as of October 1, 2013. At the end of CY 2015, the device category will have been eligible for pass-through payment for more than two years. Therefore, CMS finalized its proposal to expire pass-through payment status for HCPCS code C1841 after December 31, 2015. CMS finalized its proposal to package the costs for devices described by HCPCS code C1841 into the costs of the procedure with which it is reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish the ASC rates for CY 2016.⁴⁰

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

CMS estimates that the total estimated pass-through spending for device categories for CY 2015 would be approximately \$61.0 million and that the total estimated pass-through spending for drugs and biologicals would be approximately \$21.8 million, for a total of approximately \$82.8 million or 0.15 percent of the total projected OPPS payments for CY 2015.⁴¹

8. Payment for Drug Administration Services

For CY 2015, CMS did not propose and is not packaging low-cost drug administration services as part of its ancillary services packaging policy. CMS is examining various alternative payment policies for drug administration services, however, including the associated drug administration add-on codes.⁴²

A chart comparing the 2014 and 2015 drug administration payment rates is provided below.

Comparison of Hospital OPPS Drug Administration Rates, 2014 and 2015

HCPCS Code	Short Descriptor	SI	APC	Payment Rate	CI	SI	APC	Payment Rate	Change 2014-2015
90461	Im admin each addl component	B				B			
90471	Immunization admin	S	0437	\$43.78		S	0437	\$53.52	22.2%
90472	Immunization admin each add	N				N			
90473	Immune admin oral/nasal	S	0437	\$43.78		S	0437	\$53.52	22.2%
90474	Immune admin oral/nasal addl	N				N			
96360	Hydration iv infusion init	S	0438	\$105.90		S	0438	\$108.20	2.2%
96361	Hydrate iv infusion add-	S	0436	\$29.50		S	0436	\$32.57	10.4%

⁴⁰ *Id.* at 66870-71.

⁴¹ *Id.* at 66898.

⁴² *Id.* at 66819.

HCPCS Code	Short Descriptor	SI	APC	Payment Rate	CI	SI	APC	Payment Rate	Change 2014-2015
	on								
96365	Ther/proph/diag iv inf init	S	0439	\$172.18		S	0439	\$173.53	0.8%
96366	Ther/proph/diag iv inf addon	S	0436	\$29.50		S	0436	\$32.57	10.4%
96367	Tx/proph/dg addl seq iv inf	S	0437	\$43.78		S	0437	\$53.52	22.2%
96368	Ther/diag concurrent inf	N				N			
96369	Sc ther infusion up to 1 hr	S	0439	\$172.18		S	0439	\$173.53	0.8%
96370	Sc ther infusion addl hr	S	0437	\$43.78		S	0437	\$53.52	22.2%
96371	Sc ther infusion reset pump	N				N			
96372	Ther/proph/diag inj sc/im	S	0437	\$43.78		S	0437	\$53.52	22.2%
96373	Ther/proph/diag inj ia	S	0438	\$105.90		S	0438	\$108.20	2.2%
96374	Ther/proph/diag inj iv push	S	0438	\$105.90		S	0438	\$108.20	2.2%
96375	Tx/pro/dx inj new drug addon	S	0437	\$43.78	CH	S	0436	\$32.57	-25.6%
96376	Tx/pro/dx inj same drug adon	N				N			
96379	Ther/prop/diag inj/inf proc	S	0436	\$29.50		S	0436	\$32.57	10.4%
96401	Chemo anti-neopl sq/im	S	0438	\$105.90		S	0438	\$108.20	2.2%
96402	Chemo hormon antineopl sq/im	S	0437	\$43.78		S	0437	\$53.52	22.2%
96405	Chemo intralesional up to 7	S	0437	\$43.78		S	0437	\$53.52	22.2%
96406	Chemo intralesional over 7	S	0439	\$172.18		S	0439	\$173.53	0.8%
96409	Chemo iv push snl drug	S	0439	\$172.18		S	0439	\$173.53	0.8%
96411	Chemo iv push addl drug	S	0437	\$43.78		S	0437	\$53.52	22.2%
96413	Chemo iv infusion 1 hr	S	0440	\$299.53		S	0440	\$285.00	-4.9%
96415	Chemo iv infusion addl hr	S	0437	\$43.78		S	0437	\$53.52	22.2%
96416	Chemo prolong infuse w/pump	S	0440	\$299.53		S	0440	\$285.00	-4.9%
96417	Chemo iv infus each addl seq	S	0437	\$43.78		S	0437	\$53.52	22.2%
96420	Chemo ia push technique	S	0438	\$105.90		S	0438	\$108.20	2.2%
96422	Chemo ia infusion up to 1 hr	S	0440	\$299.53		S	0440	\$285.00	-4.9%
96423	Chemo ia infuse each addl hr	S	0438	\$105.90		S	0438	\$108.20	2.2%
96425	Chemotherapy infusion	S	0440	\$299.53		S	0440	\$285.00	-4.9%

