C. OIG Recommendations

The mission of the Office of the Inspector General (OIG) as mandated by Pub. L. 95–452 (as amended) is to protect the integrity of the Department of Health and Human Services programs and the health and welfare of program beneficiaries. The OIG conducts independent audits, inspections, and investigations to improve the efficiency of these programs and to identify and prevent fraud, waste and abuse. Since the issuance of the CY 2012 OPPS/ASC final rule with comment period, the OIG has not made any recommendations regarding the Hospital OPPS.

XIV. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to ASCs, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74378 through 74379).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under § 416.2 and § 416.166 of the regulations, subject to certain exclusions, covered surgical procedures are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when

performed in an ASC, and that would not be expected to require active medical monitoring and care at midnight following the procedure ("overnight stay"). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate for Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478).

In the August 2, 2007 final rule, we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) brachytherapy sources; (2) certain implantable items that have pass-through status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. These covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment (72 FR 42495). Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in conjunction with the annual proposed and final rulemaking

process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). In addition, as discussed in detail in section XIV.B. of this proposed rule, because we base ASC payment policies for covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, we also provide quarterly update change requests (CRs) for ASC services throughout the year (January, April, July, and October). CMS releases new Level II codes to the public or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes are recognized on Medicare claims) outside of the formal rulemaking process via these ASC quarterly update CRs. Thus, the updates are to implement newly created Level II HCPCS and Category III CPT codes for ASC payment and to update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New Category I CPT codes, except vaccine codes, are released only once a year and, therefore, are implemented only through the January quarterly update. New Category I CPT vaccine codes are released twice a year and, therefore, are implemented through the January and July quarterly updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for the process used to update the HCPCS and CPT codes (76 FR 42291).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS inpatient list), new procedures, and procedures for which there is revised coding, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of covered surgical

procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed Treatment of New Codes

1. Proposed Process for Recognizing New Category I and Category III CPT Codes and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims: (1) Category I CPT codes, which describe surgical procedures; (2) Category III CPT codes, which describe new and emerging technologies, services, and procedures; and (3) Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether they are office-based procedures (72 FR 42533 through 42535). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system.

We have separated our discussion below into two sections based on whether we are proposing to solicit public comments in this CY 2013 OPPS/ASC proposed rule (and respond to those comments in the CY 2013 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2013 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2014 OPPS/ASC final rule with comment period).

We note that we sought public comment in the CY 2012 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2012. We also sought public comments in the CY 2012 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2011. These new codes, with an effective date of October 1, 2011, or January 1, 2012, were flagged with comment indicator "NI" in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2012 OPPS/ASC final rule with comment period. We will respond to public comments and finalize the ASC treatment of these codes in the CY 2013 OPPS/ASC final rule with comment period.

2. Proposed Treatment of New Level II HCPCS Codes and Category III CPT Codes Implemented in April and July 2012 for Which We Are Soliciting Public Comments in this CY 2013 OPPS/ASC Proposed Rule

In the April and July CRs, we made effective for April 1, 2012 or July 1, 2012, respectively, a total of 12 new Level II HCPCS codes and 5 new Category III CPT codes

that were not addressed in the CY 2012 OPPS/ASC final rule with comment period. The 12 new Level II HCPCS codes describe covered ancillary services.

In the April 2012 ASC quarterly update (Transmittal 2425, CR 7754, dated March 16, 2012), we added one new radiology Level II HCPCS code and four new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 36 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9288 (Injection, centruroides (scorpion) immune f(ab)2 (equine), 1 vial);
- HCPCS code C9289 (Injection, asparaginase Erwinia chrysanthemi, 1,000international units (I.U.));
- HCPCS code C9290 (Injection, bupivacaine liposome, 1 mg);
- HCPCS code C9291 (Injection, aflibercept, 2 mg vial); and
- HCPCS code C9733 (Non-ophthalmic fluorescent vascular angiography).

In the July 2012 quarterly update (Transmittal 2479, Change Request 7854, dated May 25, 2012), we added seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 37 below, we added the following codes to the list of covered ancillary services:

- HCPCS code C9368 (Grafix core, per square centimeter);
- HCPCS code C9369 (Grafix prime, per square centimeter);
- HCPCS code Q2034 (Influenza virus vaccine, split virus, for intramuscular use (Agriflu));
- HCPCS code Q2045 (Injection, human fibrinogen concentrate, 1 mg);

- HCPCS code Q2046 (Injection, aflibercept, 1 mg);
- HCPCS code Q2048 (Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg); and
- HCPCS code Q2049 (Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg).

We note that HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

We assigned payment indicator "K2" (Drugs and biologicals paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate) to the 10 new Level II HCPCS codes that are separately paid when provided in ASCs. We assigned payment indicator "L1" (Influenza vaccine; pneumococcal vaccine; packaged item/service; no separate payment made) or payment indicator "N1" (Packaged service/item; no separate payment made) to the two new Level II HCPCS codes that are packaged when provided in ASCs. We are soliciting public comment on the proposed CY 2012 ASC payment indicators and payment rates for the covered ancillary services listed in Tables 36 and 37 below. Those HCPCS codes became payable in ASCs, beginning in April or July 2012, and are paid at the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

The HCPCS codes listed in Table 36 are included in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We note that all ASC addenda are only available via the Internet on the CMS Web site. Because the

payment rates associated with the new Level II HCPCS codes that became effective for July 2012 (listed in Table 37) are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2013 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2012 ASC quarterly update CR and their proposed CY 2013 payment rates (based on July 2012 ASP data) that are displayed in Table 37 are not included in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2013 OPPS/ASC final rule with comment period, consistent with our annual update policy. We are soliciting public comment on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were newly recognized as ASC covered ancillary services in April and July 2012 through the quarterly update CRs, as listed in Tables 36 and 37 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 36.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 Payment Indicator
C9288	Injection, centruroides (scorpion) immune f(ab)2	K2

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 Payment Indicator
	(equine), 1 vial	
C9289	Injection, asparaginase Erwinia chrysanthemi, 1,000 international units (I.U.)	K2
C9290	Injection, bupivacaine liposome, 1 mg	K2
C9291	Injection, aflibercept, 2 mg vial	K2
C9733	Non-ophthalmic fluorescent vascular angiography	N1

TABLE 37.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2012

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 Payment Indicator	Proposed CY 2013 Payment Rate
C9368	Grafix core, per square centimeter	K2	$7.96
C9369	Grafix prime, per square centimeter	K2	$0.61
Q2034	Influenza virus vaccine, split virus, for intramuscular use (Agriflu)	L1	N/A
Q2045	Injection, human fibrinogen concentrate, 1 mg*	K2	$0.73
Q2046	Injection, aflibercept, 1 mg*	K2	$980.50
Q2048	Injection, doxorubicin hydrochloride, liposomal, doxil, 10 mg*	K2	$537.21
Q2049	Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg	K2	$498.26

*HCPCS code Q2045 replaced code J1680, HCPCS code Q2046 replaced code C9291, and HCPCS code Q2048 replaced code J9001 beginning July 1, 2012.

