CY 2023 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule Summary

November 4, 2022

On November 1, 2022, the Centers for Medicare and Medicaid Services (CMS) issued the final rules for the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2023.

The CY 2023 final rule is 1,764 pages in length and located in its entirety at the following link: https://www.cms.gov/files/document/cy2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf . The format of the following information is intended to serve as a summary to the changes and readers are encouraged to view the document in its entirety for further details.

Highlights

- CMS finalized a 3.8 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the market update from the Inpatient Prospective Payment System (IPPS) of 4.1 percent and a minus 0.3 percent productivity adjustment.
    - CMS estimates total payments to HOPPS providers will be approximately $86.2 billion, an increase of approximately $6.2 billion compared to CY 2022 HOPPS payments.
    - CMS finalized a 3.8 percent productivity-adjusted hospital market basket update factor to the ASC rates. The update applies to ASCs meeting relevant quality reporting requirements and is based on the hospital market basket percentage increase of 4.1%, reduced by 0.3 percentage point for the productivity adjustment. CMS is anticipating a $130 million increase in payments to ASCs over CY 2022.
- CMS will continue to apply a 2 percent reduction to the conversion factor for hospitals that fail to meet the hospital quality reporting requirements.
- CMS finalized payments rates for new technology algorithm-driven services that assist practitioners in making clinical assessments, and providers pay for either on a subscription or per-use basis which CMS refers to as Software as a Service (SaaS). Payment will be made for Optellum LCP and QMRCP at $650.50 and $950.50 respectively.
- Due to the impact related to the COVID-19 public health emergency (PHE) and pandemic, CMS used claims data for ratesetting, but the CY 2019 cost reports (which lag a year behind claims data) rather than CY 2020.
- CMS changes to the Inpatient Only list did not include any services performed by interventional radiologists.
- CMS finalized changes for CY 2023 for clarification and consistency for definitions related to physician supervision and to revise certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law. Revisions were also made to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends.

- CMS finalized excepting 25 APCs from the 2 times rule violation. Typically, codes within the APCs violating this rule would need to be moved or a new APC created. CMS finalized allowing the classifications to continue as they all met the exception criteria.

Within the following pages are expanded details and explanations of the key highlights pertinent to interventional radiology as outlined above.

Payment Rates

CMS proposed to use CY 2021 claims data for ratesetting for CY 2023 which follows the usual 2-year difference in data for ratesetting due to allowance for 1-year of timely filing for billing. However, CMS proposed to use the CY 2019 hospital cost report data instead of CY 2020. Cost reports submitted to CMS by hospitals lag one year behind the claims data and CMS continues to believe the data from 2020 may create issues for ratesetting.

CMS finalized a 3.8 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the market update from the Inpatient Prospective Payment System (IPPS) of 4.1 percent and a -0.3 percent productivity adjustment decrease. CMS finalized a conversion factor (CF) of $85.585 for hospitals meeting the reporting criteria and applying the 2 percent reduction to those that do not with a CF equal to $83.934. CMS estimates total payments to HOPPS providers will be approximately $86.2 billion, an increase of approximately $6.2 billion compared to CY 2022 HOPPS payments.

CMS finalized a productivity-adjusted hospital market basket update factor to the ASC rates for CY 2023 of 3.8 percent. The update applies to ASCs meeting relevant quality reporting requirements and is based on the hospital market basket percentage increase of 4.1 percent, reduced by 0.3 percentage point for the productivity adjustment.

CMS is anticipating a $130 million increase in payments to ASCs over CY 2022.