HCPCS Code	Short Descriptor	SI	APC	Payment Rate	CI	SI	APC	Payment Rate	Change 2014-2015
	method								
96440	Chemotherapy intracavitary	S	0439	\$172.18		S	0439	\$173.53	0.8%
96446	Chemotx admn prtl cavity	S	0439	\$172.18		S	0439	\$173.53	0.8%
96450	Chemotherapy into cns	S	0440	\$299.53		S	0440	\$285.00	-4.9%
96521	Refill/maint portable pump	S	0439	\$172.18		S	0439	\$173.53	0.8%
96522	Refill/maint pump/resvr syst	S	0439	\$172.18		S	0439	\$173.53	0.8%
96523	Irrig drug delivery device	Q1	0624	\$80.98		Q1	0624	\$78.79	-2.7%
96542	Chemotherapy injection	S	0438	\$105.90		S	0438	\$108.20	2.2%
96549	Chemotherapy unspecified	S	0436	\$29.50		S	0436	\$32.57	10.4%

9. OPSS Payment for Hospital Outpatient Visits

For CY 2015, CMS finalized its proposal to continue the policy established in CY 2014 that HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) will represent any and all clinic visits under the OPSS and will be assigned to APC 0634. CMS also finalized its proposal to use CY 2013 claims data to develop the CY 2015 OPSS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT evaluation and management codes for clinic visits previously recognized under the OPSS. In addition, as established for CY 2014, CMS finalized its proposal for CY 2015 not to recognize a distinction between new and established patient clinic visits.

CMS continues to believe that additional study is needed to assess the most suitable payment structure for emergency department visits. For CY 2015, CMS finalized its proposal to continue to use its existing methodology to recognize the existing CPT codes for Type A emergency department visits as well as the five HCPCS codes that apply to Type B emergency department visits and to establish the CY 2015 OPSS payment rates using CMS's established standard process. CMS also notes that it may propose changes to the coding and APC assignments for emergency department visits in future rulemaking. CMS also indicates in the Final Rule that if the American Medical Association (AMA) were to create facility-specific CPT codes for reporting visits provided in the hospital outpatient departments, CMS would consider such codes for OPSS use.⁴³

10. Payment Changes for Composite APCs

a. Low Dose Rate (LDR) Prostate Brachytherapy Composite APC (APC 8001)

For CY 2015, CMS finalized its proposal to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CY 2008 through CY 2014. The final geometric mean cost for composite APC 8001 is \$3,745, and the payment rate will be

⁴³ *Id.* at 66898-99.

\$3,608.44. This payment rate is a decrease from the CY 2014 payment of \$3,844.64 for this composite APC.⁴⁴

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

For CY 2015, CMS finalized its proposal to continue paying for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. To calculate the costs, CMS used the same methodology that CMS used to calculate the final CY 2013 and CY 2014 costs for these composite APCs. The charts below show the OPPS imaging families and multiple imaging procedure composite APCs.⁴⁵

Composite APC	Description	2014 Payment	2015 Payment
8004	Ultrasound Composite	\$285.58	\$285.20
8005	CT and CTA without Contrast Composite	\$306.30	\$313.24
8006	CT and CTA with Contrast Composite	\$548.28	\$528.36
8007	MRI and MRA without Contrast Composite	\$621.30	\$607.65
8008	MRI and MRA with Contrast Composite	\$927.43	\$910.87

OPPS Imaging Families and Multiple Imaging Procedure Composite APCs

FAMILY 1 – Ultrasound

APC 8004 – Ultrasound Composite

76604	Us exam, chest
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76775	Us exam abdo back wall, lim
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76870	Us exam, scrotum
76857	Us exam, pelvic, limited

FAMILY 2 - CT and CTA with and without Contrast

APC 8005 - CT and CTA without Contrast Composite*

70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye

⁴⁴ *Id.* at 66812-13 and Addendum A.

⁴⁵ *Id.* at 66813-16.

71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74261	Ct colonography, w/o dye
74176	Ct angio abd & pelvis

* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE will assign APC 8006 rather than APC 8005.

APC 8006 - CT and CTA with Contrast Composite

70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye

74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns

FAMILY 3 – MRI and MRA with and without Contrast

APC 8007 - MRI and MRA without Contrast Composite*

70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
C8901	MRA w/o cont, abd
C8904	MRI w/o cont, breast, uni
C8907	MRI w/o cont, breast, bi
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr

* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE will assign APC 8008 rather than APC 8007.

APC 8008- MRI and MRA with Contrast Composite

70549	Mr angiograph neck w/o & w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orb/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye

70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o & w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o & w/dye, upper extr

11. OPSS APC-Specific Policies

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

For the CY 2014 OPSS update, the AMA CPT Editorial Panel deleted the image-guided breast biopsy CPT code 19102 (Biopsy of breast; percutaneous, needle core, using imaging guidance) and CPT code 19103 (Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance) and replaced them with six new CPT codes (specifically, CPT codes 19081, 19082, 19083, 19084, 19085, and 19086) that “bundled” associated imaging services, effective January 1, 2014. The six new CPT codes are differentiated based on whether the imaging services are performed using stereotactic guidance, ultrasound guidance, or magnetic-resonance guidance. For CY 2014, replacement CPT codes 19081, 19083, and 19085 were given an interim assignment of APC 0005 (Level II Needle Biopsy/Aspiration Except Bone Marrow), and CPT codes 19082, 19084, and 19086, which describe add-on procedures, were packaged under CMS’s new policy to package all add-on codes.

