CY 2021 Final Rule Summary
Provided for SIR
Hospital Outpatient Prospective Payment System (HOPPS)
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Introductory Summary

On December 2, 2020, the Centers for Medicare and Medicaid Services (CMS) issued the final rules for the Hospital Outpatient Prospective Payment System (HOPPS or OPPS) for CY 2021.

HOPPS Final Rule

The CY 2021 final rule is 1312 pages in length and located in its entirety at the following link: https://www.cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf. The format of the following information is intended to serve as a summary to the final changes and readers are encouraged to view the document in its entirety for further details.

Payment Rates

CMS is increasing payment rates under the Outpatient Department (OPD) fee schedule by 2.4 percent to the conversion factor. The CY 2021 conversion factor is finalized to be $82.797; however, for hospitals that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements, CMS will continue the 2 percent reduction to the conversion factor when calculating reimbursement. Utilizing values set as part of the inpatient prospective payment system (IPPS) CMS estimates the total payments to OPPS providers for CY 2021 will be approximately $1.61 billion compared to the CY 2020 OPPS payments.

With the increase to the fee schedule payments it is estimated urban hospitals will see an increase in payments of approximately 2.6 percent and rural hospitals will see increases of 2.9 percent. CMS will continue to maintain the rural adjustment factor of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs) for CY 2021 and subsequent years. This payment adjustment will continue to exclude separately payable drugs, biologicals and devices paid under the pass-through payment policy.

Wage Index

CMS will continue applying a wage index of 1.000 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.

In response to population shifts between urban and rural located hospitals, CMS had proposed in both FY 2021 IPPS and CY 2021 OPPS/ASC rules, an adjustment to wage indexes utilizing the Office of Management and

Budget (OMB) updated delineations applied to the IPPS post-reclassified wage index. The wage indexes for IPPS are used for OPPS ratesetting as they are both hospitals and many inpatient hospitals have outpatient services.

When calculating the reimbursement for a particular service, the APC payment rate is multiplied by 60 percent of the labor related to the service and the wage index assigned per the geographic location of the hospital, this is added to the APC rate multiplied by 40 percent of the nonlabor related share of the work. The wage index is a key component in determining the specific reimbursement of the services provided as tied to the geographic labor force.

To limit the potentially significant impact to hospitals where the revised OMB delineations would result in a decrease in the wage index from CY 2020 to CY 2021, CMS proposed and finalized a 5 percent cap on any wage index decrease. This will be a one-year cap effective January 1, 2021.

Standardizing APC 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. Ancillary services or items which are necessary components of the primary service are packaged into the APC rates and not separately reimbursed. CMS instructs providers to apply current procedure-to-procedure edits and then report all remaining services on the claim form. CMS will only pay for those services which are considered not packaged into another service.

CMS will 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 proposed to be assigned to APC 5012 (code G0463). CMS will use the factor of 1.00 and then dividing the geometric mean cost of each APC by the geometric mean cost of APC 5012 to derive the unscaled relative payment weight for each APC.

In CY 2020 CMS fully implemented changes in reimbursement to code G0463 for all off-campus departments, regardless if they had been excepted for payment of other outpatient services. This was due to the high volume of reporting for the outpatient clinic visit and what CMS believed was *"unnecessary increases in the volume of outpatient service."* To remove any incentivization in billing G0463, the most widely reported outpatient services code, CMS finalized a site-neutral method for reimbursement.

Any setting considered off-campus, more than 250 yards from the main buildings of the hospital, designated as either excepted or nonexcepted, CMS will reimburse code G0463 at 40 percent of the on-campus outpatient reimbursement rate. Due to the high rate change, CMS implemented the reduction over a two-year period (2019 and 2020), rather than all at once.

In September 2019 a lawsuit was filed in the United States District Court for the District of Columbia, stating Health and Human Services Secretary, Alex Azar, had overstepped his authority to set a site neutral policy for reimbursement of the clinic visit services. In the CY 2020 final rule, CMS indicated they were working to ensure 2019 claims were paid consistent with the court's ruling but continued with the reduction in 2020. On July 17, 2020, the United States Court of Appeals for the District of Columbia ruled in favor of CMS; indicating the changes made by CMS were reasonable in their interpretation of adopting methods for controlling unnecessary increases in the volume of relevant services.

For CY 2021, code G0463 will continue to be reimbursed a payment rate of 40 percent of the HOPPS rate for any outpatient off-campus hospital setting. The national rate for G0463 in 2021 is $118.74. The national rate for any off-campus provider, excepted and nonexcepted, will be $47.50 for code G0463, while the national rate for on-campus outpatient departments will be $118.74 in 2021.

