The Centers for Medicare and Medicaid Services (CMS) Calendar Year (CY) 2020 Outpatient Prospective Payment System (OPPS) and ASC Payment System

CY 2020 OPPS: Price Transparency Requirements for Hospitals to Make Standard Charges Public

A SIDE-BY-SIDE COMPARISON OF KEY PROVISIONS FROM THE PROPOSED AND FINAL RULES FOR CY 2020

HHS | Hart Health Strategies Inc.

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Overview

On November 1, 2019 the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2020 Hospital Outpatient Payment System (OPPS) and ASC Payment System final rule with comment period. In general, this final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2020 based on CMS' continuing experience with these systems. In this rule, CMS describes the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system; updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR); establishes a process and requirements for prior authorization for certain covered outpatient department services; revises the conditions for coverage of organ procurement organizations; revises the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status; and provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education (IME) and direct graduate medical education (DGME) payments.

Unless otherwise noted, these regulations are effective on January 1, 2020. According to CMS, comments will be considered through December 2, 2019 on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in this final rule with comment period.

In addition, on November 15, 2019, CMS finalized policies that follow directives in President Trump's Executive Order, entitled "Improving Price and Quality Transparency in American Healthcare to Put Patients First." This final rule, Price Transparency Requirements for Hospitals to Make Standard Charges Public, establishes requirements for hospitals operating in the United States to establish, update, and make public a list of their standard charges for the items and services that they provide. These requirements go into effect on January 1, 2021.

Hart Health Strategies, Inc. has prepared the below "side-by-side" comparison of the proposed and final provisions, including regulatory impact and information collection requirements where pertinent, all with the goal of helping organizations better understand how CMS modified its proposals in response to stakeholder feedback. Page numbers and hyperlinks throughout the summary refer to the public display version of the final rule, which has been posted to our website. A table of contents is also provided to help you more easily navigate the summary. To go directly to a specific section of the rule, please click on the page number listed in the table of contents. To return to the table of contents, use the "Back to Table of Contents" link in the footer of each page.

OPPS Payment Updates (p. 35)

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Recalibration of APC Relative Payment Weights (p. 35)		
Comprehensive APCs	In CY 2015, CMS implemented several new Comprehensive APCs, which included the final transition of all Device-Dependent APCs to Comprehensive APCs. For Comprehensive APCs, there is a single payment for the stay regardless of the length of the beneficiary's hospital outpatient stay. The packaging formula goes beyond what is typically packaged in an APC payment and includes payment for all services that are ancillary, supportive, dependent, and adjunctive to the primary service (to which CMS collectively refers as "adjunctive services"). By CY 2019, CMS had finalized 65 Comprehensive APCs. Payment for Comprehensive APCs does not include payment for non-OPPS charges or services that, because of statute, must be paid separately. These services include mammography and ambulance services; brachytherapy seeds; pass-through drugs and devices; and self-administered (non-Part B) drugs. CMS also excludes certain preventive services from the packaged payment. CMS lists the C-APC excluded services on its website in Addendum J. CMS made several other statements regarding its Comprehensive APC payment policy.	
	Complexity Adjustments. CMS will allow for certain add-on codes (those that had previously been assigned to Device-dependent APCs) to qualify for a "complexity adjustment." For those primary service and add-on code combinations that are determined to be sufficiently frequent and sufficiently costly, CMS believes that a payment adjustment is warranted. CMS applies the complexity adjustment when the code pairing represents "a complex, costly form or version of the primary service" according to the following criteria: ○ Frequency of 25 or more claims reporting the code combination (frequency threshold); and ○ Violation of the 2 times rule in the originating Comprehensive APC (cost threshold). If the criteria are met, CMS makes a "complexity adjustment" for the code combination by reassigning the primary services with the add-on code to the next higher cost Comprehensive APC within the same	The list of add-on codes eligible for the complexity adjustment can be found in Addendum J available on the CMS Web site. CMS acknowledged that it received comments that would allow for a complexity adjustment for "a cluster of procedures" (e.g. J1 code pair with associated add-on codes) (p. 77). CMS stated that it does not believe that changes to the complexity adjustment methodology are necessary at this time (p. 78).

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	clinical family of Comprehensive APCs (unless the primary service is already assigned to the highest cost APC in the clinical family.	
	CY 2020 Comprehensive APCs. CMS proposed continuing the Comprehensive APC payment methodology implemented in CY 2015.	***CMS finalized continuation of the Comprehensive APC policy as proposed*** (p. 80).
	CMS proposed two (2) additional Comprehensive APCs for CY 2020: • C-APC 5182 (Level 2 Vascular Procedures) • C-APC 5461 (Level 1 Neurostimulator and Related Products)	***CMS finalized the CY 2020 Comprehensive APCs as proposed*** (p. 89).
	CMS also mentions that elsewhere in the rule it is considering developing an episode-of-care for skin substitutes and seeks comment on a future Comprehensive APC for procedures using skin substitute products furnished in the HOPD.	CMS directs readers to the section dedicated to reimbursements for Skin Substitutes. Additional Comments: • CMS also acknowledged a request to develop a new Comprehensive APC for autologous hematopoietic stem cell transplant but declined to do so at this time (p. 82). • CMS received a request to discontinue the Comprehensive APC for procedures involving drugs used in ocular procedures but declined to do so (p. 83). • CMS received a request to discontinue the Comprehensive APC for single session stereotactic radiosurgery (SRS) procedures but declined to do so, but noted that it already pays separately for the related planning and preparation codes (p. 85). • CMS received a request to discontinue the Comprehensive APC for all surgical insertion codes required for brachytherapy treatment but declined to make changes (p. 86). • In response to a request for clarification, CMS reiterated its previously finalized policies regarding the Comprehensive APC for Comprehensive Observation Services (p. 87).
	Comprehensive APC Exclusion of Procedures Assigned to New Technology APCs. CMS stated that services that are assigned to New Technology APCs do not typically have sufficient claims history on which to set accurate payment. CMS noted, however, that when a procedure assigned to a New Technology APC is on a claim that also includes a primary procedure, the new technology service is typically packaged into the payment for the primary procedure. Given that the new technology is not separately paid, the number of claims available	***CMS modified its previous policy so that, in addition to excluding payment for any procedure that is assigned to a New Technology APM from being packaged when included on a claim with a "J1" (primary comprehensive APC service), CMS will exclude payment for any procedures that are assigned to a New Technology APC from being packaged into the payment for comprehensive observation services (assigned a "J2" status indicator)*** (p. 95).

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	for future price determination for the new technology is reduced, which is contrary to New Technology APC payment policy, "which is to gather sufficient claims data to enable [CMS] to assign the service to an appropriate clinical APC." Therefore, in CY 2019, CMS began excluding payment for any procedure from being packaged into a Comprehensive APC when that procedure is assigned to a New Technology APC (APCs 1491 – 1599; 1901 – 1908). CMS then received comments regarding whether the policy applied to "comprehensive observation services." For CY 2020, CMS proposed that payment for services assigned to a New Technology APC on a claim for Comprehensive Observation Services ("J2" indicator) will be packaged into the payment for the comprehensive service; however, CMS sought comment on whether it would be clinically appropriate to exclude payment for any New Technology APCs from being packaged into the comprehensive "J2" service.	
Composite APCs	CMS has had a policy since 2008 for Composite APCs which provide a "single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service."	
	CMS proposed continuing its Composite APC policy for APC 9010 (*Mental health services)*.	***CMS finalized as proposed*** (p. 99).
	CMS proposed continuing its Composite APC policy for APCs 8004, 8005, 8006, 8007, and 8008 (*Multiple imaging services)*.	***CMS finalized as proposed*** (p. 102).
Packaged Items and Services	**General**. CMS has relied on packaging policies in the OPPS to "maximize hospitals' incentives to provide care in the most efficient manner." CMS proposed to generally maintain its packaging policies.	○ CMS received requests to separately pay for Cysview ® when used with blue light cystoscopy (both in the HOPD and ASC settings), which CMS declined to do (p. 111). ○ CMS received a request to eliminate its packaging policy for "drugs that function as a supply when used in a diagnostic test or procedure," which CMS declined to do (p. 111). ○ CMS received a request to make separate payment for add-on codes for Fractional Flow Reserve Studies (FFR/iFR) and Intravascular Ultrasound (IVUS), which CMS declined to do (p. 113)
	Non-Opioid Pain Management Treatments. CMS proposed to continue its policy to pay separately (ASP +6%) for non-opioid pain management drugs that functions as surgical supplies in the ASC setting (but continue packaging in the OPPS setting).	***CMS finalized this policy as proposed*** (p. 126). CMS noted that it received several comments requesting that separate payment also be made in the OPPS setting but that it did not find the evidence compelling (p. 124).

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	CMS stated that it does not believe that there are changes needed to its packaging policies under the OPPS for drugs that functions as a surgical supply, nerve blocks, surgical injections, and neuromodulation products at this time, but requested public comments to support whether other products help deter or avoid opioid use and addiction with evidence that the packaging policies present a barrier to access to that care.	CMS stated that it did not believe that separate payment was warranted for any of the products on which it listed in the proposed rule (or any others) (p. 135). CMS stated that it received many comments requesting separate payment for continuous peripheral nerve blocks "as the commenters believed they significantly reduce opioid use (p. 131). While CMS acknowledged that use of these items may help reduce opioid use, it did not believe data suggested that the current packaging policy was a barrier to its use; however, CMS stated that it will continue to consider this for future rulemaking (p. 132). CMS also received comments on the follow products: • Prialt *(HCPCS J2278, injection, ziconitide)* (p. 127) • Omidria (*HCPCS C9447, injection, phenylephrine ketorolac*) (p. 128). • MKO Melt (non-FDA approved compounded drug comprised of midazolam/ketamine/ondansetron) (p. 130).
OPPS Conversion Factor Update (p. 142)		
	CMS proposed to increase the CY 2020 OPPS conversion factor to $81.398. This is premised on a general overall increase of 2.7 percent. The overall increase (before budget neutrality adjustments) is based on the proposed hospital inpatient market basket increase of 3.2 percent minus a productivity adjustment of 0.5 percent. CMS proposed that if more recent data becomes available, it will use the updated data to alter the conversion factor in the OPPS final rule with comment period. In total, CMS estimated that CY 2020 OPPS payments will increase by approximately $5.0 billion over CY 2019 estimated payments to a total of approximately $80 billion. In addition, CMS proposed continuing to reduce payments by 2.0 percent for hospitals that fail to meet the outpatient quality reporting requirements.	***CMS finalized continuation of its conversion factor calculation methodology*** (p. 149). ***CMS finalized a CY 2020 OPPS conversion factor of $80.784 (less than the estimate in the proposed rule of $81.398)*** (p. 150). ***This is based on a finalized overall increase of 2.6 percent. The overall increase (before budget neutrality adjustments) is based on the final estimate of the hospital inpatient market basket increase of 3.0 percent minus a productivity adjustment of 0.4 percent*** (p. 150).
OPPS Payments to Certain Cancer Hospitals (p. 175)		
	CMS proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final payment-to-cost ratio (PCR) is equal to the weighted average PCR/target PCR for the other OPPS hospitals using the most recent submitted or settled cost report data that are available reduced by 1 percentage point but did not propose an additional reduction beyond the 1 percentage point.	***CMS finalized without modification*** (p. 180).