For CY 2023, in light of the Supreme Court's decision in *American Hospital Association v. Becerra*, CMS finalized a general payment rate of Average Sale Price (ASP) plus 6% for drugs and biologicals acquired through the 340B Program, consistent with its policy for drugs not acquired through the 340B program. As required by statute, CMS is implementing a –3.09% reduction to the payment rates for non-drug services to achieve budget neutrality for the 340B drug payment rate change for CY 2023. CMS will address the remedy for 340B drug payments from 2018-2022 in future rulemaking prior to the CY 2024 OPPS/ASC proposed rule. CMS noted that claims for 340B-acquired drugs paid after the District Court's September 28, 2022, ruling are paid at the default rate (generally ASP plus 6%). More details are provided later in this summary about the 340B Drug Discount Program updates and alternate impacts to reimbursement as released by CMS to this point.

Wage Index

The Secretary of Health and Human Services (HHS) is required to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs, and accounting for the differences in labor-related costs across the country within defined geographic regions in a budget neutral manner. The labor-related portion of the set payment by CMS is 60 percent of the national rate and the other 40 percent is attributed to non-labor.

The wage index values as finalized through the Inpatient Prospective Payment System (IPPS), which runs on a fiscal year calendar of October 1 -September 30, are used under HOPPS. This is due to most outpatient hospitals having inpatient services as well. For those that do not, CMS assigns a wage index as if they were paid under IPPS, based on their geographic location and any applicable wage index policies and adjustments.

CMS finalized to continue applying a wage index of 1.0000 for frontier state hospitals, this policy has been in place since CY 2011. This ensures the lower population states are not "penalized" for reimbursement due to the low number of people per square mile when compared to other states.

CMS finalized for FY 2023 and subsequent years to apply a 5 percent cap on any decreases to a hospital's wage index from the previous year's wage index. The wage index for FY 2023 will not be less than 95 percent of the finalized wage index for FY 2022 and will continue for subsequent years where the wage index for a given year would not be less than 95 percent of final wage index for the prior year. This adjustment will also apply to outpatient hospitals.

CMS also finalized to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the HOPPS to determine the wage adjustments for both the HOPPS payment rate and the copayment rate for CY 2023. Any policies and adjustments for the FY 2023 IPPS post-reclassified wage index will be reflected in the final CY 2023 OPPS wage index beginning on January 1, 2023.

Standardizing Ambulatory Payment Classifications (APCs) Payment Weights

Ambulatory payment classifications (APCs) group services which are considered clinically comparable to each other with respect to the resources utilized and the associated costs. CMS finalized their intent *to continue using HCPCS code G0463, hospital outpatient clinic visit for assessment and management of a patient*, in APC 5012 (Level 2 Examinations and Related Services) as the standardized code for the relative payment weights. A relative payment weight of 1.00 is to be assigned to APC 5012 (code G0463).

For CY 2023, CMS finalized continuing to pay code G0463 at a payment rate of 40 percent of the HOPPS rate for any outpatient off-campus hospital setting, excepted and nonexcepted. This continues to be the method for controlling the overutilization of this code in the outpatient setting.

CMS also finalized for CY 2023 to exempt excepted off-campus provider-based departments (PBDs) (departments that bill the modifier "PO" on claim lines) of rural Sole Community Hospitals and designated as rural for Medicare payment purposes. CMS recognizes the use of the clinic visit in some settings is supported even if it means the rate is higher than in another. This is due to concerns for beneficiaries and access to quality care. To ensure this is possible there are several special payment provisions for rural providers, the exemption of the clinic visit payment policy is one of them. Rather than paid at 40 percent of the HOPPS rate, the clinic visit payment policy applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, these settings would be paid at 100 percent of the HOPPS rate.

Complexity Adjustment Payments in Ambulatory Surgical Centers

CMS provides complexity adjustments to hospitals for certain services as part of comprehensive ambulatory payment classifications (C-APCs). When multiple C-APC services with the designated status indicator (SI) "J1" are performed together, CMS assigns the payment to the next highest paying C-APC of same clinical family. A C-APC assigns payment for all ancillary services pertinent to the primary service assigned SI "J1" packaged into the primary code.