Through the July 2012 quarterly update CR, we also implemented ASC payment for five new Category III CPT codes as ASC covered surgical procedures, effective

July 1, 2012. These codes are listed in Table 38 below, along with their proposed payment indicators and proposed payment rates for CY 2013. Because the payment rates associated with the new Category III CPT codes that became effective for July are not available to us in time for incorporation into the Addenda to this OPPS/ASC proposed rule, our policy is to include the codes, their proposed payment indicators, and proposed payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The codes listed in Table 38 and their final payment indicators and rates will be included in Addendum AA to the CY 2013 OPPS/ASC final rule with comment period.

We are proposing to assign payment indicator "G2" (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to three of the five new Category III CPT codes implemented in July 2012 and to assign payment indicator "J8" (Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate) to the remaining two new Category III CPT codes implemented in July 2012. We believe that these procedures would not be expected to pose a significant safety risk to Medicare beneficiaries or would not be expected to require an overnight stay if performed in ASCs. We are soliciting public comment on these proposed payment indicators and the payment rates for the new Category III CPT codes that were newly recognized as ASC covered surgical procedures in July 2012 through the quarterly update CR, as listed in Table 38 below. We are proposing to finalize their payment indicators and their payment rates in the CY 2013 OPPS/ASC final rule with comment period.

TABLE 38.—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2012 AS ASC COVERED SURGICAL PROCEDURES

CY 2012 CPT Code	CY 2012 Long Descriptor	Proposed CY 2013 Payment Indicator	Proposed CY 2013 Payment Rate
0302T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)	J8	$7,181.95
0303T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; electrode only	G2	$2,129.99
0304T	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; device only	J8	$5,816.80
0307T	Removal of intracardiac ischemia monitoring device	G2	$968.15
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens*	G2	$940.65

* CPT code 0308T replaced HCPCS code C9732 beginning July 1, 2012.

3. Proposed Process for New Level II HCPCS Codes and Category I and III CPT Codes for Which We Will Be Soliciting Public Comments in the CY 2013 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Category I and Category III CPT codes and new Level II HCPCS codes that are effective January 1 in the final rule with comment period updating the ASC payment system for the following

calendar year. These codes are released to the public via the CMS HCPCS (for Level II HCPCS codes) and AMA Web sites (for CPT codes), and also through the January ASC quarterly update CRs. In the past, we also have released new Level II HCPCS codes that are effective October 1 through the October ASC quarterly update CRs and incorporated these new codes in the final rule with comment period updating the ASC payment system for the following calendar year. All of these codes are flagged with comment indicator ''NI'' in Addenda AA and BB to the OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. The payment indicator and payment rate, if applicable, for all such codes flagged with comment indicator ''NI'' are open to public comment in the OPPS/ASC final rule with comment period, and we respond to these comments in the final rule with comment period for the next calendar year's OPPS/ASC update.

We are proposing to continue this process for CY 2013. Specifically, for CY 2013, we are proposing to include in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2013, that would be incorporated in the January 2013 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2012 or January 1, 2013, that would be released by CMS in its October 2012 and January 2013 ASC quarterly update CRs. These codes would be flagged with comment indicator "NI" in Addenda AA and BB to the CY 2013 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim payment status. Their payment indicators and payment rates, if applicable, would be open to public comment in the CY 2013

OPPS/ASC final rule with comment period and would be finalized in the CY 2014 OPPS/ASC final rule with comment period.

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

1. Covered Surgical Procedures

a. Proposed Additions to the List of ASC Covered Surgical Procedures

We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice changed the clinical appropriateness of these procedures for the ASC setting. We are proposing to update the list of ASC covered surgical procedures by adding 16 procedures to the list. We determined that these 16 procedures would not be expected to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

The 16 procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2013 payment indicators, are displayed in Table 39 below. We invite public comment on this proposal.

TABLE 39.—PROPOSED NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2013

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 ASC Payment Indicator**

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 ASC Payment Indicator**
37205	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; initial vessel	G2
37206	Transcatheter placement of an intravascular stent(s) (except coronary, carotid, vertebral, iliac, and lower extremity arteries), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	G2
37224	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty	G2
37225	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with atherectomy, includes angioplasty within the same vessel, when performed	G2
37226	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
37227	Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J8
37228	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty	G2
37229	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with atherectomy, includes angioplasty within the same vessel, when performed	G2
37230	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed	G2
37231	Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed	J8

CY 2012 HCPCS Code	CY 2012 Long Descriptor	Proposed CY 2013 ASC Payment Indicator**
37232	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal angioplasty (list separately in addition to code for primary procedure)	G2
37233	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2
37234	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2
37235	Revascularization, endovascular, open or percutaneous, tibial/ peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (list separately in addition to code for primary procedure)	G2
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2*
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care	R2*

*If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

b. Proposed Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as "office-based" those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC list of covered surgical procedures beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the list of surgical procedures eligible for payment in ASCs, each year we identify surgical procedures as

either temporarily office-based, permanently office-based, or non-office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2013 to Covered Surgical Procedures Designated as Office-Based

In developing this proposed rule, we followed our policy to annually review and update the surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2011 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator "G2" in CY 2012, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2*," "P3*," or "R2*" in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74400 through 74408).

Our review of the CY 2011 volume and utilization data resulted in our identification of six covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that the procedures are performed more than 50 percent of the time in physicians' offices, and that our medical advisors believe the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The six CPT codes we are proposing to permanently designate as office-based are listed in Table 40 below. We invite public comment on this proposal.

TABLE 40.—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED DESIGNATION FOR CY 2013

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 ASC Payment Indicator	Proposed CY 2013 ASC Payment Indicator*
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa	G2	P2
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	G2	P2
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	G2	P2
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	G2	P2
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	G2	P3
G0365	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)	G2	P2

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

We also reviewed CY 2011 volume and utilization data and other information for the eight procedures finalized for temporary office-based status in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74404 through 74408). Among these eight procedures, there were very few claims data for six procedures: CPT code 0099T

(Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)); CPT code 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)); CPT code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy). Consequently, we are proposing to maintain their temporary office-based designations for CY 2013.

The volume and utilization data for the remaining two procedures that have temporary office-based designations for CY 2012 are sufficient to indicate that these procedures are not performed predominantly in physicians' offices and, therefore, should not be assigned an office-based payment indicator in CY 2013. Consequently, we are proposing to assign payment indicator "G2" to the following two covered surgical procedure codes in CY 2013:

- CPT code 37761 (Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg); and
- CPT code 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed).