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	CMS proposed that the payment amount associated with the cancer hospital payment adjustment is a proposed target PCR of 0.89 percent for each cancer hospital.	***CMS finalized a PCR of 0.89 percent for each cancer hospital as proposed*** (p. 181).
Hospital Outpatient Outlier Payments (p. 182)		
	CMS proposed to continue its policy of estimating aggregate outlier payments at 1 percent of total payments under the OPPS.	***CMS finalized as proposed*** (p. 187).
	CMS proposed maintaining the percentage threshold for outlier payments at 1.75 times the APC payment amount; CMS proposed increasing the dollar amount threshold to $4,950.	Using updated data, ***CMS finalized maintaining the percentage threshold for outlier payments at 1.75 times the APC payment amount; however, CMS finalized a further increase of the dollar amount threshold to $5,075*** (p. 188).
OPPS APC Group Policies (p. 200)		
Treatment of New and Revised HCPCS Codes (CPT and Level II)	Upon creation of new Level II HCPCS codes, CMS will assign the new codes to an interim status indicator and APC assignment through the quarterly update process and will finalize the policies in the OPPS/ASC final rule. CMS sought comment on the APC assignments and status indicators for the following categories of codes:	
	• CMS stated that for the April 2019 update there were no new CPT codes. However, CMS introduced 8 new Level II HCPCS codes which were effective April 1, 2019.	***CMS stated that it received no comments and finalized as listed in Table 8*** (p. 203).
	• New HCPCS Codes Implemented in July 2019.	***CMS finalized as listed in Table 9.*** Final payment rates can be found in Addendum B (p. 205).
	• New HCPCS Codes effective on October 1, 2019. CMS proposed to continue its policy of assigning these new codes an interim payment status of "NI"	COMMENT: ***CMS assigned interim payment status to these codes as found in Addendum B and notes that they are open for comment*** (CMS includes the timetable in Table 10); CMS will respond in CY 2021 rulemaking (p. 213).
	• New and Revised HCPCS Codes Effective January 1, 2020: ("NP" comment indicator to indicate that the code is new for the next calendar year *or* it is an existing code that underwent a substantial revision to its code descriptor in the next calendar year (compared to the current calendar year))	COMMENT: ***CMS assigned interim payment status to these in Addendum B and notes that they are open for comment*** (p. 218).
Variation Within APCs	According to statute, the services within an APC cannot be considered "comparable" if the highest cost service in the APC is more than 2 times greater than the lowest costs for an item or service within the same APC ("2 Times Rule"). CMS often makes exceptions when the 2	***CMS finalized its proposal to except 16 of the 18 violations of the 2 times rule for CY 2020 plus an additional exception (APC 5593 (Level 3 Nuclear Medicine and Related Services) not included in the proposed***

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	Times Rule has been violated, typically in cases of low-volume items or services (although the statute prohibits the Secretary may not make an exception for orphan drugs). CMS identified 18 violations of the 2 Times Rule for CY 2020, and CMS determined that all 18 violations qualified for an exception.	***rule*** (p. 226). The 17 APCs excepted finalized for CY 2020 can be found in Table 11.
New Technology APCs	**Establishing Payment Rates for Low-Volume New Technology Procedures.** CMS is proposing to continue to apply the policy adopted in CY 2019 under which CMS will calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC.	**Establishing Payment Rates for Low-Volume New Technology Procedures. (p. 230)** ***CMS is finalizing this proposal without modification.***
	Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414). As shown in Table 11, CMS is proposing to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with status indicator "J1" (Hospital Part B services paid through a comprehensive APC). In addition, CMS is proposing to continue to assign the services described by HCPCS C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5115 (Level 5 Musculoskeletal Procedures), with status indicator "J1". CMS is proposing to estimate the cost for the procedure by applying the median cost and assigning the procedure to APC 1575 (New Technology - Level 38 ($10,001-$15,000)), with a proposed payment rate of $12,500.50 for CY 2020, which would reflect no change from CY 2019.	**Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414). (p. 235)** ***CMS is finalizing its proposal to continue to assign CPT codes 0071T and 0072T to APC 5414, without modification.*** ***CMS is finalizing its proposal for the APC assignment of CPT code 0398T***. Specifically, CMS is continuing to assign this code to New Technology APC 1575 (New Technology—Level 38 ($10,001– $15,000)), with a payment rate of $12,500.50, for CY 2020 through use of the low-volume payment policy for new technology procedures.
	Retinal Prosthesis Implant Procedure. CMS is proposing to maintain the assignment of the procedure described by CPT 0100T in APC 1908 (New Technology - Level 52 ($145,001-$160,000)), with a proposed payment rate of $152,500.50 for CY 2020. Additionally, CMS previously found that payment for the Argus® II procedure was sometimes bundled into the payment for another procedure, and therefore, CMS is proposing to continue the policy implemented in CY 2019 based on this finding to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C-APC. While CMS is	**Retinal Prosthesis Implant Procedure. (p. 243)** ***CMS is finalizing its proposal to maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology - Level 52 ($145,001-$160,000)), with a payment rate of $152,500.50 for CY 2020.*** For CY 2020 and subsequent years, CMS is modifying its policy for excluding procedures assigned to New Technology APCs from the C-APC policy. That is, CMS is finalizing its proposal to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" service assigned to a C-APC. For CY 2020 and subsequent years, CMS is also finalizing a policy to

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	not proposing to exclude payment for a procedure assigned to a New Technology APC from being packaged when included on a claim with a service assigned to status indicator "J2," CMS is seeking public comments on this issue.	exclude payment for any procedures that are assigned to a New Technology APC from being packaged into the payment for comprehensive observation services assigned to status indicator "J2" when they are included on a claim with "J2" procedures.
	Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy. CMS is proposing to continue to assign the procedure described by HCPCS C9751 to New Technology APC 1571 (New Technology - Level 34 ($8,001-$8,500)), with a proposed payment rate of $8,250.50 for CY 2020.	**Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy. (p. 252)** ***CMS is finalizing its proposal to assign HCPCS code C9751 to New Technology APC 1571 (New Technology - Level 34 ($8,001-$8,500)), with a payment rate of $8,250.50 for CY 2020.***
	Pathogen Test for Platelets. CMS proposes reassigning the service described by HCPCS P9100 to New Technology APC 1494 (New Technology - Level 1D ($31-$40)), with a proposed payment rate of $35.50.	**Pathogen Test for Platelets. (p. 253)** ***CMS is finalizing its proposal to assign HCPCS code P9100 to New Technology APC 1494 (New Technology - Level 1D ($31- $40)), with a payment rate of $35.50.***
	Fractional Flow Reserve Derived From Computed Tomography CMS proposes reassignment of the service described by CPT 0503T to New Technology APC 1509 (New Technology - Level 9 ($701 - $800)), with a proposed payment rate of $750.50 for CY 2020.	**Fractional Flow Reserve Derived From Computed Tomography (p. 255)** CMS is utilizing its new technology low-volume payment policy to set the payment rate for the HeartFlow service CPT code 0503T based on the arithmetic mean for the procedure. Specifically, ***CMS is assigning CPT code 0503T to New Technology APC 1511 (New Technology - Level 11 ($901 - $1000)) with a payment rate of $950.50***.
APC-Specific Policies	CMS proposed several APC-specific policies.	***CMS finalized APC-specific policies in the following areas:*** • Barostim Neo™ System (APC 5464) (p. 265) • Biomechanical Computed Tomography (BCT) Analysis (APCs 5521, 5523, 5731) (p. 267) • Cardiac Magnetic Resonance (CMR) Imaging (APC 5572) (p. 269) • CardioFlux™ Magnetocardiography (MCG) Myocardial Imagine (APC 5723) (p. 274) • Cataract Removal with Endoscopic Cyclophotocoagulation (ECP) (APC 5492) (p. 278) • Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, 9194) (p. 281) • Colonoscopy and Sigmoidoscopy with Endoscopic Mucosal Resection (EMR) (APC 5313) (p. 288) • Coronary Computed Tomographic Angiography (CCTA) (APC 5571) (p. 290) • Deep Brain Stimulation (DBS) Programming (APC 5742) (p. 296) • Extracorporeal Shock Wave Lithotripsy (ESWL) (APC 5374) (p. 300) • Extravascular Implantable Cardioverter Defibrillator (EV ICD) (p. 307)

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		• Genicular and Sacroiliac Joint Nerve Injections/Procedures (APCs 5442 and 5431) (p. 310) • FemBlock® and FemChec® (p. 314) • Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194) (p. 316) • Hemodialysis Duplex Studies (APCs 5522 and 5523) (p. 321) • Intraocular Procedures (APCS 5491 through 5494) (p. 323) • Long-Term Electroencephalogram (EEG) Monitoring Services (APCs 5722, 5723, and 5724) (p. 326) • Musculoskeletal Procedures (APCs 5111 through 5116) (p. 330) • Nuclear Medicine Services (p. 334) • Radiofrequency Spectroscopy (p. 345) • Reflectance Confocal Microscopy (RCM) (p. 350) • remedē® System – Transvenous Phrenic Nerve Stimulation Therapy (APCs 5461 – 5464, 5724, and 5742) (p. 353) • Surgical Pathology Tissue Exam (APC 5673) (p. 357) • Urology Procedures (p. 358)
OPPS Payment for Devices (p. 373)		
Pass-Through Payments for Devices	**RFI on OPPS Device Pass-Through Substantial Clinical Improvement Criterion.** As CMS did in the FY 2020 Inpatient Prospective Payment System (IPPS) proposed rule in reference to IPPS New Technology Add On Payments, CMS discussed feedback from applicants on payments for new technology, here for device pass through payments, and have indicated that it would be helpful for CMS to provide greater guidance on what constitutes "substantial clinical improvement." CMS also referenced the specific questions on which it requested input in the FY 2020 IPPS proposed rule and continues to seek input in the context of the OPPS.	**RFI on OPPS Device Pass-Through Substantial Clinical Improvement Criterion. (p. 461)** CMS received only one comment on this particular RFI, requesting that CMS demonstrate greater flexibility in determining what constitutes substantial clinical improvement. CMS notes that it accepts a wide range of data and other evidence. Note that CMS also solicited comments in the FY 2020 IPPS proposed rule on specific changes to the IPPS and OPPS substantial clinical improvement criterion.
	Proposed Alternative Pathway to Device Pass-Through Substantial Clinical Improvement Criterion for "Transformative New Devices." CMS proposes an alternative outpatient pass-through pathway. CMS proposes that, for applications received for pass through payments beginning on or after January 1, 2020, if a medical device is part of the FDA's Breakthrough Devices Program and received FDA marketing authorization, it would not be evaluated in terms of the current substantial clinical improvement criterion (although would need to meet the other criterion for pass-through status).	**Proposed Alternative Pathway to Device Pass-Through Substantial Clinical Improvement Criterion for "Transformative New Devices." (p. 463)** MedPAC opposed this proposal, but most other commenters expressed support. ***CMS is finalizing its proposal*** to establish an alternative pathway to the substantial clinical improvement criterion for devices with FDA Breakthrough designation that have received FDA marketing authorization. The alternative pathway will apply to devices that will receive pass-through payments effective on or after January 1, 2020.

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		There are two devices that meet the criteria for the new pathway: Optimizer® System and ARTIFICIALIris®.
Device-Intensive Procedures	For CY 2020, CMS does not propose any changes to its device-intensive policy.	No changes to existing policy.
	Proposed Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices. CMS propose to continue to apply its no cost/full credit and partial credit policies without modification.	No changes to existing policy.
	Low Volume Device Intensive Procedures. CMS proposes to continue with its current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For CY 2020, CMS has identified that this policy would apply to CPT 0308T (Insertion of ocular telescope including removal of crystalline lens or intraocular lens prosthesis) (which CMS proposes to assign to APC 5495 (Level 5 Intraocular Procedures); based on its low volume device policy, CMS proposes a payment rate of $19,740 (the mean cost).	**Low Volume Device Intensive Procedures. (p. 486)** ***CMS is finalizing this proposal.***
OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals (p. 488)		
OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals	**Drugs and Biologicals with Expiring Pass-Through Status** CMS proposes that the pass-through payment status of six (6) drugs and biologicals would expire on December 31, 2019, as listed in Table 14. CMS proposes that if the estimated per day cost for the drug or biological is less than or equal to the applicable packaging threshold, it would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS proposes to provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2020).	**Drugs and Biologicals with Expiring Pass-Through Status (p. 491)** ***CMS is finalizing its proposal*** to end pass-through payment status of the six drugs listed in Table 40. (p. 494)
	Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2020 CMS proposes to continue pass-through payment status in CY 2020 for 61 drugs and biologicals. These drugs and biologicals are listed in Table 15.	**Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2020 (p. 494)** CMS did not receive any public comments regarding these proposals and is finalizing them for CY 2020 without modification. Drugs and biologics

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	CMS proposes to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2020 (p. 304). CMS proposes that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2020 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is $0. In the case of policy-packaged products, CMS proposes that their pass-through payment amount would be equal to ASP+6 percent for CY 2020 minus a payment offset for any predecessor drug products contributing to the pass-through payment. CMS proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2020 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For CY 2020, CMS proposes to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP+6 methodology. If ASP data are not available for a radiopharmaceutical, CMS proposes to provide pass-through payment at WAC+3 percent, If WAC information also is not available, CMS proposes to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. **Drugs, Biologicals, and Radiopharmaceuticals, with Pass-Through Status as a Result of Sec. 1301 of the Consolidated Appropriations Act of 2020** Section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141) provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products	with pass-through payment status for CY 2020 are listed in Table 41. Drugs and biologics with pass-through payment for 2020 but that will be packaged in the OPPS after October 1, 2020 are listed in Table 42. **Drugs, Biologicals, and Radiopharmaceuticals, with Pass-Through Status as a Result of Sec. 1301 of the Consolidated Appropriations Act of 2020 (p. 502)** The replacement of HCPCS code Q4172 by HCPCS codes Q4195 and Q4196 means there are five HCPCS codes for drugs and biologicals covered by section 1833(t)(6)(G) of the Act. These products are included in Table 41.