For CY 2015, in light of a public presentation at the March 2014 meeting of the Advisory Panel on Hospital Outpatient Payment (“HOP Panel”), the HOP Panel’s recommendations, and CMS’s policy of reviewing APC assignments on an annual basis for all services and items paid under the OPSS, CMS proposed to reassign all of the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity. CMS finalized this proposal as well as its proposal to delete APC 0037. CMS assigns CPT codes 19081, 19083, and 19085 to APC 0005 and packages payment for add-on CPT codes 19082, 19084, and 19086. The reassignment of the procedures assigned to APCs 0685 and 0037 increases the payment rate for APC 0005. The CY 2015 payment rate for APC 0005 is \$1,052.22, 49.9 percent higher than the CY 2014 OPSS payment rate of \$702.08. CMS believes that the increased payment rate for APC 0005 is consistent with the HOP Panel’s recommendation to reassign CPT codes 19081, 19083, and 19085 to an appropriate APC based on resource utilization and clinical coherence.⁴⁶

The table below shows the final status indicators, APC assignments, and payment rates for the image-guided breast biopsy CPT codes 19081 through 19086.

Final CY 2015 APCs to Which Image-Guided Breast Biopsy Procedure Codes Are Assigned							
CPT code	Long descriptor	CY 2014 SI	CY 2014 APC	CY 2014 payment rate	Final CY 2015 SI	Final CY 2015 APC	Final CY 2015 payment rate
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	T	0005	\$702.08	T	0005	\$1,052.22
19082	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic	N	N/A	N/A	N	N/A	N/A

⁴⁶ *Id.* at 66864-67.

Final CY 2015 APCs to Which Image-Guided Breast Biopsy Procedure Codes Are Assigned							
CPT code	Long descriptor	CY 2014 SI	CY 2014 APC	CY 2014 payment rate	Final CY 2015 SI	Final CY 2015 APC	Final CY 2015 payment rate
	guidance (List separately in addition to code for primary procedure)						
19083	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance	T	0005	\$702.08	T	0005	\$1,052.22
19084	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure)	N	N/A	N/A	N	N/A	N/A
19085	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance	T	0005	\$702.08	T	0005	\$1,052.22
19086	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)	N	N/A	N/A	N	N/A	N/A

b. Image-Guided Abscess Drainage Procedures (APC 0007)

For the CY 2014 OPPS update, the AMA CPT Editorial Panel established CPT codes 10030 and 49407 pertaining to image-guided abscess drainage procedures. For CY 2014, CMS assigned CPT code 10030 to APC 0006 (Level I Incision & Drainage) on an interim basis, with a payment rate of \$159.66, and assigned CPT code 49407 to APC 0685 on an interim basis, with a payment rate of \$757.76.

The HOP Panel recommended that CMS reassign CPT code 49407 and the image-guided breast biopsy procedures to APC 0037 and APC 0007, respectively. CMS evaluated costs associated with the procedures assigned to the existing four needle biopsy APCs (APC 0004, 0005, 0685, and 0037) and, based on this review, proposed for CY 2015 to reassign the procedures assigned to APCs 0685 and 0037 to either APC 0004 or APC 0005 based on clinical and resource homogeneity and to delete APCs 0685 and 0037. CMS finalized this proposal. CMS reassigned CPT code 49407 from APC 0685 to APC 0005 and reassigned CPT code 10030 from APC 0006 to APC 007 for CY 2015.

The chart below shows the new status indicators, APC assignments, and payment rates for CY 2015.⁴⁷

CPT code	Long descriptor	CY 2014 SI	CY 2014 APC	2014 Payment Rate	Final CY 2015 SI	Final CY 2015 APC	Final 2015 Payment Rate
10030	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous	T	0006	\$159.66	T	0007	\$865.62
49407	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal	T	0685	\$757.76	T	0005	\$1,052.22

c. Radiation Therapy (APCs 0065, 0066, 0412, 0446, 0648, 0664, and 0667)

In the Final Rule, CMS addressed the following changes to the radiation therapy APCs for CY 2015:

(i) *Changes related to correction of a violation of the 2 times rule within APC 0664*

Due to a violation of the 2 times rule within APC 0664 (Level I Proton Beam Radiation Therapy), CMS finalized its proposal to reassign CPT code 77520 from APC 0664 to APC 0412 (Level III Radiation Therapy) and to reassign CPT code 77522 from APC 0664 to APC 0667 because these CPT codes are clinically similar and comparable in geometric mean costs to other services assigned to these APCs. Due to these reassignments, there are no other codes assigned to APC 0664, so CMS deleted APC 0664 for CY 2015. CMS also finalized its proposal to rename APC 0667 from “Level II Proton Beam Radiation Therapy” to “Level IV Radiation Therapy” to make the title consistent with other APCs in the radiation therapy series. CMS also is reassigning the following three services to the newly renamed APC 0667 for CY 2015: CPT codes 77522, 77523, and 77525.⁴⁸

CPT Code	Short Description	2014 APC	2014 Payment	2015 APC	2015 Payment
77520	Proton trmt simple w/o comp	0664	\$872.37	0412	\$507.55
77522	Proton trmt simple w/comp	0664	\$872.37	0667	\$1,071.95
77523	Proton trmt intermediate	0667	\$1,205.27	0667	\$1,071.95
77525	Proton treatment complex	0667	\$1,205.27	0667	\$1,071.95

(ii) *Changes related to APCs 0066 and 0648 and deletion of APC 0065*

For CY 2015, CMS finalized its proposal to delete APC 0065 (IORT, MRgFUS, and MEG) because CMS reassigned the services assigned to APC 0065 to other more appropriate APCs based on

⁴⁷ *Id.* at 66866-67 and Addendum B.