In the ambulatory surgical center (ASC) C-APCs are not used because of system limitations for processing ASC claims for payment. ASC claims are processed as normal claims with separately payable procedure codes. When multiple procedures are performed together in an ASC, the procedure code with the lower payment is paid at 50 percent of the amount assigned. This is due to the duplicative use of resources while still providing a payment for the work done because add-on codes are not separately paid in the ASC.

Over the years CMS has received comments from stakeholders concerned the payments for services in the ASC, already paid at a much lower rate than hospitals, and the lack of complexity adjustments incentivizes procedures in the hospital setting. In response for CY 2023, CMS evaluated differences in payments for HOPPS and ASC code pairs that included a primary procedure and add-on codes eligible for complexity adjustments under HOPPS and also performed in the ASC setting.

CMS found 26 packaged procedures in ASCs with SI "N1" that combine with 42 primary procedures as C-APCs in hospitals. CMS estimated ASCs were paid approximately 55 percent of the HOPPS rate for similar services in CY 2021. When they compared the complexity adjustment for hospitals of the C-APCs and add-on codes to the payment rates for same code combinations in ASCs, the average payment rate for the ASC was 25 to 35 percent of the HOPPS rate, which is significantly lower than the 55 precent.

Due to the significant disparity in payment for the same services in hospital vs. ASC, CMS finalized for CY 2023 combinations of a primary procedure code and add-on codes eligible for a complexity adjustment under the HOPPS would be eligible for a complexity adjustment in the ASC setting. ASC payment system code combinations eligible for additional payment will consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list.

CMS assigned each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are only valid for hospital and ASCs, they cannot be billed in office-based settings or by physicians paid under the Medicare Physician Fee Schedule (MPFS). The new C codes will be added to the ASC CPL and when an ASC bills the C code, they will be paid the higher payment rate which includes the code combination for the more complex and costlier procedure performed. CMS expects the list of codes would be adjusted annually to account for changes in procedures and payments.

If the procedures part of a C code is performed with other services not part of the C code, CMS will apply the multiple procedure reduction as part of their policy. Device intensive procedures may also be assigned a C code and the calculation of the payment rate using the HOPPS complexity-adjusted C-APC rate will account for the portion of the device when determining the full adjustment.

The following table is a portion of the CY 2023 ASC Addenda AA file which lists the finalized C codes for the complexity adjustments with their corresponding payment rates. Several of the procedures which are eligible for complexity payments are performed by interventional radiologists.

Addendum AA – Final ASC Covered Surgical Procedures for CY 2023

HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Final CY 2023 Comment Indicator	Final CY 2023 Payment Indicator	Final CY 2023 Payment Weight	Final CY 2023 Payment Rate
C7500	Deb bone 20 cm2 w/drug dev	N	NC	G2	20.6832	$1,072.51
C7501	Perc bx breast lesions stero	N	NC	G2	20.6832	$1,072.51
C7502	Perc bx breast lesions MR	N	NC	G2	20.6832	$1,072.51
C7503	Open exc cerv node(s) w/ id	N	NC	G2	46.4624	$2,409.26
C7504	Perq cvt&ls inj vert bodies	N	NC	G2	60.5171	$3,138.05
C7505	Perq ls&cvt inj vert bodies	N	NC	G2	60.5171	$3,138.05
C7506	Fusion of finger joints	N	NC	G2	60.5171	$3,138.05
C7507	Perq thor&lumb vert aug	N	NC	G2	124.0889	$6,434.51
C7508	Perq lumb&thor vert aug	N	NC	G2	124.0889	$6,434.51