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OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status	whose period of drugs and biologicals pass-through payment status ended on December 31, 2017. These products are listed in Table 16. CMS proposes to extend pass-through payment for these drugs and biologicals through September 30, 2020. **Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups** CMS proposes to continue to apply its policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. CMS sets a cost threshold for packaging based on cost and is proposing a packaging threshold for CY 2020 of $130. **Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold ("Threshold-Packaged Drugs")** CMS proposes to package items with a per day cost less than or equal to $130 and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. For the calculation of per day costs of HCPCS codes, CMS proposes to use ASP data from the fourth quarter of CY 2018. For items that do not currently have an ASP-based payment rate, CMS proposes to recalculate their mean unit cost from all of the CY 2018 claims data and updated cost report information available for the CY 2020 final rule with comment period to determine their final per day cost. The packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule. Under such circumstances, CMS proposes to continue to follow established policies. **Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages**	**Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs and Biologicals to Offset Costs Packaged into APC Groups (p. 506)** ***CMS is finalizing this proposal*** without modification. ***CMS is finalizing a packaging threshold of $130 for CY 2020.*** (p. 509) **Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals under the Cost Threshold ("Threshold-Packaged Drugs") (p. 510)** CMS did not receive any public comments on its proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2018 claims data and updated cost report information available for the CY 2020 final rule with comment period to determine their final per day cost. CMS also did not receive any public comments on its proposal to continue to follow the established policies when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2020, *CMS is finalizing these two proposals without modification.* **Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages (p. 520)**

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	CMS proposes to continue its policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. **Biosimilar Biological Products** For CY 2019, CMS proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. CMS also proposed to continue its policy to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.	***CMS did not receive any comments on this proposal and is finalizing it without modification.*** ***CMS is finalizing its proposal, without modification, to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC. (p. 529)*** **Biosimilar Biological Products** (p. 531) ***CMS is finalizing its proposed payment policy for biosimilar products, without modification*****,** to continue the policy established in CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. *CMS is also finalizing its proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the reference product's ASP*. [NOTE: THIS IS LIKELY A MISTAKE BY CMS.]
CY 2020 Payment Methodology for 340B Purchased Drugs	In this section, CMS provides a history of its attempt to address concerns about the Medicare Part B drug payment methodology for 340B hospitals. CMS explains that its finalized policy, which adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP)+6 percent to ASP minus 22.5 percent, are the subject of ongoing litigation. The United States District Court for the District of Columbia concluded that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent. CMS respectfully disagreed with the district court's understanding of the scope of its adjustment authority and asked the district court to enter final judgment so as to permit an immediate appeal, which was granted. While CMS intends to pursue its appeal rights, it is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. CMS solicits initial public comment on how to formulate a solution that accounts for all of the complexities that the district court recognized.	CMS announced in the Federal Register (84 FR 51590) its intent to conduct a 340B hospital survey to collect drug acquisition cost data for CY 2018 and 2019. Such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling is upheld on appeal. To the extent the courts are limiting the size of the payment reduction the agency can permissibly apply, the agency believes it could be appropriate to apply a payment reduction that is at the upper end of that limit, to the extent it has been or could be clearly defined, given the substantial discounts that hospitals receive through the 340B program. For example, absent further guidance from the Court of Appeals on what it believes is an appropriate "adjustment" amount, CMS could look to the district court's December 27, 2018 opinion, which cites to payment reductions of 0.2 percent and 2.9 percent as "not significant enough" to fall outside of the Secretary's authority to "adjust" ASP. After considering public comments and in light of the fact that CMS is awaiting a decision on its appeal in the litigation, for CY 2020, ***CMS is finalizing its proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs*** including when furnished in nonexcepted off-campus PBDs paid under the PFS. The finalized proposal continues the 340B policies that were implemented in CY 2018 with the

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	For CY 2020, CMS proposes to continue to pay ASP-22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the PFS. CMS also seeks public comment on the appropriate OPPS payment rate for 340B-acquired drugs, including whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. CMS welcomes public comments on payment rates other than ASP+3 percent that commenters believe would be appropriate for purposes of addressing CY 2020 payment as an alternative to its proposal above, as well as for potential future rulemaking related to CY 2018 and 2019 underpayments. CMS also seeks public comment on how to structure the remedy for CYs 2018 and 2019. CMS solicits public comments on the best, most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy. CMS also solicits comment on whether, depending on the amount of those additional expenditures, it should consider spreading out the relevant budget neutrality adjustment across multiple years. CMS would be interested to receive public comment on the advantages and disadvantages of such an approach. CMS is interested in public comments on the best, most appropriate treatment of Medicare beneficiary cost-sharing responsibilities under any proposed remedy.	exception of the way CMS is calculating payment for 340B-acquired biosimilars, discussed above. CMS is taking into consideration comments received on the appropriate remedy in the event of an adverse decision on appeal. CMS may use the survey data for 2018 and 2019 that it plans to collect from 340B hospitals to devise a remedy for prior years if the district court's ruling is upheld on appeal. If, however, 340B hospital survey data are not used to devise a remedy in the event of an adverse decision from the Court of Appeals, CMS intends to consider all of the commenters' suggestions in determining the appropriate remedy to propose in the CY 2021 OPPS rulemaking.
High/Low Cost Threshold for Packaged Skin Substitutes	**CY 2020 Packaged Skin Substitute Proposal** CMS has continued the high cost/low cost categories policy since it implemented its unconditional packaging policy in CY 2014 and proposes to continue it for CY 2020. CMS proposes to continue to determine the high cost/low cost status for each skin substitute product based on either: • The product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold (the proposed CY 2020 MUC threshold is \$49 per cm^2); or	**Proposals for Packaged Skin Substitutes for CY 2020 (p. 584)** ***CMS is finalizing its proposal*** to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2019, in which case it would assign the product to the high cost group for CY 2020, regardless of whether it exceeds the CY 2020 MUC or PDC threshold.

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	• The product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold (the proposed CY 2020 PDC threshold is $789).
	
	CMS proposes to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group; CMS proposes to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. Any skin substitute product that was assigned to the high cost group in CY 2019 would be assigned to the high cost group for CY 2020, regardless of whether it exceeds or falls below the CY 2020 MUC or PDC threshold.
	
	For CY 2020, CMS proposes to continue to assign skin substitutes with pass-through payment status to the high cost category.
	
	Potential Changes to Skin Substitute Payment Policy for CY 2020 or Future Years
	CMS recounted the four potential methodologies that it sought comment on during CY 2019 rulemaking, discussing two in more detail.
	• Establish a lump-sum "episode-based" payment for a wound care episode. Because of the complexity and concerns around such a system, while CMS does not make a proposal, CMS does seek additional comment regarding substitute payment policies for future years.
	• Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products. CMS is seeking input on:
	  ○ The possibility of using a single payment category for skin substitute products under the OPPS
	  ○ Delaying implementation of a single category of payment for 1 or 2 years after it is adopted
	  ○ Gradually lowering the MUC and PDC thresholds over 2 or more years to add more products into the high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category
		CMS also is finalizing its proposal to assign to the high cost group any skin substitute product that exceeds the CY 2020 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2020 MUC or PDC thresholds and was not assigned to the high cost group in CY 2019.
		
		CMS is finalizing its proposal to continue to use payment methodologies including ASP+6 percent and 95 percent of AWP for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2020 MUC. In addition, CMS is finalizing our proposal to continue to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or claims data to determine if those products' costs exceed the CY 2020 MUC. We also are finalizing our proposal to retain our established policy to assign new skin substitute products with pricing information to the low cost group. Table 45 (p. 588) displays the final CY 2020 cost category assignment for each skin substitute product.
		
		Discussion of CY 2019 Comment Solicitation for Episode-Based Payment and Solicitation of Additional Comments for CY 2020 (p. 573)
		
		CMS continues to rethink its skin substitute reimbursement. The methodology that commenters discussed most in response to comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings has been a lump-sum "episode-based" payment for a wound care episode. However, the wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy made CMS reluctant to present a proposal for this CY 2020 rule without more review of the issues involved with episode-based payment.
		
		In addition, CMS is persuaded that a single payment category (versus high cost/low cost) could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment. CMS will use the feedback to help inform its development of payment methodology for skin substitute application procedures in future rulemaking.

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	Based on input received, CMS states that it would consider modifying its payment policy in the CY 2020 OPPS final rule.	
Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices	CMS estimates that pass-through spending in CY 2020 would equal approximately $268.8 million (approximately $10.6 million for device categories and approximately $258.2 million for drugs and biologicals) which represents 0.34 percent of total projected OPPS payments for CY 2020 (approximately $80 billion).	CMS estimates that total pass-through spending in CY 2020 is approximately $698.4 million (approximately $246.8 million for device categories and approximately $451.6 million for drugs and biologicals) which represents 0.88 percent of total projected OPPS payments for CY 2020 (approximately $79 billion).
OPPS Payment for Hospital Outpatient Visits	CMS proposes to continue its current payment policy for clinic, emergency department hospital outpatient visits, and critical care services without change.	***CMS is finalizing this policy without modification.***
Procedures Identified for Removal from the Inpatient Only List	For CY 2020, CMS has identified one (1) procedure that it proposes for removal from the Inpatient Only list: • CPT 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft). ○ CMS proposes to assign CPT 27130 to Comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) CMS also seeks input on the potential removal of 6 additional codes.	***CMS is finalizing its proposal to remove CPT 27130 and assigning the procedure to C-APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator "J1."*** In addition, CMS is removing anesthesia code 01214 (anesthesia for open procedures involving hip joint; total hip arthroplasty) as a conforming change.

Changes in Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs (p. 676)

	CMS stated that it believes "Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general" and that "the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provider medical care." CMS went on to state, "[W]e believe it is time to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services." Therefore, CMS proposed changing the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from "direct supervision" to "general supervision" for all hospitals and critical access hospitals (CAHs). CMS sought input on whether specific types of services (e.g. chemotherapy administration or radiation therapy) should be excepted from this proposal.	***CMS finalized its proposal without modification*** (p. 689). CMS did receive input from stakeholders that they believed several services should have required direct supervision (p. 685), including: • Radiation therapy • Hyperbaric oxygen treatment

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		• Wound care CMS stated that if a provider believes that more supervision is required, there is nothing that prevents a hospital or CAH from requiring a higher level of supervision (p. 686). CMS also added that Conditions of Participation, federal and state regulation, and state standards for scope of practice also remain sources of protection and remain unaffected by this change (p. 687).
Short Inpatient Hospital Stays ("2 Midnight Rule") (p. 689)		
	CMS proposed a one year exemption from Recovery Audit Contractor (RAC) review for procedures that have been removed from the Inpatient Only list beginning in CY 2020. CMS specifically sought input on the one year time frame and whether a shorter or longer exemption period would be appropriate.	***CMS finalized the proposal with modification in that the exemption for procedures that have been removed from the Inpatient Only list from RAC review for non-compliance with the 2 Midnight Rule will last for a period of 2 years rather than the proposed 1 year*** (p. 696; p. 699).
Off-Campus Provider-Based Departments: Method to Control for Unnecessary Increases in the Volume of Outpatient Services (p. 699)		
	In the CY 2019 Medicare Physician Fee Schedule, CMS reviewed that the Bipartisan Budget Act of 2015 included a provision that "applicable items and services" furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, will not be considered OPD service . . . for purposes of payment under the OPPS and will instead be paid 'under the applicable payment system'; under Medicare Part B." The statute defines "off-campus outpatient department of a provider" as "a department of a provider . . . that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility." CMS previously finalized that the "applicable payment system" for the provisions covered by the Bipartisan Budget Act of 2015 would be the Medicare Physician Fee Schedule (MPFS). That is, most nonexcepted items and services furnished by off-campus PBDs will be paid under the MPFS. CMS continued to believe "that the higher payment that is made under the OPPS, as compared to the payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting." To address this ongoing site-of-service differential for what CMS views as the same service, CMS finalized a proposal to apply an amount equal to "the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD" (i.e. the MPFS payment rate) for clinic visits (i.e., HCPCS G0463) when provided at an off-	CMS acknowledged that stakeholders believed that CMS could not move forward with the 2nd year of this payment policy due to the recent U.S. District Court decision in *American Hospital Association, et al. v. Azar* (September 17, 2019). CMS stated that it continues to believe that Social Security Act §1833(t)(2)(F) *("(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services"*) grants the Secretary authority to remove payment differentials driving site of services decisions "and as a result, is unnecessarily increasing service volume" (p. 709). While the District Court vacated the previously finalized provision that adopted the "volume control method" for clinic visits furnished by nonexcepted off campus PBDs and remanded the issue to the Secretary, the Agency requested a reversal and additional time; however, in October 2019, the motion to modify and request for stay was denied and a final judgement was entered vacating the portion of the rule that adopted the volume control method for clinic visits furnished by nonexcepted off campus PBDs (p. 710). CMS went on to state: *We acknowledge that the district court vacated the volume control policy for CY 2019 and we are working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order. We do not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy. The government has appeal rights, and is still*