The proposed CY 2013 payment indicator designations for the eight procedures that were temporarily designated as office-based in CY 2012 are displayed in Table 41 below. The procedures for which the proposed office-based designations for CY 2013 are temporary also are indicated by asterisks in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on this proposal.

TABLE 41.—PROPOSED CY 2013 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2012 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 ASC Payment Indicator	Proposed CY 2013 ASC Payment Indicator**
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	G2
67229	Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2*	R2*
0099T	Implantation of intrastromal corneal ring segments	R2*	R2*
0124T	Conjunctival incision with posterior extrascleral placement of pharmacological agent (does not include supply of medication)	R2*	R2*
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	R2*	R2*
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	R2*
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	R2*	G2

CY 2012 CPT Code	CY 2012 Long Descriptor	CY 2012 ASC Payment Indicator	Proposed CY 2013 ASC Payment Indicator**
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2*

* If designation is temporary.
** Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being developed for publication, current law authorizes a negative update to the MPFS payment rates for CY 2013. For a discussion of those rates, we refer readers to the CY 2013 MPFS proposed rule.

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures.

(2) Proposed Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2013

For CY 2013, we are proposing to update the ASC list of covered surgical procedures that are eligible for payment according to our device-intensive procedure payment methodology, consistent with the proposed OPPS device-dependent APC update, reflecting the proposed APC assignments of procedures, designation of APCs as

device-dependent, and APC device offset percentages based on the CY 2011 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this proposed rule.

The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2013 are listed in Table 42 below. The CPT code, the CPT code short descriptor, the proposed CY 2013 ASC payment indicator (PI), the proposed CY 2013 OPPS APC assignment, the proposed CY 2013 OPPS APC device offset percentage, and an indication if the full credit/partial credit (FB/FC) device adjustment policy would apply are also listed in Table 42 below. A review of the FB/FC device adjustment policy is also found below. All of these procedures are included in Addendum AA to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on this proposal.

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

We generally discuss the no cost/full credit and partial credit devices under the heading entitled "Proposed ASC Payment for Covered Surgical Procedure." However, because the no cost/full credit and partial credit device policy applies to a subset of device-intensive procedures, we believe it would be clearer to discuss the device-intensive procedure policy and the no cost/full credit and partial credit device policy consecutively and to consolidate the tables that we usually publish separately. Our ASC policy with regard to payment for costly devices implanted in ASCs at no cost/full credit or partial credit as set forth in § 416.179 is consistent with the OPPS policy. The

proposed CY 2013 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this proposed rule. The established ASC policy adopts the OPPS policy and reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices (73 FR 68742 through 68745).

Consistent with the OPPS, we are proposing to update the list of ASC covered device-intensive procedures and devices that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2013. Table 42 below displays the ASC covered device-intensive procedures that we are proposing would be subject to the no cost/full credit or partial credit device adjustment policy for CY 2013. Specifically, when a procedure that is listed in Table 42 is subject to the no cost/full credit or partial credit device adjustment policy and is performed to implant a device that is listed in Table 43 below, where that device is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS "FB" modifier on the line with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost to the ASC or with full credit. We would provide the same amount of payment reduction based on the device offset amount in ASCs that would apply under the OPPS under the same circumstances. We continue to

believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

For partial credit, we are proposing to reduce the payment for implantation procedures listed in Table 42 that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the cost of the new device. The ASC would append the HCPCS "FC" modifier to the HCPCS code for a surgical procedure listed in Table 42 that is subject to the no cost/full credit or partial credit device adjustment policy, when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 43 below. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs would have the option of either: (1) submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more of the cost of the replacement device. Beneficiary coinsurance would continue to be based on the reduced payment amount.

We invite public comments on these proposals.

TABLE 42.—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2013, INCLUDING ASC COVERED SURGICAL PROCEDURES FOR WHICH WE PROPOSE THAT

THE NO COST/FULL CREDIT OR PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CPT Code	Short Descriptor	Proposed CY 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 Device-Dependent APC Offset Percent	Proposing that the FB/FC Policy Would Apply
0282T	Periph field stimul trial	J8	0040	55%	Yes
0283T	Periph field stimul perm	J8	0318	87%	Yes
0302T	Icar ischm mntrng sys compl	J8	0089	70%	Yes
0304T	Icar isch mntrng sys device	J8	0090	71%	Yes
19296	Place po breast cath for rad	J8	0648	50%	Yes
19297	Place breast cath for rad	J8	0648	50%	Yes
19298	Place breast rad tube/caths	J8	0648	50%	Yes
19325	Enlarge breast with implant	J8	0648	50%	Yes
19342	Delayed breast prosthesis	J8	0648	50%	Yes
19357	Breast reconstruction	J8	0648	50%	Yes
24361	Reconstruct elbow joint	J8	0425	58%	Yes
24363	Replace elbow joint	J8	0425	58%	Yes
24366	Reconstruct head of radius	J8	0425	58%	Yes
25441	Reconstruct wrist joint	J8	0425	58%	Yes
25442	Reconstruct wrist joint	J8	0425	58%	Yes
25446	Wrist replacement	J8	0425	58%	Yes
27446	Revision of knee joint	J8	0425	58%	Yes
33206	Insertion of heart pacemaker	J8	0089	70%	Yes
33207	Insertion of heart pacemaker	J8	0089	70%	Yes
33208	Insertion of heart pacemaker	J8	0655	73%	Yes
33212	Insertion of pulse generator	J8	0090	71%	Yes
33213	Insertion of pulse generator	J8	0654	74%	Yes
33214	Upgrade of pacemaker system	J8	0655	73%	Yes
33221	Insert pulse gen mult leads	J8	0654	74%	Yes
33224	Insert pacing lead & connect	J8	0655	73%	Yes
33225	Lventric pacing lead add-on	J8	0655	73%	Yes
33227	Remove&replace pm gen singl	J8	0090	71%	Yes
33228	Remv&replc pm gen dual lead	J8	0654	74%	Yes