⁴⁸ *Id.* at 66860-61.

clinical similarities and comparable geometric mean cost. Specifically, CMS finalized its proposal to reassign Magnetoencephalography (MEG) CPT codes 95965 and 95966 from APC 0065 to APC 0446 (Level IV Nerve and Muscle Services) and to reassign IORT CPT codes 77424 and 77425 to C-APC 0648 (Level IV Breast and Skin Surgery). CMS also finalized its proposal to reassign the Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) HCPCS codes C9734, 0071T, and 0072T and 0301T from APC 0065 to APC 0066, which CMS is renaming “Level V Radiation Therapy.” CMS believes that MRgFUS services should be assigned to APC 0066 to align with the assignment of certain stereotactic radiosurgery services that were grouped with MRgFUS services prior to CY 2015.⁴⁹

(iii) *Renaming of C-APC 0067*

CMS finalized its proposal to rename APC 0067 from “Level II Stereotactic Radiosurgery” to “Single Session Cranial Stereotactic Radiosurgery.” CMS also finalized its proposal to make APC 0067 a C-APC in CY 2015.⁵⁰

12. OPSS APC Group Policies

a. Treatment of New CPT and Level II HCPCS Codes

In April 2014, CMS implemented the level II HCPCS codes listed in the chart below. CMS finalized the following status indicator, APC assignments, and payment rates for these Level II HCPCS codes.⁵¹

Final CY 2015 Status Indicators and APC Assignments for Level II HCPCS Codes Newly Implemented in April 2014					
CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
C9021	J9301	Injection, obinutuzumab, 10 mg	G	1476	\$54.27
C9739	C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	T	0162	\$2,084.03
C9740	C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	T	1564	\$4,750.00
Q2052	Q2052	Services, supplies and accessories used in the home under the Medicare intravenous immune globulin (ivig) demonstration)	E	N/A	N/A

In July 2014, CMS implemented additional new level II HCPCS codes. CMS finalized the status

⁴⁹ *Id.* at 66860-62.

⁵⁰ *Id.*

⁵¹ *Id.* at 66838 and Addendum B.

indicators, APC assignments, and payment rates for these Level II HCPCS codes shown in the chart below.⁵²

Final CY 2015 Status Indicators and APC Assignments for the Level II HCPCS Codes That Were Newly Implemented in July 2014					
CY 2014 HCPCS Code	CY 2015 HCPCS Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
C2644	C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie	U	2644	\$13.25
C9022	J1322	Injection, elosulfase alfa, 1 mg	G	1480	\$222.13
C9134	J7181	Factor XIII A-Subunit (Recombinant), Per IU	G	1764	\$13.69
Q9970	J1439	Injection, ferric carboxymaltose, 1 mg	G	9441	\$1.05
Q9974	J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg	N	N/A	N/A

In July 2014, CMS implemented new Category III CPT codes. CMS finalized the status indicators, APC assignments, and payment rates for these Category III CPT codes shown in the chart below.⁵³

New Category III CPT Codes Implemented in July 2014					
CY 2014 CPT Code	CY 2015 CPT Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
0347T	0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)	Q1	0420	\$131.69
0348T	0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed)	Q1	0261	\$94.98
0349T	0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)	Q1	0261	\$94.98
0350T	0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed)	Q1	0261	\$94.98
0351T	0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative	N	N/A	N/A
0352T	0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real time or referred	B	N/A	N/A
0353T	0353T	Optical coherence tomography of breast, surgical	N	N/A	N/A

⁵² *Id.* at 66839 and Addendum B.

⁵³ *Id.* at 66840 and Addendum B.

New Category III CPT Codes Implemented in July 2014					
CY 2014 CPT Code	CY 2015 CPT Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
		cavity; real time intraoperative			
0354T	0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real time or referred	B	N/A	N/A
0355T	0355T	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	T	0142	\$852.09
0356T	0356T	Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each	Q1	0698	\$100.81
0358T	0358T	Bioelectrical impedance analysis whole body composition assessment, supine position, with interpretation and report	Q1	0340	\$52.35
0359T	0359T	Behavior identification assessment by the physician or other qualified health care professional, face-to-face with patient and caregiver(s), includes administration of standardized and non-standardized tests, detailed behavior history, patient observation and caregiver interview, interpretation of test results, discussion of findings and recommendations with the primary guardian(s)/caregiver(s), and preparation of report	V	0632	\$106.23
0360T	0360T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; first 30 minutes of technician time, face-to-face with the patient	V	0632	\$106.23
0361T	0361T	Observational behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by one technician; each additional 30 minutes of technician time, face-to-face with the patient (List separately in addition to code for primary service)	N	N/A	N/A
0362T	0362T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; first 30 minutes of technician(s) time, face-to-face with the patient	V	0632	\$106.23
0363T	0363T	Exposure behavioral follow-up assessment, includes physician or other qualified health care professional direction with interpretation and report, administered by physician or other qualified health care professional with the assistance of one or more technicians; each additional 30 minutes of technician(s) time, face-	N	N/A	N/A