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	campus PBD excepted from the BBA provisions. Non-excepted off-campus PBDs already receive a reduced rate from the usual OPPS rate. CMS is using its authority to reduce the OPPS rates for G0463 visits (to match MPFS rates) for even those off-campus PBDs excepted from the BBA provisions. Those that were "excepted" under the statute were off-campus PBDs billing covered OPD services furnished "prior to November 2, 2015." When CMS finalized this policy, it also finalized a two year phase in of the new payments. In CY 2019, the policy would have generated a 60 percent reduction, but CMS reduced that by half so as to only implement a 30 percent reduction. For CY 2020, CMS had stated that it would apply the total reduction for departments that bill the ~PO modifier (Excepted service provided at off-campus, outpatient, provider-based outpatient departments). In essence, this requires in CY 2020 that departments that bill G0463 with the PO modifier will be paid 40 percent of the OPPS payment. CMS proposed to continue a non-budget neutral application of the policy in CY 2020.	*evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment* (p. 710). CMS listed the remedies for the 2019 payments submitted by stakeholders in the event the court decision is not overturned (p. 712). ***CMS finalized continuing with the second year of its phase-in*** (p. 705; p. 714). *For CY 2020, CMS will be going forward with the phase-in. We respectfully disagree with the district court and continue to believe the Secretary has the authority to address unnecessary increases in the volume of outpatient services. CMS is still considering how we would remedy hospitals if we either do not appeal this ruling or do not succeed on appeal if one is so authorized* (p. 713). CMS notes that budget neutrality is only required when the Secretary makes an "adjustment" and that because CMS believes its authority derives from Social Security Act §1833(t)(2)(F) ("(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services"), it is not making an "adjustment" as referenced in the budget neutrality portion of the statute and therefore is not required to apply the policy in a budget neutral manner (p. 704).
Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services (p. 975)		
	CMS proposes to use its authority to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage before a covered OPD service is furnished to the beneficiary and before the claim is submitted for processing. CMS proposes that this requirement would begin for dates of service on or after July 1, 2020. CMS proposes to establish a new subpart I under part 419 (containing §§ 419.80 through 419.89 (§§ 419.84 through 419.89 would be reserved)) to codify the following proposed policies for prior authorization for certain covered OPD services.	***CMS finalized its proposed prior authorization policy as proposed, including the proposed regulation text, with the following modifications: CMS added additional language at § 419.83(c) regarding the notice of exemption or withdraw of an exemption. CMS is including in this process the two additional botulinum toxin injections codes, J0586 and J0588.*** (p. 1010) CMS received a multitude of comments regarding its prior authorization proposals, some in support and some opposing. CMS continues to believe it has the requisite authority to implement prior authorization for HOPDs under section 1833(t)(2)(F) of the Act as a method to control unnecessary

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		increases in services. (p. 1014) CMS also said it cannot extend this prior authorization policy to ASCs given its authority is specific to the OPPS. (p. 1016) With regard to burden, CMS said there are no new documentation requirements and that prior authorization has the added benefit of giving hospitals some assurance of payment for services for which they received a provisional affirmation, which will reduce the burden of appeals. (p. 1018) CMS made specific remarks in response to concerns about the inclusion of Botox, which start on page 1007.
Definitions	CMS proposes to define key terms associated with the proposed prior authorization process for certain covered OPD services under its proposed new subpart, as noted below: • "Prior authorization" means a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted. • "Provisional affirmation" means a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules. "List of hospital outpatient department services requiring prior authorization" means the list of outpatient department services CMS publishes in accordance with proposed new subpart that require prior authorization as a condition of payment.	***Finalized as proposed.*** See above.
Prior Authorization as a Method for Controlling Unnecessary Increases in the Volume of Covered Outpatient Services	CMS proposes that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital outpatient department services requiring prior authorization to CMS that meets CMS' proposed new requirements. • CMS proposes that claims submitted for services that require prior authorization (including associated anesthesiology services, physician services, and/or facility services) that have not received a provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt (see below). • CMS proposes that even when a provisional affirmation has been received, a claim for services may be denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or	***Finalized as proposed.*** See above.

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	information not available at the time the prior authorization request is received (see below). • CMS proposes that CMS or its contractor would initiate an expedited review of a prior authorization request when requested by a provider and where CMS or its contractor determines that a delay could seriously jeopardize the beneficiary's life, health or ability to regain maximum function, and a provisional affirmation or non-affirmation would be provided under an expedited timeframe of two (2) business days. • CMS proposes that the agency (or its contractor) will review a prior authorization request for compliance with applicable Medicare coverage, coding, and payment rules, and if the request is compliant (or not compliant), CMS or its contractor would issue a provisional affirmation (or non-affirmation decision) to the requesting provider within ten (10) business days. • CMS proposes that, if the provider receives a non-affirmation decision, it would allow the provider to resubmit a prior authorization request with any applicable additional relevant documentation. CMS proposes to update its regulations such that OPD prior authorization requests that are determined non-affirmed also would not be considered an initial determination and, therefore, would not be appealable. CMS also proposes that any claims associated with or related to a service that requires prior authorization (e.g., anesthesiology services, physician services, and/or facility services) for which a claim denial is issued will be denied as well since these services would be unnecessary if the service requiring prior authorization had not been provided. CMS requests public comments on whether this requirement should be included in the new subpart for prior authorization of OPD services or be co-located with the regulatory provisions governing initial determinations.	
Proposed List of Outpatient Department Services That Would	CMS proposes that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 38.	See Table 64 for the final list of outpatient department services requiring prior authorization.

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Require Prior Authorization	CMS proposes that CMS may elect to exempt a provider from the prior authorization process upon its demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption. • CMS would exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. • CMS proposes that it might withdraw an exemption if evidence becomes available based on a review of claims that the provider has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements (i.e., the rate of nonpayable claims submitted becomes higher than 10 percent during a biannual assessment). CMS proposes that it may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' webpage.	***Finalized as proposed.*** See above.
Regulatory Impact		The overall economic impact is approximately $5.7 million in the first year based on 6 months. The 5-year impact is approximately $46.5 million, and the 10-year impact is approximately $98.7 million. Table 74 lists an estimate for the overall economic impact to the health sector for the services combined. Together, Tables 75 and 76 combine to convey the overall economic impact to the health sector, which is illustrated in Table 74. CMS expects quantifiable benefits due to a reduction in the unnecessary utilization of those Medicare OPD services subject to prior authorization. For the first 6 months CMS estimates the savings to be $6,059,950 and the net savings as $2,112,362. Annually, the estimated savings are $12,119,899 and the net savings are $4,679,966. CMS will closely monitor utilization and billing practices. (p. 1092)

Response to Comments Received in Response to Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters & Related Medicare Payment Issues (p. 1032)

	The Department is seeking public comments on innovative and streamlined methods for establishing hospital payment to the extent permitted by law.	CMS received approximately 46 timely pieces of correspondence in response to its request for information. CMS does not provide any detail on comments received, but notes that it appreciates the input. (p. 1032)

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	CMS is seeking public comments on: • The continued value of the chargemaster charges in setting hospital payment and to other stakeholders, as well as the costs associated with maintaining the chargemaster for purposes of Medicare cost reporting and payment. • Whether it would be possible to modernize or streamline the Medicare cost reporting process, for example, by replacing it with other processes, or if it could be modified in content, methodology, or approach. • Whether and how the replacement or modification of the chargemaster might affect the submission of data used by CMS to calculate payments (e.g. recalibrating relative weights, outlier payments, CAH payments, new technology add-on payments, and pretransplant cost reimbursement), as well as alternative sources that could be used for the information necessary to calculate these payments. The decision process, and why the chargemaster might be updated more frequently than on an annual basis, and how this more frequent updating could affect costs for patients.	

Requirements for Hospitals to Make Public a List of Their Standard Charges and Request for Information (RFI) (p. 926)

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Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information (p. 926)		
Background	Note that the following provisions were proposed in the CY 2020 OPPS proposed rule (and are thus included here). CMS made brief reference to it in the standard CY 2020 OPPS/ASC Final Rule (p. 926), but the finalized provisions and discussion of comments were issued in a *separate* final rule, *CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates Price Transparency Requirements for Hospitals to Make Standard Charges Public* (CMS-1717-F2). These provisions are included below. Page number references for these provisions will appear with the indicator "F2" to denote their location in the separate document (e.g. "F2 p. 1"). ***CMS finalized an effective date for these provisions of January 1, 2021*** (F2 p. 2; F2 p. 110; F2 p. 244). CMS also noted that these provisions alone will not resolve "surprise billing," but state that they believe "it is possible that disclosure of hospital standard charges could help mitigate some surprise billing experienced by consumers" (F2 p. 26). Note that when CMS issued this second OPPS final rule addressing these hospital transparency provisions, it simultaneously released a new *proposed* rule directed at transparency provisions but for health plans (rather than at hospitals). That proposed rule can be viewed here (and HHS, Inc. will provide a separate summary of that proposed rule).	
Definitions	**Definition of "Hospital."** CMS did not anchor to existing definitions of "hospital" out of concern that it would inappropriately limit the institutions who would be covered by the provisions. Rather, CMS proposed defining a "hospital" as "*an institution in any State in which State or applicable local law provides for licensing of hospitals, (1) is licensed as a hospital pursuant to such law or (2) is approved, by the agency of such State or locality responsible for licensing hospitals as meeting the standards established for such licensing*." CMS cites that it is its intent that this definition captures critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals, and inpatient rehabilitation facilities (IRFs); and that it does not include ambulatory surgery centers (ASCs) or "other non-hospital sites-of-care" (also mentioning laboratory or imaging services).	***CMS finalized the definition of "hospital" as proposed*** (F2 p. 31; F2 p. 34).
	Special Requirements for Certain Hospitals. CMS proposed that the requirements would not apply to federally-owned or operated hospitals (including Indian Health Service (IHS) facilities, VA facilities, and Department of Defense Military Treatment Facilities (MTFs) by deeming these facilities to have met the requirements "when their charges for hospital provided services are publicized to their patients in advance" (including the *Federal Register*).	***CMS finalized the proposal to deem "federally owned or operated hospitals" as having met the requirements*** (F2 p. 29).
	CMS sought input on whether it should make similar accommodations for hospitals in rural areas, CAHs, or non-federally-owned or operated	CMS declined to make any accommodations for other facilities (F2 p. 37). CMS also stated that it "recognized that some small hospitals, and rural hospitals, including CAHs and SCHs may face challenges in implementing

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	hospitals that treat special populations (e.g., children's hospitals or State psychiatric hospitals).	these requirements, but we do not believe that such challenges are insurmountable" (F2 p. 38).
	Definition of "Items and Services" Provided by Hospitals. CMS proposed defining "items and services" provided by a hospital as "all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or outpatient department visit for which the hospital has a standard charge." CMS also proposed defining "chargemaster" as "the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge." CMS proposed defining "service package" as "an aggregation of individual items and services into a single service with a single charge." CMS stated that this definition is intended to include "the services furnished by physicians and non-physician practitioners who are employed at the hospital." CMS stated that it considered (but decided against) including services provided by physicians and non-physician practitioners who are not employed by the hospitals (but provide services at that hospital location); however, CMS stated that it believes that this information would be "exceptionally valuable to give consumers a more complete picture of the total amount they be charged in connection with an inpatient admission or an outpatient department visit at a hospital location" citing the ongoing concerns with "surprise billing." However, because these clinicians practice independently, CMS did not believe they were services "provided by the hospital" as the statute dictates.	***CMS finalized the definition of "items and services" as proposed*** (F2 p. 45; F2 p. 53). Additional discussion on comments received regarding "service packages" can be found on F2 p. 44. CMS received request for clarification on the term "employment" given the variation in employment arrangements (F2 p. 48). ***CMS declined to define "employment" and stated instead that it believes "it is important to preserve flexibility for hospitals to identify employed physicians or non-physician practitioners under their organizational structure"*** (F2 p. 49). • CMS did not agree with commenters who suggested that this could create confusion by making hospitals who employ physicians look more expensive since professional service costs would not be included for hospitals that do not have employment arrangements with the physicians providing services (F2 p. 50). • CMS noted that it received some comments suggesting that CMS post charges for "all practitioners who *affiliate* with a hospital" (beyond just those that are "employed") (F2 p. 47). CMS replied that it still believes that would be beyond the bounds of its authority to require posting of charges for items and services "provided by the hospital" (F2 p. 48). • CMS also did not agree with commenters that suggested that CMS did not have the authority to include employed physician services in its definition of "items and services" (F2 p. 51). • CMS did not share the EMTALA-related concerns shared by stakeholders, stating it believes the policies finalized "are distinct from EMTALA's requirements and prohibitions and that the two bodies of law are not inconsistent and can harmoniously coexist. To be clear, the price transparency provisions that we are finalizing do not require that hospitals post any signage or make any statement at the emergency department regarding the cost of emergency care