CPT Code	Short Descriptor	Proposed CY 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 Device-Dependent APC Offset Percent	Proposing that the FB/FC Policy Would Apply
33229	Remv&replc pm gen mult leads	J8	0654	74%	Yes
33230	Insrt pulse gen w/dual leads	J8	0107	83%	Yes
33231	Insrt pulse gen w/dual leads	J8	0107	83%	Yes
33240	Insert pulse generator	J8	0107	83%	Yes
33249	Eltrd/insert pace-defib	J8	0108	84%	Yes
33262	Remv&replc cvd gen sing lead	J8	0107	83%	Yes
33263	Remv&replc cvd gen dual lead	J8	0107	83%	Yes
33264	Remv&replc cvd gen mult lead	J8	0107	83%	Yes
33282	Implant pat-active ht record	J8	0680	74%	Yes
37227	Fem/popl revasc stnt & ather	J8	0319	53%	No
37231	Tib/per revasc stent & ather	J8	0319	53%	No
53440	Male sling procedure	J8	0385	63%	Yes
53444	Insert tandem cuff	J8	0385	63%	Yes
53445	Insert uro/ves nck sphincter	J8	0386	70%	Yes
53447	Remove/replace ur sphincter	J8	0386	70%	Yes
54400	Insert semi-rigid prosthesis	J8	0385	63%	Yes
54401	Insert self-contd prosthesis	J8	0386	70%	Yes
54405	Insert multi-comp penis pros	J8	0386	70%	Yes
54410	Remove/replace penis prosth	J8	0386	70%	Yes
54416	Remv/repl penis contain pros	J8	0386	70%	Yes
55873	Cryoablate prostate	J8	0674	54%	No
61885	Insrt/redo neurostim 1 array	J8	0039	86%	Yes
61886	Implant neurostim arrays	J8	0315	88%	Yes
62361	Implant spine infusion pump	J8	0227	82%	Yes
62362	Implant spine infusion pump	J8	0227	82%	Yes
63650	Implant neuroelectrodes	J8	0040	55%	Yes
63655	Implant neuro-electrodes	J8	0061	66%	Yes
63663	Revise spine eltrd perq aray	J8	0040	55%	Yes
63664	Revise spine eltrd plate	J8	0040	55%	Yes
63685	Insrt/redo spine n generator	J8	0039	86%	Yes
64553	Implant neuro-electrodes	J8	0040	55%	Yes

CPT Code	Short Descriptor	Proposed CY 2013 ASC PI	Proposed CY 2013 OPPS APC	Proposed CY 2013 Device-Dependent APC Offset Percent	Proposing that the FB/FC Policy Would Apply
64555	Implant neuro-electrodes	J8	0040	55%	Yes
64561	Implant neuro-electrodes	J8	0040	55%	Yes
64565	Implant neuro-electrodes	J8	0040	55%	Yes
64568	Implant neuro-electrodes	J8	0318	87%	Yes
64575	Implant neuro-electrodes	J8	0061	66%	Yes
64580	Implant neuro-electrodes	J8	0061	66%	Yes
64581	Implant neuro-electrodes	J8	0061	66%	Yes
64590	Insrt/redo pn/gastr stimul	J8	0039	86%	Yes
65770	Revise cornea with implant	J8	0293	65%	No
69714	Implant temple bone w/stimul	J8	0425	60%	Yes
69715	Temple bne implnt w/stimulat	J8	0425	60%	Yes
69717	Temple bone implant revision	J8	0425	60%	Yes
69718	Revise temple bone implant	J8	0425	60%	Yes
69930	Implant cochlear device	J8	0259	84%	Yes
G0448	Place perm pacing cardiovert	J8	0108	84%	Yes

TABLE 43.—PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2013 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
C1762	Conn tiss, human(inc fascia)
C1763	Conn tiss, non-human
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)
C1777	Stent, non-coat/cov w/o del
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1781	Mesh (implantable)
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1789	Prosthesis, breast, imp
C1813	Prosthesis, penile, inflatab
C1815	Pros, urinary sph, imp
C1820	Generator, neuro rechg bat sys
C1881	Dialysis access system
C1882	AICD, other than sing/dual
C1891	Infusion pump, non-prog, perm
C1895	Lead, AICD, endo dual coil
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1900	Lead coronary venous
C2618	Probe, cryoablation
C2619	Pmkr, dual, non rate-resp

CY 2012 Device HCPCS Code	CY 2012 Short Descriptor
C2620	Pmkr, single, non rate-resp
C2621	Pmkr, other than sing/dual
C2622	Prosthesis, penile, non-inf
C2626	Infusion pump, non-prog, temp
C2631	Rep dev, urinary, w/o sling
L8600	Implant breast silicone/eq
L8614	Cochlear device/system
L8680	Implt neurostim elctr each
L8685	Implt nrostm pls gen sng rec
L8686	Implt nrostm pls gen sng non
L8687	Implt nrostm pls gen dua rec
L8688	Implt nrostm pls gen dua non
L8690	Aud osseo dev, int/ext comp

e. ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2013

As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68724), we adopted a policy to include in our annual evaluation of the ASC list of covered surgical procedures, a review of the procedures that are being proposed for removal from the OPPS inpatient list for possible inclusion on the ASC list of covered surgical procedures. We evaluated each of the two procedures we are proposing to remove from the OPPS inpatient list for CY 2013 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that these two procedures should continue to be excluded from the ASC list of covered surgical procedures for CY 2013 because they would be expected to pose a significant risk to beneficiary safety

or to require an overnight stay in ASCs. The CPT codes for these two procedures and their long descriptors are listed in Table 44 below.

TABLE 44.—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2013 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2013 OPPS INPATIENT LIST

CPT Code	Long Descriptor
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)

We invite public comments on this proposal.

2. Covered Ancillary Services

Consistent with the established ASC payment system policy, we are proposing to update the ASC list of covered ancillary services to reflect the proposed payment status for the services under the CY 2013 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary items and services because of changes that are being proposed under the OPPS for CY 2013. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2012 may be proposed for packaged status under the CY 2013 OPPS and, therefore, also under the ASC payment system for CY 2013. Comment indicator "CH," discussed in section XII.B. of this proposed rule, is used in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site) to indicate covered ancillary services for which we are proposing a change in the ASC

payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2013.

Except for the Level II HCPCS codes listed in Table 37 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2013 are included in Addendum BB to this proposed rule.

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

1. Proposed Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy for the revised ASC payment system, the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year is used to calculate the national unadjusted payment rates for procedures with payment indicators "G2" and "A2." Payment indicator "A2" was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and were, therefore, subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator "A2" because it is used to identify procedures that are exempted from application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74451), we updated the CY 2011 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2," "G2," and "J8" using CY 2010 data, consistent with the CY 2012 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2012 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the MPFS nonfacility PE RVU-based amount (we refer readers to the CY 2013 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2012 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators "P2," "P3," and "R2") using the most recent available MPFS and OPPS data. We compared the estimated CY 2012 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2012 payment rate for the procedure according to the final policy of the revised ASC payment system (§ 416.171(d)).

b. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2013

We are proposing to update ASC payment rates for CY 2013 using the established rate calculation methodologies under § 416.171. We note that, as discussed in section

II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. We are proposing to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2."

We are proposing that payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") be calculated according to our established policies, incorporating the device-intensive procedure methodology as appropriate. Thus, we are proposing to update the payment amounts for device-intensive procedures based on the CY 2013 OPPS proposal that reflects updated proposed OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the proposed CY 2013 MPFS nonfacility PE RVU-based amount or the proposed CY 2013 ASC payment amount calculated according to the standard ratesetting methodology.