New Category III CPT Codes Implemented in July 2014

CY 2014 CPT Code	CY 2015 CPT Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
		to-face with the patient (List separately in addition to code for primary procedure)			
0364T	0364T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; first 30 minutes of technician time	S	0322	\$89.45
0365T	0365T	Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)	N	N/A	N/A
0366T	0366T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; first 30 minutes of technician time	S	0325	\$66.03
0367T	0367T	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)	N	N/A	N/A
0368T	0368T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; first 30 minutes of patient face-to-face time	S	0322	\$89.45
0369T	0369T	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; each additional 30 minutes of patient face-to-face time (List separately in addition to code for primary procedure)	N	N/A	N/A
0370T	0370T	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)	S	0324	\$123.95
0371T	0371T	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)	S	0324	\$123.95
0372T	0372T	Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients	S	0325	\$66.03
0373T	0373T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); first 60 minutes of technicians' time, face-to-face with patient	S	0323	\$115.47
0374T	0374T	Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); each additional 30 minutes of technicians' time,	N	N/A	N/A

New Category III CPT Codes Implemented in July 2014					
CY 2014 CPT Code	CY 2015 CPT Code	CY 2015 Long Descriptor	Final CY 2015 Status Indicator	Final CY 2015 APC	Final CY 2015 Payment Rate
		face-to-face with patient (List separately in addition to code for primary procedure)			

In the Final Rule and in accordance with past practice, CMS finalized its proposal to flag new Level II HCPCS codes that become effective October 1, 2014 and new Category I and III CPT and Level II HCPCS codes that become effective January 1, 2015 with comment indicator “NI” in Addendum B to the Final Rule to indicate that these codes have been assigned an interim OPSS payment status for CY 2015. The status indicators, APC assignments, and payment rates for these codes remain open to public comment and will be finalized in the CY 2016 OPSS/ASC final rule with comment period.⁵⁴

13. Process for Soliciting Public Comments for New and Revised CPT Codes That Would Be Released by AMA Before the January 1 Effective Date

Beginning with the CY 2016 OPSS, CMS finalized its proposal to make changes to the process used to establish APC assignments and status indicators for new and revised CPT codes that are effective January 1. Historically, because the AMA’s CPT Editorial Panel’s coding cycle occurs concurrently with CMS’s calendar year rulemaking cycle for the OPSS, CMS has incorporated into the OPSS final rule with comment period new or substantially revised CPT codes that are effective January 1. CMS historically has established interim APC and status indicator assignments for the coming year and has requested public comments on the interim assignments. CMS has responded to comments and finalized the APC and status indicator assignments for these CPT codes in the following year’s OPSS final rule with comment period.

CMS indicates that a variety of stakeholders have expressed concern about the process that CMS uses to recognize new and revised CPT codes. These stakeholders have urged CMS to publish proposed APCs and status indicators for the new and revised CPT codes that will be effective January 1 in the OPSS proposed rule and request public comments prior to finalizing them. Stakeholders believe public comments would assist CMS in assigning the CPT codes to appropriate APCs. CMS notes that stakeholders have raised similar concerns regarding CMS’s process for assigning interim payment values for new, revised, and potentially misvalued codes under the Medicare Physician Fee Schedule (PFS).

Beginning with the CY 2016 OPSS update, CMS finalized its proposal to include in the OPSS proposed rule the proposed APC and status indicator assignments for most new and revised CPT codes before they are used for payment purposes. For the new and revised CPT codes that CMS receives from AMA’s CPT Editorial Panel in time, CMS will include codes that would be effective January 1 in the OPSS/ASC proposed rule, along with the proposed APC and status indicator assignments for them, and then will finalize the APC and status indicator assignments in the OPSS/ASC final rules. For those new and revised CPT codes that CMS receives too late for inclusion in the OPSS/ASC proposed rule, CMS will create and use HCPCS G-codes that mirror the

⁵⁴ *Id.* at 66841.

predecessor CPT codes and will retain the current APC and status indicator assignments for a year until CMS can propose an APC and status indicator assignments in the following year's rulemaking cycle.

CMS notes that even if CMS needs to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, CMS does not anticipate that these HCPCS G-codes always will be necessary for OPSS purposes. CMS will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for CMS to include in the proposed rule and to avoid resorting to G-codes and the resulting delay in utilization of the most current CPT codes. CMS also finalizes its proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as a new technology or new surgical procedure), solicit public comments, and finalize the APC and status indicator assignments for those codes in the following year's final rule.⁵⁵

14. OPSS Payments to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the SSA

The Secretary of the Department of Health and Human Services was required under section 3138 of the ACA to conduct a study to determine whether costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the SSA (Hospital Inpatient Prospective Payment System (IPPS)-exempt cancer hospitals) exceeded the costs of hospitals furnishing services under section 1833(t) of the SSA (other hospitals furnishing services under the OPSS). The statute instructs the Secretary to provide an appropriate adjustment if the study shows that cancer hospitals' costs with respect to APC groups are determined to be greater than the costs of other hospitals furnishing services under the OPSS.

Based on the study's findings that costs incurred by cancer hospitals were greater than the costs incurred by other OPSS hospitals, CMS finalized a policy to provide a payment adjustment to 11 specified cancer hospitals that reflect the higher outpatient costs. IPPS-exempt cancer hospitals remain eligible for transitional outpatient payments (TOPs) that are designed to ensure that their payments under the OPSS are not lower than they would have been prior to implementation of the OPSS system and other outlier payments.