C7509	Dx bronch w/ navigation	N	NC	G2	27.2566	$1,413.36
C7510	Bronch/lavag w/ navigation	N	NC	G2	27.2566	$1,413.36
C7511	Bronch/bpsy(s) w/ navigation	N	NC	G2	27.2566	$1,413.36
C7512	Bronch/bpsy(s) w/ ebus	N	NC	G2	27.2566	$1,413.36
C7513	Cath/angio dialcir w/aplasty	N	NC	R2	27.8465	$1,443.95
C7514	Cath/angio dial cir w/stents	N	NC	R2	27.8465	$1,443.95
C7515	Cath/angio dial cir w/embol	N	NC	R2	27.8465	$1,443.95
C7516	Cor angio w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7517	Cor angio w/ilic/fem angio	N	NC	G2	44.8773	$2,327.07
C7518	Cor/gft angio w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7519	Cor/gft angio w/ flow resrv	N	NC	G2	44.8773	$2,327.07
C7520	Cor/gft angio w/ilic/fem ang	N	NC	G2	44.8773	$2,327.07
C7521	R hrt angio w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7522	R hrt angio w/flow resrv	N	NC	G2	44.8773	$2,327.07
C7523	L hrt angio w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7524	L hrt angio w/flow resrv	N	NC	G2	44.8773	$2,327.07
C7525	L hrt gft ang w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7526	L hrt gft ang w/flow resrv	N	NC	G2	44.8773	$2,327.07
C7527	R&L hrt angio w/ ivus or oct	N	NC	G2	44.8773	$2,327.07
C7528	R&L hrt angio w/flow resrv	N	NC	G2	44.8773	$2,327.07
C7529	R&L hrt gft ang w/flow resrv	N	NC	G2	44.8773	$2,327.07
C7530	Cath/aplasty dial cir w/stnt	N	NC	G2	88.3120	$4,579.33
C7531	Angio fem/pop w/ us	N	NC	J8	105.7203	$5,482.02
C7532	Angio w/ us non-coronary	N	NC	J8	102.0024	$5,289.23
C7533	PTCA w/ plcmt brachytx dev	N	NC	J8	106.5754	$5,526.36
C7534	Fem/pop revasc w/arthr & us	N	NC	J8	194.5291	$10,087.11
C7535	Fem/pop revasc w/stent & us	N	NC	J8	192.8382	$9,999.43
C7537	Insrt atril pm w/L vent lead	N	NC	J8	194.7346	$10,097.77
C7538	Insrt vent pm w/L vent lead	N	NC	J8	194.1979	$10,069.94
C7539	Insrt a & v pm w/L vent lead	N	NC	J8	197.9109	$10,262.47
C7540	Rmv&rplc pm dul w/L vnt lead	N	NC	J8	194.5441	$10,087.89
C7541	ERCP w/ pancreatoscopy	N	NC	G2	43.8422	$2,273.39
C7542	ERCP w/bx & pancreatoscopy	N	NC	G2	43.8422	$2,273.39
C7543	ERCP w/otomy, pancreatoscopy	N	NC	G2	43.8422	$2,273.39
C7545	Exch bil cath w/ rmv calculi	N	NC	G2	43.8422	$2,273.39
C7546	Rep nph/urt cath w/dil stric	N	NC	G2	28.8611	$1,496.56
C7547	Cnvrt neph cath w/ dil stric	N	NC	J8	33.4466	$1,734.34
C7548	Exch neph cath w/ dil stric	N	NC	G2	28.8611	$1,496.56
C7549	Chge urtr stent w/ dil stric	N	NC	G2	28.8611	$1,496.56
C7550	Cysto w/ bx(s) w/ blue light	N	NC	G2	28.8611	$1,496.56
C7551	Exc neuroma w/ implnt nv end	N	NC	G2	50.7505	$2,631.62

Multiple Imaging Composite APC

CMS finalized its proposal to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. Standard APC assignments will continue to apply for single imaging procedures and multiple imaging procedures performed across imaging families. A single imaging session performed "with contrast" is part of a composite APC when at least one or more imaging procedures from the same family are also performed with contrast on the same date of service. For example, if a hospital performs one MRI without contrast during the same session as one with, the payment rate will be for the "with contrast" composite APC.

The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

Table 3 within the CY 2023 HOPPS final rule contains the imaging families and multiple imaging procedures for the composite APCs.