We invite public comment on these proposals.

c. Waiver of Coinsurance and Deductible for Certain Preventive Services

Section 1833(a)(1) and section 1833(b)(1) of the Act waive the coinsurance and the Part B deductible for those preventive services under section 1861(ddd)(3)(A) of the Act as described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population and that are appropriate for the individual. Section 1833(b) of the Act also waives the Part B deductible for colorectal

cancer screening tests that become diagnostic. In the CY 2011 OPPS/ASC final rule with comment period, we finalized our policies with respect to these provisions and identified the ASC covered surgical procedures and covered ancillary services that are preventive services that are recommended by the USPSTF with a grade of A or B for which the coinsurance and the deductible are waived. For a complete discussion of our policies and identified services, we refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72047 through 72049). We are not proposing any changes to our policies or the list of services. We identify these services with a double asterisk in Addenda AA and BB to this proposed rule.

d. Payment for the Cardiac Resynchronization Therapy Composite

Cardiac resynchronization therapy (CRT) uses electronic devices to sequentially pace both sides of the heart to improve its output. CRT utilizes a pacing electrode implanted in combination with either a pacemaker or an implantable cardioverter defibrillator (ICD). CRT performed by the implantation of an ICD along with a pacing electrode is referred to as "CRT–D." In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to establish the CY 2012 ASC payment rate for CRT-D services based on the OPPS payment rate applicable to APC 0108 when procedures described by CPT codes 33225 and 33249 are performed on the same date of service in an ASC. ASCs use the corresponding HCPCS Level II G-code (G0448) for proper reporting when the procedures described by CPT codes 33225 and 33249 are performed on the same date of service. For a complete discussion of our policy regarding payment for CRT-D services in ASCs, we refer readers to the CY 2012 OPPS/ASC final

rule with comment period (76 FR 74427 through 74428). We are not proposing any changes to our current policy regarding ASC payment for CRT-D services for CY 2013.

e. Proposed Payment for Low Dose Rate (LDR) Prostate Brachytherapy Composite

LDR prostate brachytherapy is a treatment for prostate cancer in which hollow needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through the needles/catheters. At least two CPT codes are used to report the treatment service because there are separate codes that describe placement of the needles/catheters and the application of the brachytherapy sources: CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with our without cystoscopy) and CPT code 77778 (Interstitial radiation source application; complex). Generally, the component services represented by both codes are provided in the same operative session on the same date of services to the Medicare beneficiary being treated with LDR brachytherapy for prostate cancer.

As detailed in section II.A.2.e.(2) of this proposed rule, beginning in CY 2008 under the OPPS, we began providing a single payment for LDR prostate brachytherapy when the composite service, reported as CPT codes 55875 and 77778, is furnished in a single hospital encounter. We based the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778 and that do not contain other separately paid codes that are not on the bypass list. We implemented this policy in the OPPS because reliance on single procedure claims to set payment rates for these services resulted in the use of mainly incorrectly coded claims for LDR prostate brachytherapy

because a correctly coded claim should include, for the same date of service, CPT codes for both needle/catheter placement and application of radiation sources, as well as separately coded imaging and radiation therapy planning services (72 FR 66652 through 66655).

Currently under the ASC payment system, ASCs receive separate payment for the component services that comprise the LDR Prostate Brachytherapy Composite when the two services are provided on the same date of service. Specifically, ASCs that report CPT codes 55875 and 77778 on the same date of service receive a payment for CPT code 55875 where the payment rate is based on the OPPS relative payment weight for single procedure claims, and a separate payment for CPT code 77778 where payment is the lower of the rate based on the OPPS relative payment weight for single procedure claims or the MPFS non-facility PE-RVU based amount.

A commenter to the CY 2012 OPPS/ASC proposed rule (76 FR 74429 through 74430) requested that CMS pay for LDR prostate brachytherapy services under the ASC payment system based on the composite OPPS payment rate rather than making two separate payments for the service reported by CPT codes 55875 and 77778. The commenter asserted that basing ASC payments for the services on the composite APC methodology in which one payment is made for the combination of the two services would result in a more accurate payment than is currently being made to ASCs because ASC payment is based on costs from single-service claims that CMS has acknowledged are mostly incorrectly coded claims. We responded that we would take the commenter's request into consideration in future rulemaking, recognizing the lead time that is necessary for the creation of the associated G-code that would be used to identify when

the procedures in the LDR prostate brachytherapy composite are performed on the same date of service in an ASC.

Because we agree that data from OPPS claims reporting both services required for LDR prostate brachytherapy provide the most accurate relative payment weight upon which to base ASC payment for the component services, we are proposing to establish an ASC payment rate that is based on the OPPS relative payment weight applicable to APC 8001 when CPT codes 55875 and 77778 are performed on the same date of service in an ASC. We also are proposing to create a HCPCS Level II G-code so that ASCs can properly report when the procedures described by CPT codes 55875 and 77778 are performed on the same date of service to receive the appropriate LDR Prostate Brachytherapy Composite payment. The payment rate associated with the LDR Prostate Brachytherapy Composite will be temporarily identified by G-code "GXXX1" in Addendum AA of this proposed rule. The permanent G-code that will identify the LDR Prostate Brahytherapy Composite for ASCs will appear in the CY 2013 OPPS/ASC final rule with comment period. When not performed on the same day as the service described by CPT code 55875, the service described by CPT code 77778 will continue to be assigned to APC 0651. When not performed on the same day as the service described by CPT code 77778, the service described by CPT code 55875 will continue to be assigned to APC 0163. We invite public comment on this proposal.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our final payment policies under the revised ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy

under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS. We want to further clarify our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indictor "N1") under the ASC payment system. Thus, we established a final policy to align ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we generally pay for separately payable radiology services at the lower of the MPFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through

78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount, regardless of which is lower. This modification to the ASC payment methodology for ancillary services was finalized in response to a comment on the CY 2011 OPPS/ASC proposed rule that suggested it is inappropriate to use the MPFS-based payment methodology for nuclear medicine procedures because the associated diagnostic radiopharmaceutical, although packaged under the ASC payment system, is separately paid under the MPFS. We set the payment indicator to "Z2" for these nuclear medicine procedures in the ASC setting so that payment for these procedures would be based on the OPPS relative payment weight rather than the MPFS nonfacility PE RVU-based amount to ensure that the ASC will be compensated for the cost associated with the diagnostic radiopharmaceuticals.

In addition, because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430) to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent.