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		or any hospital policies regarding prepayment of fees or payment of co-pays and deductibles. But we do believe that the policies we are finalizing, for hospitals to make public standard charges, offer consumers opportunities for informed decision-making by providing them with information about the cost of care which, for example, they might consider prior to visiting a hospital emergency department for treatment of a non-life threatening condition" (F2 p. 52).
	Definition for Types of "Standard Charges." CMS proposed defining "standard charges" as "gross charges" and "payer-specific negotiated charges."	***CMS finalized the definition of "standard charges" as " the regular rate established by the hospital for an item or service provided to a specific group of paying patients"*** (F2 p. 67). In addition, ***CMS finalized the inclusion of "gross charges" and "payer-negotiated charges" in its definition of "standard charges" in addition to three 3 additional charge types: (1) Discounted Cash Price, (2) De-identified Minimum Negotiated Charge; and (3) De-identified Maximum Negotiated Charge*** (See below) (F2 p. 67). CMS provides a lengthy discussion what it believes to be its statutory and legal authority beginning on F2 p. 62.
	• Gross Charges: CMS proposed to define a "gross charge" as "*the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts*."	***CMS finalized the definition of "gross charges" as proposed*** (F2 p. 74).
	• Payer-Specific Negotiated Charge: CMS proposed to define a "payer-specific negotiated charge" as "*the charge that the hospital has negotiated with a third party payer for an item or service*."	***CMS finalized the definition of "payer-specific negotiated charge" as proposed*** (F2 p. 111). CMS noted its agreement with commenters that payer-specific negotiated charges in isolation to not provide a patient with individualized estimates on out-of-pocket costs, but nonetheless, CMS still finds value in sharing this information (F2 p. 80). CMS addresses some of the authority and legal challenges to requiring disclosure of payer-specific negotiated charges beginning on F2 p. 82. CMS also acknowledged receipt of comments suggesting that disclosure of payer-negotiated specific charges would *increase* health care costs "due to anticompetitive behaviors or increases in prices as a result of hospital knowledge of better rates negotiated by neighboring hospitals" (F2 p. 97). CMS disagreed with this theory and presented information it believes supports that the disclosure of this information will help decrease prices (F2 p. 98). CMS also responded to complaints about the burden this will place on hospitals that have negotiated rates with a significant number of plans, stating that "the burden to hospitals for making public all payer-specific negotiated charges is outweighed by the public's need for access to such information" (F2 p. 110).

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	• Alternative: "Standard Charges" Related to Groups of Individuals with Third Party Payer Coverage: CMS noted that it can be difficult to obtain the rate that a third payer has negotiated on behalf of its insured lives. CMS noted that its definition would not capture charges that are not "negotiated." CMS specifically considered (but did not propose) the following definitions and seeks input:	***CMS finalized three additional categories of "standard charges" as listed below*** (F2 p. 66):
	○ "Volume Driven Negotiated Charge": CMS considered defining "Standard Charge" as "Modal Negotiated Charge," which would in turn be defined as "*the most frequently charged rate across all rates the hospital has negotiated with third party payers for an item or service*." CMS believed using this definition could provide useful information but limit the amount of data hospitals are required to make public.	***CMS did not finalize the inclusion of "Volume Driven Negotiated Charge" out of concern it could be confusing to consumers*** (F2 p. 113).
	○ Minimum, Median & Maximum Negotiated Charge: CMS considered defining this as "*the lowest, median, and highest charges of the distribution of all negotiated charges across all third party payer plans and products*." CMS again believed this could be useful information. In addition, CMS stated that it could address concerns about the potential that the release of charge data could have on increasing health care costs in some markets.	***CMS finalized the inclusion of De-identified Minimum Negotiated Charge and De-identified Maximum Negotiated Charge in the definition of "standard charges"*** (F2 p. 67; F2 p. 127). CMS believes that the de-identified version of these negotiated charges "could each provide a benchmark for determining the value of a hospital item or service for referring providers or employers" (F2 p. 124). • ***CMS finalized defining "De-Identified Minimum Negotiated Charge" as "the lowest charge that a hospital has negotiated with all third party payers for an item or service"*** (F2 p. 126). • ***CMS finalized defining "De-Identified Maximum Negotiated Charge" as "the highest charge that a hospital has negotiated with all third party payers for an item or service"*** (F2 p. 126).
	○ All Allowed Charges: This would be "*the charges for all items and services for all third party payer plans and products, including charges that are non-negotiated (such as FFS Medicare rates).*" CMS declined proposing this option, however, because it believes consumers already have "adequate and centralized access" to non-negotiated charges, and for those that do have non-negotiated health care coverage, CMS stated they are largely protected from out-of-pocket costs which would make them less sensitive to price shopping.	***CMS did not finalize the inclusion of "All Allowed Charges" under the rationale that allowed amounts that are not "negotiated" (e.g. FFS Medicare and Medicaid) are already publicly disclosed*** (F2 p. 115).

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	• Alternative: "Standard Charges" for Groups of Individuals that are Self-Pay: CMS stated that for the most part self-pay patients do not need additional charge information beyond "gross charges" to determine out-of-pocket liabilities. However, CMS did receive comments that hospitals "often offer discounts off the gross charge or make other concessions to individuals who are self-pay." Because of this, CMS specifically considered (but did not propose) the following definitions and sought input:	
	○ *Discounted Cash Price*: CMS would define this as "*the price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or services package*." Noting that the latest data show that there were 24.7 million uninsured individuals in the United States in 2017, CMS stated that there is a large number of individuals who could benefit from the information. CMS also said that insured individuals who are willing to bear the full cost of services not covered or out-of-network could also benefit from the information.	***CMS finalized the inclusion of Discounted Cash Price as a "standard charge"*** (F2 p. 66; F2 p. 67; F2 p. 121). CMS noted that it is distinguishing between "Discounted Cash Price" and "Median Cash Price" (which it is not including) because the latter would take into account any and all cash prices accepted by hospitals "including cash payments accepted following sliding scale discounts as a result of charity care" (F2 p. 120). CMS clarifies that "Discounted Cash Price" is intended to "reflect the discounted rate published by the hospital, unrelated to any charity care or bill forgiveness that a hospital may choose or be required to apply to a particular individual's bill (F2 p. 120).
	○ *Median Cash Price*: This option was considered so that the policies could take into account sliding scale cash discounts. CMS noted that for uninsured patients who could qualify for financial assistance, median cash price information could be useful to raise awareness of availably options including the ability to apply for financial assistance.	***CMS did not finalize the inclusion of "Median Cash Price"*** (F2 p. 120).
Public Disclosure Requirements	**Standardized Data Elements.** CMS proposed that hospitals will be required to make public a list of each "item or service" the hospital provides with the corresponding information (as applicable):	***CMS finalized its data elements proposals with modification***, as described below (F2 p. 145). CMS provides an example of how a hospital could provide standard charges (including professional services) in a comprehensive machine readable file in Table 1. CMS noted that creation of a "data dictionary" and increased specificity on data file formats would be productive and that it will consider it for future rulemaking (F2 p. 138).
	• Description of each item or service (including both individual items and services and service packages)	***CMS finalized this data element*** (F2 p. 145).

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	• The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting	***CMS finalized this data element*** (F2 p. 145). Noting that some supplies may not have corresponding "common billing codes," ***CMS again clarified that the required data elements just be included "as applicable"*** (F2 p. 136).
	• The corresponding payer-specific negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third party payer	***CMS finalized this data element*** as "The corresponding payer-specific negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan" (F2 p. 145).
	• Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG), National Drug Code (NDC), or other common payer identifier	***CMS finalized this data element*** (F2 p. 146).
	• Revenue code, as applicable	***CMS did not finalize inclusion of the Revenue Code as a required data element*** (F2 p. 143). CMS encourages its inclusion, but is concerned that if required, in certain circumstances it could lead to unnecessary duplication. ***CMS finalized the additional data element of "The corresponding de-identified minimum negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting"*** (F2 p. 145). ***CMS finalized the additional data element of "The corresponding de-identified maximum negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting"*** (F2 p. 146). ***CMS finalized the additional data element of "The corresponding discounted cash price that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting"*** (F2 p. 146).
	Comprehensive Machine-Readable File.	

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	• CMS proposed requiring that hospitals post charge information "in a single digital file that is in a machine-readable format." • CMS proposed to define "machine-readable format" as "a digital representation of data or information in a file that can be imported or read into a computer system for further processing." CMS sought comment on whether it should designate a single file type.	***CMS finalized the requirement that a hospital is required to post the information in a "machine-readable format"*** (F2 p. 145; F2 p. 149). ***CMS finalized the proposed definition of "machine-readable format"*** (F2 p. 149). CMS cited .XML, .JSON, and .CSV formats as examples of "machine readable formats" but noted that this list was not exclusive, but did note that a .PDF would not meet the definition. While CMS acknowledged stakeholder comments on the potential value of standardizing the data, it believes finalizing that the information be made available simply in "machine readable format" would be a good initial step (F2 p. 149).
	Location and Accessibility Requirements. CMS proposed that hospitals will have the discretion to choose the Internet location where it posts its file so long as the file is displayed on a publicly available webpage, it is "displayed prominently," and it clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are "easily accessible," without barriers, and the data can be digitally searched. CMS proposed that hospitals make the required data available online "in such a way that the payer-specific negotiated charge and associated data elements can be located and accessed easily by consumers." CMS requested comment on an alternative that would require hospitals to submit a link to the standard charges file to CMS, which CMS would make public. CMS sought comment on potential additional requirements (e.g. easily-searchable file name conventions) and whether it should specify the website location for posting.	***CMS finalized this requirement with modification*** (F2 p. 156). ***CMS finalized that the files must be posted with the following naming convention: "[__standardcharges.[json|xml|csv] in which the EIN is the Employer Identification Number of the hospital, followed by the hospital name, followed by "standardcharges" followed by the hospital's chosen file format"*** (F2 p. 155). ***CMS finalized that "the hospital must ensure the standard charge data are easily accessible and without barriers, including but not limited to that the data can be accessed free of charge, without having to establish a user account or password, and without have to submit personally identifying information*** (F2 p. 157). While CMS declined to add additional requirements or standards, CMS noted that it will "consider a requirement for hospitals to submit to CMS their files, or a link to where such files may be located on the Internet, for future rulemaking (F2 p. 154).
	Frequency of Updates. CMS proposed requiring hospitals to make public and update the file "at least once annually" containing the list of all standard charges for all items and services "at least once annually."	***CMS finalized this as proposed*** (F2 p. 160). ***CMS finalized this as proposed*** (F2 p. 160).

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	CMS proposed requiring hospitals to clearly indicate date of last update.	
	Requirements for Separate Files for Different Hospital Locations. CMS acknowledged that State licensing can affect whether sites are consolidated or functioning separately (and with separate charges). To address this, CMS proposed that the policies would separately apply to each hospital location such that each hospital location would be required to make public a separate identifiable list of standard charges.	***CMS finalized this as proposed*** (F2 p. 161).
"Consumer-Friendly" Display of "Shoppable Services"	CMS proposed that "hospitals must make public their payer-specific negotiated charges for common services for which consumers may have the opportunity to shop."	CMS included a sample display of shoppable services in Table 2. CMS reminds readers that it did not propose or finalize that hospitals post "gross charges" for hospital services (F2 p. 173).
	• Definition of "Shoppable Services": CMS proposed to define a "shoppable service" as "a service package that can be scheduled by a health care consumer in advance."	***CMS modified the finalized definition to remove the reference to "service package,"*** (F2 p. 171) ***and thus, defines "Shoppable Services" as "a service that can be scheduled by a healthcare consumer in advance"*** (F2 p. 175).
	• "Ancillary Services": CMS proposed to define "ancillary service" as "an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service."	***CMS finalized that if a "shoppable service is customarily accompanied by the provision of ancillary services, the hospital must present the shoppable service as a grouping of related services, meaning that the charge for the primary shoppable service (whether an individual item or service or service package) is displayed along with charges for ancillary services"*** (F2 p. 175). In addition, ***CMS finalized its definition of "ancillary service" as "an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service*** (F2 p. 175).
	• Proposed "Shoppable Services": ○ CMS proposed to require hospitals to make public a list of their payer-specific negotiated charges for a specific list of services. CMS particularly seeks comment on "the specific services . . . identified as shoppable services and whether other services should be included because they are more common, more shoppable or both."	***CMS finalized the required list of 70 CMS-identified specific "shoppable services" as proposed and as indicated in Table 3*** (F2 p. 182; F2 p. 183; F2 p. 189). CMS divided the list of 70 CMS-identified "shoppable services" into four (4) categories: E&M Services; Laboratory and Pathology Services; Radiology Services; and Medicine & Surgery Services (F2 p. 187).
	○ CMS proposed that each hospital would select at a minimum 230 additional shoppable services (as identified by a primary HCPCS, CPT, or DRG or other widely used industry code as applicable) and make	***CMS finalized that if a hospital does not provide some of the 70 CMS-identified "shoppable services" that it identifies enough services so that the total number posted is at least 300*** (F2 p. 187). However, ***CMS modified its proposal to also add that if a hospital does not provide 300 shoppable***