APC Assignments for LDCT

CMS assigned CPT® 71271 (*Low Dose CT for Lung Cancer Screening*) to APC 5522 with a payment rate of $106.88. CMS placed G0296 (*visit to determine lung LDCT eligibility*) in APC 5822 with a payment rate of $75.85.

Procedures Assigned to New Technology APC Groups for CY 2023

When new technology is assigned a billing code the establishment of a payment rate by CMS can be difficult because there is no claims data to determine utilization and cost by the hospital. Due to this CMS created New Technology APCs which are similar to pass-through payments for new drugs, biologicals, radiopharmaceuticals and devices. The new technology is assigned to a temporary APC until claims data is available, typically this is a minimum of two years, but can be less if there is sufficient data available sooner. Once there is sufficient data the new technology is moved to a clinically appropriate APC.

To be considered new technology by CMS the following criteria must be met:

- Service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC;
- Service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and
- Service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary.

When new technology does have claims data but there are less than 100 claims a year, this is also considered low volume. To establish a payment rate for Low Volume APCs CMS will use up to four years of claims data to establish a payment rate. CMS will calculate the cost from the claims data using the value which is the highest, arithmetic mean cost, median cost, or geometric cost over the four-year period.

CMS finalized payments rates for the following new technology algorithm-driven services that assist practitioners in making clinical assessments, and providers pay for either on a subscription or per-use basis which CMS refers to as Software as a Service (SaaS). CMS has stated they will not recognize codes 0722T and 0724T as add-on codes. According to CMS these codes do not fit their description of add-on codes. However, they will reimburse these codes separately under APCs 1508 and 1511 respectively.

CPT® Code	Trade Name	Long Descriptor	Final CY 2023 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 National Rate
0721T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508	S	$650.50
0722T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	1508	S	$650.50
0723T	QMRCP	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	1511	S	$950.50
0724T	QMRCP	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	1511	S	$950.50

Supervision by NPPs of Hospital and CAH Diagnostic Services Furnished to Outpatients

Supervision requirements for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests paid under the MPFS are outlined at the code level in the files provided by CMS. Prior to 2020 and the waivers and provisions related to the COVID-19 pandemic, only physicians were allowed to supervise the performance of diagnostic tests as defined by Medicare guidelines. An exception was made to ensure an adequate number of

health care professionals were available to support critical COVID-19-related and other diagnostic testing needs and provide needed medical care during the PHE as outlined in the President's Executive Order 13890 on ''Protecting and Improving Medicare for Our Nation's Seniors.'' This directed the Secretary of HHS to identify and modify Medicare regulations that contained more restrictive supervision requirements than existing scope of practice laws, or limited healthcare professionals from practicing at the top of their license.

CMS has finalized changes for CY 2023 for clarification and consistency for definitions related to physician supervision and to revise certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

CMS also finalized updates to the definitions for general and personal supervision. Previously, direct supervision is the only one that indicated "supervising practitioner" as the person who can supervise the procedure. The definitions for general and personal both refer to only a physician providing the level of supervision. Revisions were also made to extend the end date of the flexibility allowing for the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) from the end of the PHE to the end of the calendar year in which the PHE ends.

Applications for Device Pass-Through Status for CY 2023

CMS received eight complete applications for consideration of device pass- through status. One of the applications was from Elucent Medical, Inc. for the SmartClip™ Soft Tissue Marker. Per the applicant it is an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. The SmartClip™ delivers independent coordinates of location when used in conjunction with the applicant's EnVisio™ Navigation System. Per Elucent Medical, Inc. at time of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm x 50cm x 35cm volume. The SmartClip™ contains an application-specific integrated circuit (ASIC), customized for use with the EnVisio™ Navigation System, which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision. The applicant asserted this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D.

CMS has determined that the SmartClip™ device does not meet the newness or substantial clinical improvement criteria, and therefore, is not eligible for approval for transitional pass-through payment status for CY 2023. They are not making a determination on the cost criteria in this final rule.