For CY 2015, CMS finalized its proposal to continue its policy of providing additional payments to cancer hospitals so that the hospital's payment-to-cost ratio (PCR) with the payment adjustment is equal to the weighted average PCR for the other OPSS hospitals using the most recent submitted or settled cost report data. Based on those data, the payment amount associated with the cancer hospital payment adjustment for CY 2015 would be the additional payment needed to result in a target PCR equal to 0.89 for each cancer hospital. For CY 2014, the target PCR for this adjustment also was 0.89.⁵⁶

15. Hospital Outpatient Outlier Payments

⁵⁵ *Id.* at 66841-44.

⁵⁶ *Id.* at 66831-32.

For CY 2015, CMS finalized its proposal to continue estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. To ensure that the estimated CY 2015 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, CMS finalized its proposal that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$2,775 fixed-dollar threshold. If the cost of a service exceeds both thresholds, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount.⁵⁷

16. Procedures That Would Be Paid Only as Inpatient Procedures

CMS removes CPT codes 63043 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace) and 63044 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace) from the inpatient list. Because CPT codes 63043 and 63044 are add-on codes, CMS assigns status indicator “N” to them for CY 2015. CMS also adds CPT code 22222 (Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic) to the CY 2015 inpatient list.⁵⁸

17. Collecting Data on Services Furnished in Off-Campus Provider-Based Departments

In light of a growing trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and an increase in the delivery of physician’s services in a hospital setting, CMS seeks a better understanding of how this trend impacts payments under the PFS and OPSS as well as beneficiary cost-sharing obligations. CMS is particularly interested in this information because the total payment amount for outpatient services made by Medicare is generally higher than the total payment amount made by Medicare when a physician furnishes those same services in a freestanding clinic or in a physician’s office. The Medicare Payment Advisory Commission (MedPAC) has questioned the appropriateness of increased Medicare payment and beneficiary cost-sharing when physician offices become hospital outpatient departments and has recommended that Medicare pay selected hospital outpatient services at PFS rates.

CMS cites SSA § 1848(c)(2)(M) as granting CMS the authority to engage in data collection to support valuation of services paid under the PFS. CMS is interested in obtaining more information on the frequency and type of services furnished in provider-based departments under this authority to improve the accuracy of the PFS. CMS notes that the current PFS practice expense methodology primarily distinguishes between the resources involved in furnishing services in either the non-facility or the facility setting. As more physician practices become hospital-based and are treated as off-campus provider-based departments, CMS wants to develop a better understanding of which practice expense costs are typically incurred by the hospital, the physicians and practitioners in the setting, and whether the facility and non-facility site of service differentials adequately account for the typical resource costs in light of these new ownership arrangements.

⁵⁷ *Id.* at 66832-34.

⁵⁸ *Id.* at 66909-10.

CMS seeks to gather information on the extent to which this shift is occurring. In the CY 2014 OPDS rulemaking, CMS requested public comments regarding the best method for collecting information and data that would allow CMS to analyze the frequency, type, and payment for physicians' and outpatient hospital services furnished in off-campus provider-based hospital outpatient departments. Based on the comments received, CMS proposed to create a HCPCS modifier to be reported beginning January 1, 2015 with every code for physicians' services and outpatient hospital services furnished in an off-campus provider-based department of a hospital on both the CMS-1500 claim form for physicians' services and the UB-04 form for hospital outpatient services.

CMS finalized its proposal with certain modifications. For hospital claims, CMS is creating a HCPCS modifier that is to be reported with every code for outpatient hospital services furnished in an off-campus provider-based department of a hospital, but CMS adopted a voluntary reporting period of the new HCPCS modifier for one year during CY 2015. Reporting the new HCPCS modifier for services furnished at an off-campus provider-based hospital department will not be mandatory until January 1, 2016, in order to allow providers time to make systems changes, test these changes, and train staff on use of the new modifier before reporting is required. This code will not be required to be reported for remote locations of a hospital, satellite facilities of a hospital, or for services furnished in an emergency department. CMS defines "campus" using the definition in 42 CFR 413.65(a)(2) to be "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."⁵⁹ The term "remote location of a hospital" is defined at 42 CFR 413.65(a)(2) as "a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider"⁶⁰

The two-digit modifier will be added to the HCPCS annual file as of January 1, 2015 with the label "PO," the short descriptor "Serv/proc off-campus pbd," and the long descriptor "Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments." Additional instructions and provider education will be published in subregulatory guidance. CMS explains that hospitals that have questions about which departments are considered to be off-campus provider-based hospital departments should work with the appropriate CMS regional office if individual, specific questions remain.

For PFS claims, instead of finalizing a HCPCS modifier, CMS will be deleting current POS code 22 (outpatient hospital department) and establishing two new place of service (POS) codes – one to identify outpatient services furnished in on-campus, remote, or satellite locations of a hospital, and one to identify services furnished in an off-campus provider-based hospital department setting. CMS will maintain the separate POS code 23 (Emergency room – hospital) to identify services furnished in an emergency department of the hospital. The new POS codes will be required to be reported as soon as they become available. More information on the availability of the new POS codes will be forthcoming in subregulatory guidance, but CMS does not expect the new POS codes to be available prior to July 1, 2015. There will be no voluntary reporting period of the POS codes for

⁵⁹ *Id.* at 66913.