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are

unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Other separately paid covered ancillary services in ASCs, specifically corneal tissue acquisition and device categories with OPPS pass-through status, do not have prospectively established ASC payment rates according to the final policies of the revised ASC payment system (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the revised ASC payment system, corneal tissue acquisition is paid based on the invoiced costs for acquiring the corneal tissue for transplantation. Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system. Currently, the four devices that are eligible for pass-through payment in the OPPS are described by HCPCS code C1749 (Endoscope, retrograde imaging/illumination colonoscope device (Implantable)), HCPCS code C1830 (Powered bone marrow biopsy needle), HCPCS code C1840 (Lens, intraocular (telescopic)), and HCPCS code C1886 (Catheter, extravascular tissue ablation, any modality (insertable)). Payment amounts for HCPCS codes C1749, C1830, C1840, and C1886 under the ASC payment system are contractor priced. In the CY 2012 OPPS/ASC final rule with comment period, we finalized the expiration of pass-through payment for HCPCS code C1749, which will expire after December 31, 2012 (76 FR 74278). Therefore, after December 31, 2012, the HCPCS code C1749 device costs will be packaged into the costs of the procedures with which the devices are reported in the hospital claims data used in the development of the OPPS relative payment weights that will be used to establish ASC payment rates for CY 2013.

b. Proposed Payment for Covered Ancillary Services for CY 2013

For CY 2013, we are proposing to update the ASC payment rates and make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2013 OPPS and ASC payment rates. The proposed CY 2013 OPPS payment methodologies for brachytherapy sources and separately payable drugs and biologicals are discussed in section II.A. and section V.B. of this proposed rule, respectively, and we are proposing to set the CY 2013 ASC payment rates for those services equal to the proposed CY 2013 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2013 payment for separately payable covered radiology services is based on a comparison of the CY 2013 proposed MPFS nonfacility PE RVU-based amounts (we refer readers to the CY 2013 MPFS proposed rule) and the proposed CY 2013 ASC payment rates calculated according to the ASC standard ratesetting methodology and then set at the lower of the two amounts (except as discussed below for nuclear medicine procedures and radiology services that use contrast agents). Alternatively, payment for a radiology service may be packaged into the payment for the ASC covered surgical procedure if the radiology service is packaged or conditionally packaged under the OPPS. The payment indicators in Addendum BB to this proposed rule indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU-based amount or the ASC standard ratesetting methodology, or whether payment for a radiology service is packaged into the payment for the covered surgical procedure (payment indicator "N1"). Radiology services that we are proposing to pay based on the

ASC standard ratesetting methodology are assigned payment indicator "Z2" (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS relative payment weight) and those for which the proposed payment is based on the MPFS nonfacility PE RVU-based amount are assigned payment indicator "Z3" (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

As finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the OPPS relative payment weights rather than the MPFS nonfacility PE RVU-based amount, regardless of which is lower. We are proposing to continue this modification to the payment methodology and, therefore, set the payment indicator to "Z2" for these nuclear medicine procedures in CY 2013. As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), we are proposing that payment indicators for radiology services that use contrast agents will be set to "Z2" in CY 2013 so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent.

Most covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule (which is available via the Internet on the CMS Web site). We invite public comment on these proposals.

E. New Technology Intraocular Lenses (NTIOLs)

1. NTIOL Cycle and Evaluation Criteria

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68176), we finalized our current process for reviewing applications to establish new classes of new technology intraocular lenses (NTIOLs) and for recognizing new candidate intraocular lenses (IOLs) inserted during or subsequent to cataract extraction as belonging to an NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- We announce annually in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

- In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

  - Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments; and

  - Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68227), we finalized our proposal to base our determinations on consideration of the following major criteria set out at 42 CFR 416.195:

- 42 CFR 416.195(a)(1): The IOL is approved by the FDA;
- 42 CFR 416.195(a)(2): Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs are approved by the FDA for use in labeling and advertising;
- 42 CFR 416.195(a)(3): The IOL is not described by an active or expired NTIOL class; that is, it does not share the predominant, class-defining characteristic associated with the improved clinical outcome with designated members of an active or expired NTIOL class; and
- 42 CFR 416.195(a)(4): Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The statute requires us to consider the following improved outcomes:
    - Reduced risk of intraoperative or postoperative complication or trauma;
    - Accelerated postoperative recovery;
    - Reduced induced astigmatism;
    - Improved postoperative visual acuity;
    - More stable postoperative vision; or
    - Other comparable clinical advantages.

Since implementation of the process for adjustment of payment amounts for NTIOLs that was established in the June 16, 1999 **Federal Register**, we have approved three classes of NTIOLs, as shown in the table with the associated qualifying IOL models, at the link entitled "NTOL Application Determination Reference document Updated 01/06/2012," posted on the CMS Web site at:

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html.

2. NTIOL Application Process for Payment Adjustment

For a request to be considered complete, we require submission of the information that is found in the guidance document entitled "Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lens (NTIOL)" posted on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html. For each completed request for a new class that is received by the established deadline, a determination is announced annually in the final rule updating the ASC and OPPS payment rates for the next calendar year.

We also summarize briefly in the final rule the evidence that we reviewed, the public comments we received timely, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. When a new NTIOL class is created, we identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome. The date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class would be set prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

3. Requests to Establish New NTIOL Classes for CY 2013 and Deadline for Public Comments

We received no requests for review to establish a new NTIOL class for CY 2013 by the March 2, 2012 due date (76 FR 74443).

4. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2013.

5. Proposed Revisions to the Major NTIOL Criteria Described in 42 CFR 416.195

The last significant revisions to the regulations containing the substantive NTIOL evaluation criteria under 42 CFR 416.195 occurred in 2007. We are proposing significant revisions to § 416.195(a)(2) and § 416.195(a)(4). We believe that revising § 416.195 is necessary in order to improve the quality of the NTIOL applications. In recent years, we have received low quality NTIOL applications that may have been due in part to overly-broad evaluation criteria.

We are proposing to revise § 416.195(a)(2) to require that the IOL's FDA-approved labeling contains a claim of a specific clinical benefit imparted by a new lens characteristic. The IOL shall have a new lens characteristic in comparison to currently available IOLs. We also are proposing to revise § 416.195(a)(4) to require that any specific clinical benefit referred to in § 416.195(a)(2) must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved

outcome. Improved outcomes include: (i) reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

The proposed revision to § 416.195(a)(2) is necessary because recent NTIOL applications have not included FDA labeling claims of clinical benefit. Instead, the candidate IOLs have, in most cases, had some characteristic for which the applicant has tried to prove clinical relevance through various kinds of evidence that have not been evaluated by the FDA because the evidence is not associated with a labeling claim. The result has been the submission of low quality evidence that has been insufficient for NTIOL status. We believe that the quality of the evidence would improve if applicants were required to obtain a labeling claim for the NTIOL benefit and therefore have the evidence for such benefit evaluated by FDA. We believe that this proposed approach would better serve CMS, FDA, and the applicants because any ultimate grant of NTIOL status would be supported by a labeling claim. The manufacturer could then advertise the NTIOL benefit without running afoul of FDA advertising limitations. We would have the benefit of an FDA review of the relevant evidence, which would be particularly valuable because the FDA has a dedicated team of scientists, physicians, and engineers who are experts in evaluating IOLs.