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	publicly available a list of its payer-specific negotiated charges in both the inpatient and outpatient setting. CMS proposed that hospitals make public the list of as many of the specifically CMS-identified shoppable services as possible "plus as many additional shoppable procedures as is necessary to reach a total of at least 300 shoppable services."	***services that the hospital list "as many shoppable services as they provide*** (F2 p. 189).
	○ CMS also sought comment on whether it should require more or less than a total of 300 shoppable services (and whether a list of 100 shoppable services (or less) is a reasonable starting point).	***CMS finalized that the hospital must considered the rate at which it provides and bills for a shoppable service;*** CMS continues, "That is the shoppable services selected for display by the hospital should be commonly provided to the hospital's patient population" (F2 p. 189).
	"*Consumer Friendly:* • Data Elements: CMS proposed that the "consumer-friendly display of payer-specific negotiated charge information contain the following corresponding information":	***CMS finalized the data elements with modification beginning on F2 p. 204.***
	○ A plain-language description of each shoppable service	***CMS finalized the requirement that the hospital include a plain-language description of each shoppable service*** (F2 p. 200).
	○ The payer-specific negotiated charge that applies to each shoppable service ○ A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service	***CMS finalized the including of payer-specific negotiated charges and ancillary services with modification*** (F2 p. 198): • The payer-specific negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable) • The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its gross charge. • The de-identified minimum negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable). • The de-identified maximum negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable).
	○ Each payer-specific charge must be clearly associated with the name of the third party payer	

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	○ The location at which each shoppable service is provided by the hospital ("for example, Smithville Campus or XYZ Clinic"); Whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting or both; If the payer-specific negotiated charge for the shoppable service varies based upon location or whether the hospital provides the shoppable service in the inpatient setting versus the outpatient setting, the hospital would be required to identify each payer-specific negotiated charge	***CMS finalized that the hospital must include the location which each shoppable service is provided, including whether the standard charges for the shoppable service applies at that location (to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both)*** (F2 p. 200).
	○ Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, (including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis-Related Group (DRG), or other commonly used service billing code)	***CMS finalized this as proposed*** (F2 p. 200).
		CMS also finalized that if a hospital does not offer one or more of the 70 CMS-identified shoppable services that it must "clearly indicate the fact with respect to every type of standard charge required for consumer-friendly display" (F2 p. 199).
	Format of Display CMS proposed that hospitals retain the flexibility on how to display payer-specific negotiated charge data online so long as the website is easily accessible to the public.	***CMS finalized this provision*** (F2 p. 220). However, ***CMS also finalized a modification to its proposal in that a hospital may <u>voluntarily</u> provide "an Internet-based price estimator tool and thereby be deemed to have met . . . requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner"*** (F2 p. 216). CMS provides the requirements of the price estimator tool beginning on F2 p. 217.
	CMS proposed that hospitals make also the data elements listed above available in a consumer-friendly manner offline. CMS proposed that the hospital must provide a paper copy of the information to consumers "upon request within 72 hours of the request."	***CMS did <u>not</u> finalize its proposal for hospitals to provide a paper copy within 72 hours of a request*** (F2 p. 220).

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Monitoring and Enforcement	CMS proposed that its monitoring methods may include, but are not limited to: • CMS evaluation of complaints made by individuals or entities to CMS • CMS review of individuals' or entities' analyses of noncompliance.	***CMS finalized its proposal to monitor hospital compliance with the requirements*** (F2 p. 238; F2 p. 247).
	CMS proposed that hospitals identified as noncompliant "would be notified of their deficiencies and given an opportunity to take corrective action. CMS proposed that for hospitals determined to be noncompliant that fail to respond to CMS requests to submit a corrective action plan (CAP) or comply with the requirements of a CAP, it may impose Civil Monetary Penalties (CMPs) on hospitals and publicize the penalties on the CMS website.	***CMS finalized this provision with modification*** (F2 p. 243; F2 p. 247). CMS acknowledged that its proposal to require that the CAP submitted by the hospital to include "the deficiency or deficiencies that caused noncompliance to occur" could raise due process considerations (F2 p. 242). CMS states that the finalized provision will require identification of corrective actions to address the deficiencies "identified by CMS."
	CMS made proposals related to CMS imposition of CMPs.	***CMS finalized its provisions related to imposition of CMPs on hospitals identified as noncompliant that fail to respond to CMS requests to submit a CAP or comply with the CAP requirements*** (F2 p. 263).
	• CMS also proposed the addition of an appeals process.	***CMS finalized its appeals process beginning on*** F2 p. 268.

ASC Payment System Updates (p. 720)

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Definition of ASC Covered Surgical Procedures (p. 723)		
	In the CY 2019 OPPS/ASC final rule, CMS revised the definition of a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that it determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS. CMS did not specifically propose to continue the modified definition of surgery for CY 2020 in the CY 2020 OPPS/ASC proposed rule, although it did not propose to remove any procedures from the ASC list of covered surgical procedures that had been added as a result of the modified definition.	For this final rule with comment period, after consideration of the public comments, ***CMS adopted a policy to continue to apply the modified definition of a surgical procedure for CY 2020.*** CMS intends to address subsequent calendar years in future rulemaking. (p. 726)
Treatment of New and Revised Codes (p. 726)		
April 2019 HCPCS Codes for Which CMS Solicited Public Comments in the Proposed Rule	Table 25 lists the new Level II HCPCS codes that were implemented April 1, 2019, along with their proposed payment indicators for CY 2020 (see Addendum BB, DD1 and DD2 for more details). CMS proposes to finalize their payment indicators in the CY 2020 OPPS/ASC final rule with comment period.	Absent comments, ***CMS finalized the proposed ASC payment indicator assignments for these codes*** (see Table 50). CMS notes that several of the temporary drug HCPCS C codes were replaced with permanent drug HCPCS J-codes, effective January 1, 2020.
July 2019 HCPCS Codes for Which CMS Solicited Public Comments in the Proposed Rule	Table 26 lists the new HCPCS codes that are effective July 1, 2019 (see Addendum AA, BB, DD1 and DD2 for more details). In addition, through the July 2019 quarterly update CR, CMS is also implementing an ASC payment for one new Category III CPT code as an ASC covered ancillary service, effective July 1, 2019, listed in Table 27. CMS proposes to finalize the payment indicators in the CY 2020 OPPS/ASC final rule with comment period.	Absent comments, ***CMS finalized the proposed ASC payment indicator assignments for these codes*** (see Tables 51 and 52). CMS notes that several of the HCPCS C codes have been replaced with HCPCS J-codes, effective January 1, 2020.
October 2019 HCPCS Codes for	CMS proposes that the Level II HCPCS codes that will be effective October 1, 2019, would be flagged with comment indicator "NI" in Addendum BB to the	**COMMENT:** ***CMS invites public comments on the interim ASC payment indicator for the codes that the agency intends to finalize in the CY 2021 OPPS/ASC final rule with comment period.***

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Which CMS Is Soliciting Public Comments in this CY 2020 OPPS/ASC Final Rule with Comment Period	CY 2020 OPPS/ASC final rule with comment period to indicate that CMS has assigned the codes an interim ASC payment status for CY 2020.	
January 2020 HCPCS Codes	CMS proposes to assign comment indicator "NI" in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2020 to indicate that the agency is assigning them an interim payment indicator, which is subject to public comment. For new and revised CPT codes effective January 1, 2020 that were received in time to be included in this proposed rule, CMS proposes the appropriate payment indicator assignments, and solicits public comments on the payment assignments.	**COMMENT:** ***CMS solicits comment on the new Level II HCPCS codes that are effective January 1, 2020 in the CY 2020 OPPS/ASC final rule with comment period, thereby updating the ASC payment system for the calendar year.*** **COMMENT:** ***CMS public comments in the CY 2020 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2021 OPPS/ASC final rule with comment period.***
Update to Lists of ASC Covered Surgical Procedures and Covered Ancillary Services (p. 738)		
Covered Surgical Procedures Designated as Office-Based	**Permanent office-based designations.** CMS' review of the CY 2018 volume and utilization data resulted in the identification of 9 covered surgical procedures that meet the criteria for designation as permanently office-based (see Table 29), therefore, CMS proposes to permanently designate these 9 codes as office-based for CY 2020. CMS does not propose to designate CPT codes 36902 and 36905 (dialysis vascular access procedures) as office-based procedures.	***CMS finalized its proposal with modification, to designate the four ASC covered surgical procedures in Table 55 as permanently office-based for CY 2020 and subsequent years.*** Regarding CPT code 36902, ***CMS finalized a payment indicator of "G2" – nonoffice-based surgical procedure paid based on OPPS relative weights.*** (p. 743) Regarding CPT codes 31634, 31647, 50727, 59414, and 61880, CMS agreed with commenters that the volume and utilization data do not suggest the procedure are performed more than 50 percent of the time in physicians' offices. ***For CPT codes 31634, 50727, 59414, 61880, CMS assigned payment indicators "G2" - non office-based surgical procedure based on OPPS relative weights – for CY 2020. Additionally, as CPT code 31647 exceeds the device offset percentage threshold of 30 percent for device-intensive designation, CMS assigned this procedure a payment indicator of "J8" - device-intensive procedure; paid at adjusted rate – for CY 2020.*** (p. 743)
	Temporary office-based designations. CMS proposes to maintain the temporary office-based designations for 11 CPT codes for CY 2020 (see Table 30).	Absent public comments, ***CMS finalized its proposal, without modification, to designate the procedures shown in Table 56 and 57 below as temporarily office-based.***

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	CMS proposes to assign CPT code 38222 (Diagnostic bone marrow; biopsy(ies) and aspiration(s)) a non-office-based payment indicator -- "G2" – for CY 2020, given CY 2018 data shows this code was not performed predominantly in physicians' offices. CMS proposes to designate 7 new CY 2020 CPT codes for ASC covered surgical procedures as temporarily office-based (see Table 31) based on its review of clinical characteristics, utilization, and volume of related procedure codes.	
ASC Covered Surgical Procedures To Be Designated as Device-Intensive	CMS proposes to update the ASC CPL to indicate procedures that are eligible for payment according to its device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2018 OPPS claims and cost report data available for this proposed rule. For CY 2020 and subsequent calendar years, CMS proposes to only apply its device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices).	***These policies are finalized.*** (p. 753) The ASC covered surgical procedures that are designated as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2020, are assigned payment indicator "J8" and are included in ASC Addendum AA to the CY 2020 OPPS/ASC final rule.
Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices	CMS is not proposing any changes to its existing policies finalized in the CY 2019 OPPS/ASC final rule with comment period.	***CMS did not propose any changes to these policies and finalized continuing its existing policies for CY 2020.*** (p. 759)
Additions to the List of ASC Covered Surgical Procedures	CMS proposes to update the list of ASC covered surgical procedures by adding a mosaicplasty procedure and three coronary intervention procedures (including their add-on procedures) to the list for CY 2020 (See Table 32). CMS proposes to add total knee arthroplasty (TKA) to the ASC CPL (see Table 32). CMS seeks public comment on methods to ensure beneficiaries receive surgical procedures in the ASC setting only as clinically appropriate. Options CMS identifies include: • A claims-based modifier to indicate the physician believes that the beneficiary would not be expected to require active medical	***CMS finalized its proposal to add three coronary intervention procedures as well as three associated add-on procedures*** (p. 767) ***as well as its proposal to add mosaicplasty to the ASC CPL for CY 2020*** (p. 780). With support from many comments, ***CMS finalized its proposal to add TKA, CPT code 27447, to the ASC CPL for CY 2020 and subsequent years.*** CMS did not finalize additional requirements on adding a modifier or requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare. (p. 772) CMS received requests to add additional services to the ASC CPL (Table 58), but declined to add these codes.