⁶⁰ *Id.*

applicable professional claims because each professional claim requires a POS code in order to be accepted by Medicare.⁶¹

18. Exceptions to the 2 Times Rule

Per section 1833(t)(2) of the SSA, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group. The Secretary of the Department of Health and Human Services is authorized to make exceptions to the 2 times rule in unusual cases, however, such as low-volume items and services. In the CY 2015 proposed rule, CMS proposed nine exceptions to the 2 times rule. CMS finalized its proposal to except 7 of the 9 proposed APCs from the two times rule for CY 2015. CMS is not, however, finalizing its proposal to except APC 0012 (Level I Debridement & Destruction) and APC 0015 (Level II Debridement and Destruction), as CMS's analysis shows that these two APCs no longer violate the 2 times rule. In addition, CMS has identified three new APCs that violate the 2 times rule. These are APC 0095 (Cardiac Rehabilitation), APC 0388 (Discograph), and APC 0420 (Level III Minor Procedures). The table below lists the ten APCs that CMS is excepting from the 2 times rule for CY 2015.⁶²

Final APC Exceptions to the 2 Times Rule for CY 2015	
CY 2015 APC	CY 2015 APC Title
0057	Bunion Procedures
0066	Level V Radiation Therapy
0095	Cardiac Rehabilitation
0330	Dental Procedures
0388	Discography
0420	Level III Minor Procedures
0433	Level II Pathology
0450	Level I Minor Procedures
0634	Hospital Clinic Visits
0661	Level III Pathology

19. Updates to the ASC Payment System

a. Payment for LDR Prostate Brachytherapy Services

CMS did not propose and is not making any changes to its current policy regarding ASC payment for LDR prostate brachytherapy services for CY 2015.⁶³

⁶¹ *Id.* at 66910-14.

⁶² *Id.* at 66846.

⁶³ *Id.* at 66931-32.

20. Hospital Outpatient Quality Reporting (OQR) Program Updates

a. Removal of Quality Measures from the Hospital OQR Program Measure Set

For CY 2015, CMS finalized its proposal to refine the criteria for determining when a measure is “topped-out.” CMS will consider a finalized measure to be “topped-out” when measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance no longer can be made. CMS finalized its proposal that a measure under the Hospital OQR Program is “topped-out” when it meets both of the following criteria:

- (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and
- (2) A truncated coefficient of variation less than or equal to 0.10.

CMS notes, however, that it evaluates different factors in considering the removal of measures and will assess the benefits of retaining a measure on a case-by-case basis before proposing to remove a measure from the Hospital OQR program.

CMS finalized its proposal to remove two measures from the Hospital OQR Program for the CY 2017 payment determination and subsequent years. Specifically, CMS removed OP-6 (Timing of Prophylactic Antibiotics) and OP-7 (Prophylactic Antibiotic Selection for Surgical Patients) because these measures meet both of CMS’s previously finalized criteria for being “topped-out” (i.e. measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made) as well as the two new criteria that CMS finalized for determining “topped-out” status. CMS also proposed to remove OP-4 (Aspirin at Arrival) but, upon further review of the data, retains that measure in the Hospital OQR because performance for OP-4 is still low in some hospitals.⁶⁴

b. Quality Measures Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

With respect to data submission requirements for OP-27: influenza vaccination coverage among healthcare personnel reported via National Healthcare Safety Network (NHSN) for the CY 2017 payment determination and subsequent years, CMS clarifies that the deadline for hospitals to submit this data will be May 15, 2015, with respect to the October 1, 2014 through March 31, 2015 encounter period and that the data to be submitted are “Healthcare Personnel Influenza Vaccination summary reporting data,” rather than “HAI measure collection data.” CMS also clarifies that hospitals should report to NHSN a single count per enrolled facility by the facility OrgID, rather than per CMS Certification Number.

In the CY 2014 OP/ASC final rule, CMS adopted OP-29: Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients and OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use beginning with the CY 2016 payment determination. CMS notes in the Final Rule that, on December 31, 2013, CMS issued guidance indicating that CMS would delay the implementation of OP-29 and OP-30 for 3 months for the CY 2016 payment determination to allow hospitals more time to put the necessary mechanisms in place to collect these

⁶⁴ *Id.* at 66942-44.

data. CMS also notes that it has changed the encounter period from January 1, 2014 through December 31, 2014 to April 1, 2014 through December 31, 2014.

In the CY 2014 OPPTS/ASC final rule, CMS adopted OP-31: Cataracts - Improvement in Patient's Visual Function within 90 days Following Cataract Surgery for the CY 2016 payment determination and subsequent years. In the CY 2015 Final Rule, CMS corrects previous statements made by the agency to clarify that this measure has not been field-tested in the hospital outpatient department setting. CMS also notes that it has determined it can be operationally difficult for hospitals to collect and report this measure and that CMS is concerned about the use of inconsistent surveys to assess visual function. As such, CMS issued guidance stating that it will delay the implementation of OP-31, and in the Final Rule, CMS finalizes its proposal to exclude OP-31 from the CY 2016 payment determination measure set as proposed. CMS also finalized its proposal that hospitals have the option to voluntarily collect and submit OP-31 data for the CY 2015 encounter period/CY 2017 payment determination and subsequent years.⁶⁵

c. New Quality Measure for the CY 2018 Payment Determination and Subsequent Years