The proposed revision to § 416.195(a)(4) is necessary to insure that the claim is clinically relevant and represents an improved outcome for Medicare beneficiaries. We request public comments on these proposed revisions to the NTIOL regulations.

6. Request for Public Comment on the "Other Comparable Clinical Advantages" Improved Outcome

Section 416.195(a)(4)), discussed above, lists the following improved outcomes: (i) reduced risk of intraoperative or postoperative complication or trauma; (ii) accelerated postoperative recovery; (iii) reduced induced astigmatism; (iv) improved postoperative visual acuity; (v) more stable postoperative vision; and (vi) other comparable clinical advantages.

This list is from the original 1994 NTIOL statutory provision. Because this provision is almost 20 years old, outcomes (i) through (v) have only limited relevance to modern cataract surgery. For example, regarding outcome (i), it is unclear what, if any, type of IOL could reduce the risk of complication or trauma associated with cataract surgery, or what, if any, contemporary cataract surgery complication could be affected by a new type of IOL. As for outcome (ii), postoperative recovery is already rapid in uncomplicated cataract surgery; therefore, it is difficult to see how it could be significantly accelerated. Also, regarding outcome (iii), clinically significant induced astigmatism would be reflective of poor surgical technique and would not depend upon IOL design. Regarding outcome (iv), currently available IOLs provide such high quality postoperative visual acuity that it would be difficult to measure clinically significant improved postoperative visual acuity due to a new type of IOL. Finally, for outcome (v), postoperative vision is typically stable after uncomplicated cataract surgery, so again it would be difficult to improve upon this outcome.

The last of the listed improved outcomes is the nonspecific category described as "other comparable clinical advantages." Given that present-day cataract surgery is such a

successful procedure that results in significantly improved vision for almost all patients who undergo the procedure and who are appropriate candidates for cataract surgery, we are soliciting comments on what potential benefits associated with a new IOL could be considered to be a "comparable clinical advantage" as compared to the list of the five improved outcomes from the statute and regulation described above.

F. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we also created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC list of covered services prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the

status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NI" is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NI" is also assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2013 OPPS/ASC final rule with comment period, we will respond to public comments and finalize the ASC treatment of all codes that are labeled with comment indicator "NI" in Addenda AA and BB to the CY 2012 OPPS/ASC final rule with comment period. These addenda can be found in a file labeled "January 2012 ASC Approved HCPCS Code and Payment Rates" in the ASC Addenda Update section of the CMS Web site.

The "CH" comment indicator is used in Addenda AA and BB to this CY 2013 OPPS/ASC proposed rule (which are available via the Internet on the CMS Web site) to indicate that the payment indicator assignment has changed for an active HCPCS code; an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The "CH" comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. Proposed ASC Payment and Comment Indicators

We are not proposing any changes to the definitions of the ASC payment and comment indicators for CY 2013. We refer readers to Addenda DD1 and DD2 to this

proposed rule (which are available via the Internet on the CMS Web site) for the complete list of ASC payment and comment indicators proposed for the CY 2013 update.

G. ASC Policy and Payment Recommendations

MedPAC was established under section 1805 of the Act to advise Congress on issues affecting the Medicare program. Subparagraphs (C) and (D) of section 1805(b)(1) of the Act require MedPAC to submit reports to Congress not later than March 15 and June 15 of each year that present its Medicare payment policy reviews and recommendations and its examination of issues affecting the Medicare program, respectively. The March 2012 MedPAC "Report to the Congress: Medicare Payment Policy" included the following recommendations relating specifically to the ASC payment system for CY 2013:

Recommendation 5-1: "The Congress should update the payment rates for ambulatory surgical centers by 0.5 percent for calendar year 2013. The Congress should also require ambulatory surgical centers to submit cost data."

Regarding the ASC payment update for CY 2013, MedPAC further stated that: "On the basis of our payment adequacy indicators, the lack of ASC cost data, and our concerns about the potential effect of ASC growth on overall program spending, we believe a moderate update of 0.5 percent is warranted for CY 2013." With regard to the collection of cost data, MedPAC indicated that cost data are needed to fully assess ASC payment adequacy under the revised ASC payment system and to examine whether an alternative input price index would be an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed to annually update ASC payment rates.

CMS Response: We note that MedPAC's recommendation is for the Congress to increase ASC payment rates by 0.5 percent in CY 2013 and require ASCs to submit cost data. Congress has not acted on these recommendations. We are proposing to continue our current policy to update the ASC conversion factor using the CPI-U, and we are not proposing to require ASC to submit cost data in this proposed rule. However, as discussed in section XIV.H.2.b. of this proposed rule, the CPI-U may not be the best measure of inflation for the goods and services provided by ASCs and, therefore, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs that would assist us in determining possible alternatives to using the CPI-U to update ASC payment rates for inflation.

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

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion

factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533).

We note that we consider the term "expenditures" in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the

CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIV.D.2.b. of this proposed rule) the established policy is to set the payment rate at the lower of the MPFS unadjusted non-facility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage indices to the labor-related share, which is 50 percent of the ASC payment amount. Beginning in CY 2008, CMS accounted for geographic wage variation in labor cost when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available raw pre-floor and pre-reclassified hospital wage indices results in the most appropriate adjustment to the labor portion of ASC costs. In addition, use of the unadjusted hospital wage data avoids further reductions in certain rural statewide wage index values that result from

reclassification. We continue to believe that the unadjusted hospital wage indices, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs.

We note that in certain instances there might be urban or rural areas for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indices for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where "contiguous" is defined as sharing a border). We have applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 Hinesville-Fort Stewart, GA, and CBSA 22 Rural Massachusetts.

In CY 2011, we identified another area, specifically, CBSA 11340 Anderson, SC for which there is no IPPS hospital whose wage index data would be used to set the wage index for that area. Generally, we would use the methodology described above; however, in this situation, all of the areas contiguous to CBSA 11340 Anderson, SC are rural. Therefore, in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72058 through 72059), we finalized our proposal to set the ASC wage index by calculating the average of all wage indices for urban areas in the State when all contiguous areas to a CBSA are rural and there is no IPPS hospital whose wage index data could be used to set the wage index for that area. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we will continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indices for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Proposed Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2013 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and MPFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). We note that, as discussed in section II.A.2.f. of this proposed rule, because we are proposing to base the OPPS relative payment weights on geometric mean costs for CY 2013, the ASC system would shift to the use of geometric means to determine relative payment weights under the ASC standard ratesetting methodology. Consistent with our established policy, we are proposing to scale the CY 2013 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2011, we are proposing to compare the total payment using the CY 2012 ASC relative payment weights with the total payment using the CY 2013 relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2012 and CY 2013. We would use the ratio of CY 2012 to CY 2013 total payment (the weight scaler) to scale the ASC relative payment weights for CY 2013. The proposed CY 2013 ASC scaler is 0.9331 and scaling would apply to the ASC relative payment weights of the covered surgical procedures and covered ancillary radiology services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights),

such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We currently have available 98 percent of CY 2011 ASC claims data.