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	monitoring and care at midnight following a particular procedure furnished in the ASC setting, • requiring that an ASC has a defined plan of care for each beneficiary following a surgical procedure, and • establishing certain requirements for ASCs that choose to perform certain surgical procedures on Medicare patients, such as requiring an ASC to have a certain amount of experience in performing a procedure before being eligible for payment for performing the procedure under Medicare. CMS solicits comment on these options, and other options, for ensuring that beneficiaries receive surgical procedures, including TKA, that do not pose a significant safety risk when performed in an ASC. CMS also solicits comment on how it should think about the role of the ASC-CPL compared to State regulations and market forces in providing payment for certain surgical procedures in an ASC and whether any modifications should be made to the ASC-CPL. Finally, CMS seeks comment on how its proposed additions to the list of ASC covered surgical procedures might affect rural hospitals to the extent rural hospitals rely on providing such procedures. **Comment Solicitation on Coronary Intervention Procedures.** As noted above, CMS proposes to add three coronary intervention procedures (along with the codes describing their respective add-on procedures). CMS also reviewed several other coronary intervention procedures but did not believe the procedures (see Table 33) met the agency's criteria for inclusion on the ASC CPL at this time. However, CMS solicits comment on whether stakeholders believe they can be safely performed in an ASC setting and to provide any materials supporting their position.	Table 60 shows all additions to the ASC CPL for CY 2020, including the 8 procedures CMS added to the ASC CPL above, and 12 new CPT and new HCPCS codes effective January 1, 2020 that CMS inadvertently omitted from its CY 2020 OPPS/ASC proposed rule. **Comment Solicitation on Coronary Intervention Procedures.** Given public comments, CMS agrees that coronary invention procedures listed in Table 59 would expose beneficiaries to significant safety risk if performed in an ASC setting at this time and would not meet CMS' criteria established under § 416.166(b).
Covered Ancillary Services	CMS proposes to continue its policy of updating the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2020 OPPS.	CMS notes that all ASC covered ancillary services and their proposed payment indicators for CY 2020 are included in Addendum BB to the CY 2020 OPPS/ASC proposed rule One commenter requested that CMS add CPT code 91040 *(Esophageal balloon distension study, diagnostic, with provocation when performed)* to the list of covered ancillary services, but CMS declined since they did not agree it was integral to the performance of other procedures. (p. 785)

Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services (p. 786)

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Update to ASC Covered Surgical Procedure Payment Rats for CY 2020	CMS proposes to update ASC payment rates for CY 2020 and subsequent years using the established rate calculation methodologies and using the definition of device-intensive procedures. CMS proposes to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2." CMS proposes to calculate payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") according to established policies and, for device intensive procedures, using the modified definition of device-intensive procedures. As such, CMS proposes to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2020 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Note that payment for office-based procedures would be at the lesser of the proposed CY 2020 MPFS nonfacility PE RVU-based amount or the proposed CY 2020 ASC payment amount calculated according to the ASC standard ratesetting methodology. For CY 2020, CMS proposes to continue its policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.	***CMS finalized its proposed policies without modification, to calculate the CY 2020 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures.*** For covered office-based surgical procedures, the payment rate is the lesser of the final CY 2020 MPFS nonfacility PE RVU-based amount or the final CY 2020 ASC payment amount calculated according to the ASC standard ratesetting methodology, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2020. ***CMS finalized its proposed APC assignment and payment indicators for CPT codes 36465, 36466, 31298, 36482, and 36902.*** CMS assigned CPT codes 36465, 36466, and 31298 to a P2 payment indicator; CPT code 36482 to a P3 payment indicator; and CPT code 36902 to a G2 payment indicator. (p. 790) ***CMS also finalized the payment indicators for HCPCS codes C9754 and C9755 and CPT codes 37243, 53854, 22869, and 22870 for CY 2020.*** (p. 792) Finally, CMS continues to disagree with commenters about its unlisted CPT surgical procedure codes policy, and will not add these codes to the ASC CPL list. (p. 792)
Limit on ASC Payment Rates for Low Volume Device-Intensive Procedures	To address concerns where large differences in cost calculations occur, CMS proposes to limit the ASC payment rate for low-volume device intensive procedure to a payment rate equal to the OPPS payment rate for that procedure. Where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, CMS proposes to establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. CMS proposes to add regulatory language to require that low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the same procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.	***CMS finalized its proposed policy to limit the ASC payment rate for a low-volume device-intensive procedure to a payment rate equal to the OPPS payment rate for that procedure, including its proposed regulation text at § 416.171(b)(4).*** (p. 797)

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Payment for Covered Ancillary Services	CMS proposes to update the ASC payment rates and to make changes to ASC payment indicators to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2020 OPPS and ASC payment rates and subsequent year payment rates. CMS also proposes to continue to set the CY 2020 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2020 and subsequent year payment rates. CMS does not propose to add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) as a covered ancillary service. Based on available data and other information related to CPT code 91040, CMS does not believe this diagnostic test is integral to the covered surgical procedures of CPT codes 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple).	Covered ancillary services and their proposed payment indicators for CY 2020 are listed in Addendum BB of the CY 2020 OPPS/ASC proposed rule (which is available via the Internet on the CMS website).
CY 2020 ASC Packaging Policy for Non-Opioid Pain Management Treatments	As required by the SUPPORT Act, CMS will continue to review and revise ASC payments for non-opioid alternatives for pain management, as appropriate.	With support from multiple commenters, ***CMS will to continue to unpackage and pay separately at ASP+6 percent for the cost of nonopioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2020. Also, CMS will continue to analyze the issue of access to non-opioid alternatives in the OPPS and ASC settings as it implements section 6082 of the SUPPORT Act and section 1833(i)(8).*** (p. 813) In this section, CMS notes that multiple commenters supported the proposal to continue unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies, such as Exparel, in the ASC setting for CY 2020. According to CMS, preliminary data suggest that utilization of Exparel has increased significantly in the ASC setting in 2019. CMS intends to continue to monitor Exparel utilization in the ASC setting and monitor whether there is an associated decrease under Part B or D in opioids once more data are available. (p. 804) CMS believes separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies, like Exparel, when furnished in the ASC setting and finalized this policy for CY 2020. (p. 813) CMS notes that several commenters suggested separate payment for continuous peripheral nerve blocks as they significantly reduce opioid use. The commenters also said that separate payment for A4306 would remove

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		the financial disincentive for HOPDs and ASCs and encourage continuous nerve blocks as a non-opioid alternative for post-surgical pain management. CMS responded that the geometric mean cost for A4306 was approximately $30 from CY 2014 – CY 2017, and that while these may help in the reduction of opioid use, packaged payment does not prevent their use. CMS said it would consider the suggestion regarding the need for separate payment for A4306 in future rulemaking. (p. 809) Also, multiple comments also identified other non-opioid pain management alternatives (e.g., continuous nerve blocks (neuromodulation, radiofrequency ablation, implants for lumbar stenosis, protocols (ERAS®) IV acetaminophen, IV ibuprofen, Polar ice devices for postoperative pain relief, THC oil, acupuncture, and dry needling procedures) that they believe decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) and may warrant separate payment for CY 2020. CMS responded that it has not found compelling evidence for other non-opioid pain management alternatives described above to warrant separate payment under the OPPS or ASC payment systems for CY 2020, however CMS plans to take these comments and suggestions into consideration for future rulemaking. (p. 812)
Calculation of the ASC Payment Rates and Conversion Factor (p. 819)		
Calculation of the ASC Payment Rates	The proposed CY 2020 ASC weight scalar is 0.8452.	***The final CY 2020 ASC weight scalar is 0.8550.*** (p. 826)
Updating the ASC Conversion Factor	For CY 2020, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the MFP-adjusted hospital market basket update factor of 2.7 percent, which results in a proposed CY 2020 ASC conversion factor of $47.827 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.7 percent discussed above, which results in a proposed CY 2020 ASC conversion factor of $46.895.	***The final CY 2020 conversion factor is $47.747.*** (p. 836) ***CMS finalized the hospital market basket update of 3.0 percent minus the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.6 percent for ASCs meeting the quality reporting requirements.*** (p. 834) CMS reminded stakeholders that it intends to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and potentially propose a plan to collect such information over a 5-year period. (p. 833)

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Hospital Outpatient Quality Reporting (OQR) Program (p. 837)		
Hospital OQR Program Quality Measures	OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases: CMS proposes to remove this measure under its previously finalized measure removal criteria Factor 8: the costs associated with a measure outweigh the benefit of its continued use in the program. According to CMS, the measure steward is no longer maintaining this measure and there are issues with the measure as specified. This measure would be removed beginning with October 2020 encounters used in the CY 2022 payment determination and for subsequent years.	OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases: ***CMS finalized a modification of what was proposed for the removal of OP-33 from the Hospital OQR Program. Instead of removing the measure beginning with October 2020 encounters as inadvertently stated, CMS finalized removal beginning with January 2020 encounters used in the CY 2022 payment determination and for subsequent years*** (p. 849). Table 61 summarizes the finalized Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years.
	Measures and Topics for Future Consideration. *Request for Comment on the Potential Future Adoption of Four Patient Safety Measures*: CMS seeks comment on the potential future adoption of four patient safety measures for the Hospital OQR Program that were previously adopted for the ASCQR Program: • ASC-1: Patient Burn: assesses the percentage of admissions experiencing a burn prior to discharge; • ASC-2: Patient Fall: assesses the percentage of admissions experiencing a fall; • ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant: assesses the percentage of admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant • ASC-4: All-Cause Hospital Transfer/Admission: assesses the rate of admissions requiring a hospital transfer or hospital admission upon discharge	**Measures and Topics for Future Consideration.** *Request for Comment on the Potential Future Adoption of Four Patient Safety Measures* (p. 851). Several commenters suggested that these measures should be specified for the HOPD setting, field tested, reliability tested, and reviewed by the Measure Applications Partnership (MAP) before inclusion in the Hospital OQR Program. Others expressed concern that the measures are not endorsed by the National Quality Forum. CMS will take these suggestions into consideration as it considers adding these measures to the Hospital OQR Program in the future.
	Future Outcome Measures: CMS is moving towards greater use of outcome measures and away from clinical process measures across its Medicare quality reporting programs. As such, CMS requests comment on any outcome measures that would be useful to ad, as well as feedback on any process measures that should be eliminated from the Hospital OQR Program to further its goal of developing a comprehensive set of quality measures for informed decision-making and quality improvement in HOPDs.	*Future Outcome Measures* (p. 861): A few commenters recommended that CMS add more measures to the Hospital OQR Program that would align with the ASCQR Program, and CMS agreed that such alignment is important. Other commenters suggested that CMS incorporate patient experience, safety and reliability, and provider engagement measures in the Hospital OQR Program, while another suggested that CMS include the Adult Immunization Status measure in the Hospital OQR Program. CMS will take these suggestions into consideration as it develops future Hospital OQR Program measures and topics.
Payment Reduction for Hospitals that	CMS proposes to continue: • Its established policy of applying the reduction of the Outpatient Department (OPD) fee schedule increase factor through the use of	***For the CY 2020 OPPS, the final reporting ratio is 0.981, which when multiplied by the final full conversion factor of 80.784 equals a final conversion factor for hospitals that fail to meet the requirements of the***

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Fail to Meet the Hospital OQR Program Requirements for CY 2020 Payment Determination	a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2020 annual payment update factor. For the CY 2020 OPPS, the proposed reporting ratio is 0.980. • To apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2020 OPPS, it proposes to apply the reporting ratio, when applicable, to all HCPCS codes to which CMS has proposed status indicator assignments of "J1", "J2", "P", "Q1", "Q2", "Q3", "R", "S", "T", "V", and "U" (other than new technology APCs to which CMS has proposed status indicator assignment of "S" and "T"). • To exclude services paid under New Technology APCs. • To continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. • To continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. • To continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.	***Hospital OQR Program (that is, the reduced conversion factor) of 79.250. CMS finalized the remainder of its proposals regarding the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements*** (p. 875).
ASC Quality Reporting (ASCQR) Program (p. 875)		
New Quality Measure for the ASCQR Program Measure Set	CMS proposes to adopt ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357) into the ASCQR Program for the CY 2024 payment determination and subsequent years. CMS also proposes that if the proposed ASC-19 measure is adopted, it would publicly report results only for facilities with sufficient case numbers to meet moderate reliability standards.	***CMS finalized its proposal to adopt ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers for the CY 2024 payment determination and subsequent years*** (p. 907). A few commenters expressed concern that because the measure assesses mainly skin and soft tissue procedures, it assesses only a small subset of the procedures performed in ASCs. CMS clarified that the measure focuses only on the subset of surgeries on Medicare's list of covered ASC procedures that impose a meaningful risk of post-procedure hospital visits. In response to a concern that some hospital visits post procedure may be due to a patient's underlying condition (e.g., for "Lumpectomy, quadrantectomy of breast and Mastectomy" procedures), CMS clarified that the measure is adjusted to account for variation in patients' underlying risk of using the hospital within 7 days of a procedure. Therefore, the measure

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		score is designed to reflect differences in quality rather than differences in pre-procedure patient risk. Further, CMS noted that this measure is designed to include only unplanned inpatient admissions occurring after general surgery procedures performed at ASCs. For more information on the measure calculation in regard to planned versus unplanned admissions, we refer readers here. In this section, CMS also addressed concerns about the measure having inadequate reliability. CMS tested the measure and does not believe that it is necessary increase the minimum number of qualifying procedures for reliability purposes as it views the measure as having a sufficient level of reliability for adoption by the ASCQR Program. It is also consistent with current ASCQR Program claims-based measures of hospital visits post-specified procedures in the ASC setting, as well as with similar outcome measures endorsed by NQF. Finally, some commenters found the title of this measure confusing, including the fact that the title refers to General Surgery Procedures and may mislead beneficiaries by suggesting that the score reflects the practice of general surgery, rather than "abdominal, alimentary tract, breast, skin/soft tissue, wound, and varicose vein stripping procedures" specifically. CMS opted not to change the title since it had previously revised it from Hospital Visits after General Surgery Ambulatory Surgical Center Procedures to, Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers to clarify the scope of the procedures included in the measure's cohort. Table 63 summarizes the finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years (including previously adopted measures).
ASCQR Program Measures and Topics for Future Consideration	CMS requests comment about, in the future, potentially updating the data submission method to a CMS online data submission tool for the following measures: ASC-1: Patient Burn, ASC-2: Patient Fall, ASC-3: Wrong Site, Side, Patient, Procedure Implant, and ASC-4: All-Cause Hospital Transfer/Admission.	CMS will take comments into consideration as it determines future updates to these measures.
Payment Reduction for ASCs That Fail to Meet the	The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act, any annual increase shall be reduced by 2.0	CMS did not propose any changes or receive any comments on these policies.