CMS proposed to adopt one new measure for the Hospital OQR Program for the CY 2017 payment determination and subsequent years: OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. CMS finalized adoption of this measure but will begin with CY 2018, rather than CY 2017 as proposed, to allow sufficient time to further analyze this measure. CMS plans to perform a preliminary analysis of the measure in 2015. Testing during the measure dry-run with 100 percent of the sample per facility will help CMS to determine the appropriate cutoff volume of colonoscopies per facility. In addition, the delay will allow hospital outpatient departments sufficient time to review their measure data from the dry run and use the confidential facility reports with patient-level associated hospital event information.⁶⁶

d. Possible Hospital OQR Program Measures and Topics for Future Consideration

CMS is considering expanding its current measure domains of process of care, imaging efficiency patterns, care transitions, emergency department throughput efficiency, and the use of health information technology. In the Final Rule, CMS summarizes and responds to comments that it received on its proposal to explore measures in the following areas in future years: electronic clinical quality, partial hospitalization, behavioral health, and measures that align with the National Quality Strategy and CMS Quality Strategy domains.⁶⁷

21. Ambulatory Surgical Center Quality Reporting (ASCQR) Program Updates

a. Topped Out Quality Measures

For CY 2015, CMS finalized its proposal to adopt the same criteria for determining when a measure is "topped-out" under the ASCQR Program as CMS proposes for the OQR Program.⁶⁸

⁶⁵ *Id.* at 66944-48.

⁶⁶ *Id.* at 66948-55.

⁶⁷ *Id.* at 66956-61.

⁶⁸ *Id.* at 66967-69.

b. Quality Measures Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

CMS finalized its proposal without modification to adopt May 15 of the year in which the influenza season ends as the data submission deadline for the ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel measure for each payment determination year, beginning with the CY 2016 payment determination. For the CY 2017 payment determination and subsequent years, ASCs will collect data from October 1 of the year 2 years prior to the payment determination year to March 31 of the year prior to the payment determination year.⁶⁹

In the CY 2014 OPPTS/ASC final rule with comment period, CMS adopted for CY 2016 ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use. CMS notes that, on December 31, 2013, the agency issued guidance stating that it would delay the implementation of these two measures for three months for the CY 2016 payment determination. CMS notes that the data submission timeframe and encounter period for subsequent years remains as previously finalized.⁷⁰

CMS is excluding ASC-11: Cataracts – Improvements in Patient’s Visual Function within 90 Days Following Cataract Surgery for the CY 2016 payment determination and permitting voluntary data collection for this measure for the CY 2017 payment determination and subsequent years.⁷¹

c. New Quality Measure for the CY 2018 Payment Determination and Subsequent Years

For the CY 2017 payment determination and subsequent years, CMS proposed to adopt one new measure for the ASCQR Program: ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. CMS finalized the adoption of this measure beginning with CY 2018, rather than beginning with CY 2017 as proposed, to allow sufficient time to conduct further analysis of this measure. CMS plans to perform a preliminary analysis of the measure in 2015, and the general information on the dry run as well as the confidential dry run reports will be available for ASCs to review. With national implementation of a dry run of this measure, CMS also will review the appropriate cutoff volume for facilities, if necessary, in reporting the measure score.⁷²

d. Possible ASCQR Program Measures and Topics for Future Consideration

In the Final Rule, CMS summarizes and responds to comments received pertaining to ASCQR Program measures domains in which CMS is considering future measures, including making care safer, strengthening person and family engagement, promoting effective communication and coordination of care, promoting effective prevention and treatment, working with communities to promote best practices of healthy living, and making care affordable.⁷³

⁶⁹ *Id.* at 66986.

⁷⁰ *Id.* at 66983-84.

⁷¹ *Id.* at 66984-85.

⁷² *Id.* at 66970-78.

⁷³ *Id.* at 66979-81.

22. Revision of the Requirements for Physician Certification of Hospital Inpatient Services Other Than Psychiatric Inpatient Services

In the fiscal year 2014 IPPS proposed rule, CMS discussed the statutory requirement for certification of hospital inpatient services for payment under Medicare Part A other than psychiatric inpatient services. The certification requirement, found in SSA § 1814(a)(3), provides that Medicare Part A payment will only be made for such services “which are furnished over a period of time, [if] a physician certifies that such services are required to be given on an inpatient basis.” CMS disagrees with commenters’ assertion that the only possible interpretation of the statute is that the requirement for physician certification only applies to long-stay cases. According to CMS, the statute does not define “over a period of time,” and further provides that “such certification shall be furnished only in such cases, and with such frequency, and accompanied by such supporting material... as may be provided by regulations.”⁷⁴ CMS believes that, through this language, Congress explicitly delegated authority to CMS to clarify this provision of the statute by regulation.

CMS continues to believe that the inpatient admission order is necessary for all inpatient admissions but finalizes its proposal to require such orders as a condition of payment based upon CMS’s general rulemaking authority under SSA § 1871. In addition, CMS changes its interpretation of § 1814(a)(3) of the Act to require a physician certification only for long-stay cases and outlier cases. The SSA specifically requires that certification must occur no later than the 20th day, and the regulations also specify that the physician certification for cost outlier cases occur no later than 20 days into the hospital stay. In light of these requirements, CMS believes that 20 days also is an appropriate minimum threshold for the physician certification for non-outlier cases. CMS also finalizes its proposals to define long-stay cases as cases with stays of 20 days or longer and to revise CMS regulations to specify that certifications for long-stay cases must be furnished no later than 20 days into the hospital stay.⁷⁵

⁷⁴ *Id.* at 66997.

⁷⁵ *Id.* at 66997-99.