To create an analytic file to support calculation of the weight scaler and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2011 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2011 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to

the conversion factor. Consistent with our final ASC payment policy, for the CY 2013 ASC payment system, we are proposing to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2013, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2011 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2011 ASC utilization and service-mix and the proposed CY 2013 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2012 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2012 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2013 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0002 (the proposed CY 2013 ASC wage index budget neutrality adjustment) to the CY 2012 ASC conversion factor to calculate the proposed CY 2013 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, "if the Secretary has not updated amounts established" under the revised ASC payment system in a calendar year, the payment amounts "shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the

12-month period ending with the midpoint of the year involved." The statute, therefore, does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years. Therefore, the annual update to the ASC payment system is the CPI-U (referred to as the CPI-U update factor).

ASC stakeholders, as well as MedPAC, have commented throughout the years that the CPI-U may not adequately measure inflation for the goods and services provided by ASCs (see, for example, 76 FR 74444, 74448 through 74450; 73 FR 68757; and 72 FR 66859). While we believe the CPI-U is appropriate to apply to update the ASC payment system, the CPI-U is highly weighted for housing and transportation and may not best reflect inflation in the cost of providing ASC services. In developing this proposed rule, we considered possible alternatives to using the CPI-U to update ASC payment rates for inflation.

ASC stakeholders have urged us to adopt the hospital market basket to update ASC payment rates for inflation when commenting on each proposed rule since the beginning of the revised ASC payment system (72 FR 66859; 73 FR 68757; 74 FR 60628 through 60629; 75 FR 72063; 76 FR 74449). We considered the hospital market basket as an alternative to the CPI-U and, while the items included in the hospital market basket seem reflective of the kinds of costs incurred by ASCs, as stated in the CY 2012 OPPS/ASC final rule with comment period, we believe that the hospital market basket does not align with the cost structures of ASCs. A much wider range of services, such as

room and board and emergency services, are provided by hospitals but are not costs associated with providing services in ASCs (76 FR 74450). As other possible alternatives to the CPI-U update, we considered using the physician's practice expense (PE) component of the Medicare Economic Index (MEI) update, as well as using an average of the hospital market basket update and the PE component of the MEI update. However, until we have more information regarding the cost inputs of ASCs, we are not confident that any of these alternatives are a better proxy for ASC costs than the CPI-U. Therefore, we are proposing a continuation of the established policy of basing the ASC update on the CPI-U. In addition, we are seeking public comment on the type of cost information that would be feasible to collect from ASCs in the future in order to determine if one of these alternative updates or an ASC-specific market basket would be a better proxy for ASC cost inflation than the CPI-U.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v) which requires that "any annual update under [the ASC payment] system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)" of the Act effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). Clause (iv) authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) states that application of the MFP adjustment to the ASC

payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASCQR Program. Section XVI.D. of this proposed rule provides a discussion of the proposed payment reduction to the annual update for ASCs that fail to meet the ASCQR Program requirements. In summary, we are proposing to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements. The reduced rates would apply beginning in CY 2014. We are proposing that application of the 2.0 percentage point reduction to the annual update factor, which currently is the CPI-U, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We are proposing changes to §§ 416.160(a)(1) and 416.171 to reflect this proposal.

In accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determines the "percentage increase" in the CPI-U, which we interpret cannot be a negative number. Thus, in the instance where the percentage change in the CPI-U for a year is negative, we would hold the CPI-U update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent payment determination years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality

information under the rules established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction by the MFP adjustment, and states that application of the MFP adjustment may reduce this percentage change below zero. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. Illustrative examples of how the MFP adjustment would be applied to the ASC payment system update are found in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064).

For this proposed rule, for the 12-month period ending with the midpoint of CY 2013, the CPI-U update is projected to be 2.2 percent. Because the ASCQR Program does not affect payment rates until CY 2014, there would be no quality reporting reduction to the CPI-U for CY 2013. The MFP adjustment for the period ending with the midpoint of CY 2013 is projected to be 0.9 percent based on the methodology for calculating the MFP adjustment finalized in the CY 2011 MPFS final rule with comment period (75 FR 73394 through 73396) as revised in the CY 2012 MPFS final rule with comment period (76 FR 73300 through 73301). We are proposing to reduce the CPI-U update of 2.2 percent by the MFP adjustment of 0.9 percent, resulting in an MFP-adjusted CPI-U update factor of 1.3 percent. Therefore, we are proposing to apply a 1.3 percent MFP-adjusted CPI-U update factor to the CY 2012 ASC conversion factor.

For CY 2013, we also are proposing to adjust the CY 2012 ASC conversion factor ($42.627) by the wage adjustment for budget neutrality of 1.0002 in addition to the MFP-adjusted update factor of 1.3 percent discussed above, which results in a proposed CY 2013 ASC conversion factor of $43.190.

We invite public comment on these proposals.

3. Display of Proposed CY 2013 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available via the Internet on the CMS Web site) display the proposed updated ASC payment rates for CY 2013 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2013 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "Subject to Multiple Procedure Discounting" indicates that the surgical procedure will be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session. Display of the comment indicator "CH" in the column titled "Comment Indicator" indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2012. Display of the comment indicator "NI" in the column titled "Comment Indicator" indicates that the code is new (or substantially

revised) and that the payment indicator assignment is an interim assignment that is open to comment on the final rule with comment period.

The values displayed in the column titled "CY 2013 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2013. The payment weights for all covered surgical procedures and covered ancillary services whose ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Thus, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the proposed CY 2013 payment rate displayed in the "CY 2013 Payment" column, each ASC payment weight in the "CY 2013 Payment Weight" column was multiplied by the proposed CY 2013 conversion factor of $43.190. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XV.H.2.b. of this proposed rule).

In Addendum BB, there are no relative payment weights displayed in the "CY 2013 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "CY 2013 Payment" column displays the proposed CY 2013 national unadjusted ASC payment rates for all items and services. The proposed CY 2013 ASC payment rates listed in Addendum BB

for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in April 2012.

XV. Hospital Outpatient Quality Reporting Program Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (Hospital OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the quality data reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (Hospital IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). Both of these quality reporting programs for hospital services have financial incentives for the reporting of quality data to CMS.

CMS also has implemented quality reporting programs for long term care hospitals, inpatient rehabilitation hospitals, the hospice program, ambulatory surgical centers (the Ambulatory Surgical Center Quality Reporting (ASCQR) Program), as well as a program for physicians and other eligible professionals, known as the Physician Quality Reporting System (PQRS) (formerly known as the Physician Quality Reporting Initiative (PQRI)). CMS has recently proposed to implement quality reporting programs for inpatient psychiatric facilities and PPS-exempt cancer hospitals.