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ASCQR Program Requirements	percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program.	

Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) (p. 927)

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Revision of the Definition of "Expected Donation Rate" (p. 927)		
	Due to an oversight, CMS did not make a corresponding change to the definition in the CfCs for OPOs at the time that the Scientific Registry of Transplant Recipients (SRTR) made its change. Thus, CMS proposes to change its requirements so that it is consistent with the SRTR's definition for the second outcome measure. • This change would take effect on the effective date of the final rule with comment period, which would occur during the 2022 recertification cycle. • Because the final regulation change would not be retroactive and, in order to give OPOs adequate time to comply with the change to the definition for "expected donation rate," CMS proposes to reduce the time period for the observed donation rate for the second outcome measure for the 2022 recertification cycle only. • It proposes to calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2020). • After the 2022 recertification cycle, and if there are no other changes to the OPO outcome measures, CMS would assess OPO performance based on 36 months of data.	After reviewing comments, ***CMS agrees that using 12 out of the 24 months of data may have unintended consequences on OPOs and the recertification process, and therefore CMS is not finalizing this proposal***. ***CMS is finalizing a policy that would not require all OPOs to meet the standards of the second outcome measure for the 2022 recertification cycle only. CMS is requiring OPOs to meet one of the two other outcome measures in order to be recertified (the OPO's donation rate measure and aggregate donor yield measure) for the 2022 recertification cycle only***. By deferring the use of the new standard, CMS would ensure that no OPOs would be prejudiced by the limited time period and OPOs that may not be able to meet the second measure due to limitations of the data or other variables as described by the commenters would not be decertified based only on the changed regulation. ***If no subsequent changes are made to the outcome measure requirements via rulemaking, the new definition of "expected donation rate" will apply after the 2022 recertification cycle***. OPOs must continue to comply with the other CfCs and continue their quality improvement efforts through their Quality Assurance and Performance Improvement (QAPI) program.
Request for Information Regarding Potential Changes to the to the OPO and Transplant Center Regulations (p. 932)		
	Since the OPO and the transplant center regulations were finalized, CMS has received substantial feedback from the organ procurement and transplant communities recommending modifications to the current requirements. Thus, CMS seeks input regarding what revisions may be appropriate for the current CfCs for OPOs that are set forth at 42 CFR 486.301 through 486.360 and the current CoPs for transplant centers that are set forth at 42 CFR 482.68 through 482.104. Specific issues of interest to CMS are listed on p. 664. CMS also solicits comment on whether the following two potential OPO outcome measures would be valid measures and would be consistent with statutory requirements. CMS is especially interested in comments about the validity and reliability of these possible measures: • A potential measure evaluating the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or	CMS received a wide range of comments in response to this RFI. CMS will continue to review these for future rulemaking and potential revisions to the CfCs for OPOs and the CoPs for transplant centers.

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	younger with a cause of death consistent with organ donation. The data on inpatient deaths, including additional related demographic data, would be derived from the CDC Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report • A potential measure evaluating the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. This measure also would reward efforts to maximize total organ procurement and efforts to improve placements of all procured organs CMS is also interested in comments on appropriate parameters for these measures: • How should it determine what percentage indicates that an OPO's performance is acceptable or successful? • If commenters cannot recommend a specific percentage, how should CMS determine what the parameters for the outcome measures should be?	

Clinical Laboratory Fee Schedule: Revisions to Laboratory Date of Service Policy (p. 934)

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	CMS provides background on its laboratory date of service (DOS) policies. CMS is considering three options for potential changes to the laboratory DOS exception at § 414.510(b)(5) discussed above, and CMS seeks comment on these changes as follows. 1. Changing the Test Results Requirement at 42 CFR 414.510(b)(5)(iv); 2. Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs; and/or 3. Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5).	CMS again reviewed the current laboratory DOS policy (p. 934); the 14-day rule (p. 935); billing and payment rules under the OPPS (p. 938); payment for advanced diagnostic laboratory tests (ADLTs) under the Clinical Laboratory Fee Schedule (CLFS) (p. 940); and an additional laboratory DOS policy exception for the hospital outpatient setting (p. 941).
Potential Revisions to Laboratory DOS Policy and Request for Public Comments (p. 947)		
Changing the Test Results Requirements at 42 CFR 414.510(b)(5)(iv)	CMS is considering a revision to its current laboratory DOS policy at § 414.510(b)(5)(iv) to specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under § 414.510(b)(5) are met. Under this approach, the test would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter: • If the ordering physician determines that the test results are not intended to guide treatment during the hospital outpatient encounter from which the specimen was collected or during a future hospital outpatient encounter, the DOS service of the test would be the date of test performance. In this situation, the test would not be considered a hospital service and the performing laboratory would be required to bill for the test. • Conversely, if the ordering physician determines that the results of the laboratory test are intended to guide treatment during a hospital outpatient encounter, the DOS would be the date of specimen collection. As a result, the hospital that collected the specimen would bill for the laboratory test under arrangements and the laboratory would seek payment from the hospital for the test. CMS is requesting comments from hospitals, laboratories, physicians and non-physician practitioners, and other interested stakeholders regarding	***CMS is not finalizing any change to test requirements at 42 CFR 414.510(b)(5)(iv).*** (p. 957) CMS details comments and responses starting on p. 951, noting agreement with commenters' concerns that the potential change would reduce beneficiary access, be inconsistent with clinical practice, increase burden and administrative complexity, and be inconsistent with CMS policy related to services performed outside the hospital outpatient setting.

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	this potential revision to the laboratory DOS exception at § 414.510(b)(5). CMS is particularly interested in comments regarding its position that when the results of molecular pathology testing and Criterion (A) ADLTs are intended to guide treatment during a future hospital outpatient encounter, the test is a hospital service. CMS also is interested in receiving public comments regarding the administrative aspects of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter, as well as the process for the ordering physician to document this decision and provide notification to the hospital that collected the specimen for billing purposes.	
Limiting the Laboratory DOS Exception at 42 CFR 414.510(b)(5) to ADLTs	CMS is considering a potential revision that would limit the laboratory DOS provisions of § 414.510(b)(5) to tests designated by CMS as an ADLT under paragraph (A) of the definition of an ADLT in § 414.502. Molecular pathology tests would be removed from the provisions of § 414.510(b)(5). However, CMS notes that molecular pathology tests would still be subject to the 14-day rule and chemotherapy sensitivity test laboratory DOS exceptions. CMS is requesting comments on potentially limiting the laboratory DOS exception policy at § 414.510(b)(5) to Criterion (A) ADLTs that have been granted ADLT status by CMS.	***CMS is not finalizing its potential revision to limit the laboratory DOS policy exception at 414.510(b)(5) to laboratory tests that have been granted criterion (A) ADLT status by CMS.*** (p. 962) CMS details comments and responses starting on p. 960, noting agreement with commenters' concerns that the potential change could harm patient access to care and increase burden. Commenters specifically raised the following concerns: • Many of the same beneficiary access issues that exist for ADLTs apply to molecular pathology tests (p. 960), so the policy would lead to delayed test orders and concerns about timely beneficiary access. (p. 961) • Many molecular pathology tests are performed by a single laboratory for specific clinical indications (or a few laboratories), and few "kits" have been approved by the FDA. (p. 960) • Hospitals rarely perform molecular pathology tests (p. 960) and would not have the capability or resources to perform specialized testing. (p. 961) • The policy would result in administrative burden for hospitals, laboratories, and CMS. (p. 963)
Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception at 42 CFR 414.510(b)(5)	Stakeholders informed CMS that blood banks and blood centers perform some of the molecular pathology test codes that are subject to the laboratory DOS exception policy at § 414.510(b)(5). However, blood banks and blood centers perform molecular pathology tests for different reasons (e.g. to identify compatibility of blood products rather than for diagnostic purposes) than billing laboratories. Under the current laboratory DOS exception at § 414.510(b)(5), blood banks or blood centers that perform tests meeting the criteria would have to bill Medicare separately. However, CMS now believes that such testing is so connected to the treatment furnished to the patient in the hospital that it must be considered a hospital service.	***CMS is finalizing the revision to exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). CMS is also revising § 414.510(b)(5) to exclude molecular pathology tests when performed by a laboratory that is a blood bank or center. CMS defining the term "blood bank or center" instead of "blood bank and center" to reflect that a molecular pathology test is excluded when performed by either a blood bank or blood center. CMS is also defining "blood bank or center" at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation. (p. 968)***

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Additional Comments	CMS is considering a regulatory change that would exclude blood banks and centers from the laboratory DOS exception at § 414.510(b)(5). Under this potential revision, the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection. As a result, the hospital would bill for the laboratory test under arrangements and the blood bank or center performing the test would seek payment from the hospital. In addition, for purposes of excluding blood banks and centers from the provisions of § 414.510(b)(5), CMS would define a blood bank and center as an entity whose primary function is the collection, storage and dissemination of blood products. CMS is requesting comments from hospitals, blood banks and centers, and other interested stakeholders regarding a potential revision to laboratory DOS policy that would exclude blood banks and centers from the laboratory DOS exception policy at § 414.510(b)(5). CMS also is requesting specific comments as to how a blood bank and blood center may be defined in the context of this provision, and particularly how to distinguish blood banks and centers from other laboratories.	CMS details comments and responses starting on p. 967, including the following: • Many commenters strongly supported the potential revision, agreeing that the work of blood banks and blood centers is inherently tied to a hospital service. (p. 967) • Many blood banks and centers are typically not Medicare enrolled entities, and therefore cannot bill Medicare directly. As such, requiring compliance with existing DOS policies would create burden and could jeopardize beneficiaries' access to care. (p. 967) • A few commenters recommended changes to the definition of blood banks and blood centers, which were among those finalized by CMS. (p. 968) • In response to comments, CMS clarifies that this policy change categorically excludes molecular pathology testing performed by laboratories that are blood banks or blood centers from the laboratory DOS exception at § 414.510(b)(5). CMS believes the burden on hospitals will be mitigated with this final policy. (p. 970) CMS notes that this policy does not impose any information collection requirements (p. 1048) and will not result in net costs or savings for the Medicare program (p. 1095). CMS addresses additional comments submitted under this topic starting on p. 971. • CMS details two alternative policy proposals submitted by a commenter that would either (1) allow hospitals the flexibility to negotiate with independent laboratories to determine which entity is responsible for billing Medicare for tests subject to the laboratory DOS exception at § 414.510(b)(5) or (2) involve amending the referring laboratory billing for referred laboratory testing provision. CMS declines to adopt these suggestions but states that it will consider the suggestions as it continues to review, evaluate, and refine its laboratory DOS exception policy at § 414.510(b)(5). (p. 971) • Two commenters asked CMS to articulate a final implementation date for the laboratory DOS policy exception at § 414.510(b)(5). CMS clarifies that it has already implemented this policy, but also notes that it has issued consecutive enforcement discretions to allow hospitals and laboratories time to make necessary systems changes. (p. 973)

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		• One commenter requested that CMS apply the same laboratory DOS exception to tests ordered for hospital inpatients. CMS notes that such a change would have broader policy implications that need to be carefully considered. However, CMS intends to continue studying the DOS exception and, if warranted, consider changes for inpatient stays in future rulemaking. (p. 973) • Several commenters requested that CMS add the technical component of physician pathology services, such as in situ hybridization and flow cytometry to the list of test codes subject to the laboratory DOS exception at § 414.510(b)(5). They also requested that molecular tests furnished as technical components of physician pathology services be excluded from OPPS packaging policy and paid at the Medicare physician fee schedule rate. CMS noted that it will consider the suggestions as it continues to refine its DOS policy exception. (p. 974) • A few commenters requested that CMS clarify that the date of performance is the date of a laboratory's final report, but CMS continues to have concerns with this approach and declines to make the requested clarification. (p. 975)