Another application was received for the Evoke® Closed-Loop Spinal Cord Stimulation (SCS) System. The Evoke® SCS System is a rechargeable, upgradeable, implantable spinal cord stimulation system that provides closed-loop stimulation controlled by measured evoked compound action potentials (ECAPs). This technology is used in the treatment of chronic intractable pain of the trunk and/or limbs. CMS agreed that Evoke® met all criteria and finalized approval for transitional pass-through payment (TPT), including that it provides a substantial clinical improvement over open loop, legacy SCS systems. A new device category and HCPCS code are available for the Evoke® SCS System effective January 1, 2023. The HCPCS code is C1826. This code should be included on the facility claim, along with the associated charges for the Evoke® implant and charger.

340B Drug Discount Program

The 340B Drug Discount Program was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992 and is administered by the Health Resources and Services Administration (HRSA) within HHS. This program allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers.

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (does not include drugs on pass-through payment status or vaccines) to be reimbursed at the rate of ASP minus 22.5 percent. This was significantly different than the previous rate of ASP+6 percent.

Since this payment policy was updated in CY 2018 there has been significant litigation which has resulted in varying decisions, some which favored the plaintiff and some which favored the defendant (CMS). In response to those rulings, the payment policy for the 340B Drug Discount Program has had some adjustments back and forth between the ASP+6 percent and ASP -22.5 percent.

On June 1, 2022, the Supreme Court filed a decision in *the American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 case. Originally, in December 2018, the United States District Court for the District of Columbia concluded the HHS Secretary lacked the authority to bring the default rate in line with average acquisition cost unless the Secretary obtained survey data from hospitals. CMS appealed to the United States Court of Appeals for the District of Columbia Circuit, and on July 31, 2020, the court entered an opinion reversing the District Court's judgment in this matter. Plaintiffs then petitioned the United States Supreme Court for a writ of certiorari, which was granted on July 2, 2021.

On June 15, 2022, the Supreme Court reversed the decision of the D.C. Circuit, citing HHS may not vary payment rates for drugs and biologicals among groups of hospitals under section 1833(t)(14)(A)(iii)(II) in the absence of having conducted a survey of hospitals' acquisition costs. The decision by the Supreme Court concerned the payments for CYs 2018 and 2019 but has implications for CY 2023.

Utilizing the separately paid line items with modifier "JG" in the CY 2021 claims available for HOPPS ratesetting, which is the modifier used to identify drugs purchased under the 340B Drug Discount Program, the estimated payment differential would be an increase of approximately $1.96 billion in HOPPS drug payments. To ensure budget neutrality CMS would apply this offset of approximately $1.96 billion to decrease the HOPPS conversion factor, resulting in a budget neutrality adjustment of 0.9596 to the HOPPS conversion factor, for a revised conversion factor of $83.279. CMS is maintaining their policy to require 340B hospitals to report the "JG" and "TB" modifiers for informational purposes, but they will have no impact on payment rates.

For CY 2023, in light of the Supreme Court decision in *American Hospital Association v. Becerra*, CMS is applying the default rate, generally ASP plus 6 percent, to 340B acquired drugs and biologicals in the final rule with comment period for CY 2023 and removing the increase to the conversion factor that was made in CY 2018 to implement the 340B policy in a budget neutral manner.

CMS is still evaluating how to apply the Supreme Court's decision to prior calendar years. In the CY 2023 OPPS/ASC proposed rule, the organization solicited public comments on the best way to craft any potential remedies affecting cost years 2018-2022 and will take these comments into consideration for separate rulemaking that will be published in advance of the CY 2024 OPPS/ASC proposed rule.

Submitting Comments

Comments to CMS regarding the HOPPS final rule must refer to file code **CMS-1772-FC** and be received no later than **5 pm EST January 1, 2023.** Electronic submission is encouraged by CMS, http://www.regulations.gov. Follow the instructions under the "submit a comment" tab.