Cost-to-Charge Ratio (CCRs) Calculation

In the hospital CMS calculates a cost-to-charge ratio (CCR) to assist in setting the base rate for OPPS reimbursement. Most CCRs are calculated at the hospital-specific department level and based on reports submitted to CMS of the cost for services incurred by the hospital. In 2014, CMS finalized the policy to add a cost center for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT), and cardiac catheterization. Stakeholder feedback at the time indicated most hospitals used a less precise "square feet" allocation method for cost reporting of large moveable equipment like CT and MRI machines. CMS suggested reporting by "direct assignment" or "dollar value", rather than "square feet".

To calculate the imaging ambulatory payment classification (APC) relative payment weights, CMS would remove the claims in which the hospitals used the "square feet" to calculate their cost of related services as they did not believe this was accurate to include in the ratesetting. Due to stakeholder pushback CMS delayed the policy of using all claims data regardless of how the costs were calculated. CMS believes the use of more claims data will result in a more accurate ratesetting process.

Effective CY 2021, CMS is moving forward with including all claims for cost reporting, even those submitted by hospitals which continue to use "square feet" rather than "dollar value" or "direct assignment". In response to comments received to the OPPS proposed rule, CMS indicated they had provided hospitals six years to adopt the more accurate method for reporting and believed this to be more than enough time to adjust. This transition by CMS is important because it not only impacts hospital reimbursement, but also nonfacility reimbursement paid under the Physician Fee Schedule (PFS).

The Deficit Reduction Act (DRA) of 2005 requires Medicare to limit payments for certain imaging services covered by PFS to not exceed what Medicare pays for these services under OPPS. For certain imaging services the technical component under PFS cannot be paid more than the applicable year OPPS payment amount. The potential CCRs when calculating all claims for the CT and MRI imaging centers will likely result in reimbursement decrease. Any OPPS decrease in payment will impact the PFS technical reimbursement as well since they are tied together by law.

The table below reflects the estimated reimbursement for a sample of CT and MR imaging codes from 2020 to 2021, which may not entirely be attributed to the CCR calculation alone. It is possible with additional payment information updates by CMS these values and impacts could change.

HCPCS Code	Short Descriptor	2020 National Payment Rate	2021 National Payment Rate	Variance	% of Change
72131	Ct lumbar spine w/o dye	$ 112.08	$ 108.97	$ (3.11)	-3%
72132	Ct lumbar spine w/dye	$ 381.85	$ 368.12	$ (13.73)	-4%
72133	Ct lumbar spine w/o & w/dye	$ 182.22	$ 178.55	$ (3.67)	-2%
72148	Mri lumbar spine w/o dye	$ 233.04	$ 230.13	$ (2.91)	-1%

72149	Mri lumbar spine w/dye	$	381.85	$	368.12	$	(13.73)	-4%
72158	Mri lumbar spine w/o & w/dye	$	381.85	$	368.12	$	(13.73)	-4%

Ambulatory Payment Classification Updates CY 2021

Ambulatory Payment Classifications (APCs) are groups of services which are clinically comparable to the use of resources to provide the service. All services (codes) associated with an APC are paid the exact same amount. If the resources and cost of services changes enough that the code with the highest cost of resources is more than 2 times that of the code with the lowest cost, CMS must adjust the placement of codes. This would be considered a 2 times rule violation and to correct it, codes would need to be moved to other APCs which better match resource cost or create a new APC for identified services.

Over the past few years, CMS has been providing an exception to the identified 2 times rule violations. The belief is many will work themselves out in the next claims data period with more accurate reporting. CMS had originally identified 18 APCs with 2 times rule violations, in the OPPS final rule they identified another 5 APCs.

Based on stakeholder feedback and further analysis of cost report data, the following table of the identified APCs in violation of the 2 times rule violations will be excepted for CY 2021, no adjustments will be made.

TABLE 9.— APC EXCEPTION TO THE 2 TIMES RULE FOR CY 2021	
Final CY 2021 APC	**Final CY 2021 APC Title**
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures

5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

APC Assignment Changes

Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (APC 5593)

CMS had proposed to reassign CPT® 78803 *(Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect), single area (eg, head, neck, chest, pelvis), single day imaging)* from APC 5593 *(Level 3 Nuclear Medicine and Related Services)* which has a CY 2021 payment rate of $1,305.94 to APC 5592 *(Level 2 Nuclear Medicine and Related Services)* which has a CY 2021 payment rate of $489.40. After feedback and review of updated claims data, CMS is not finalizing the move as proposed, CPT® 78803 will remain in APC 5593 for CY 2021 and will review again for the next rulemaking.

Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (non-HEU) Sources (APC 1442)

Radioisotopes like Technetium-99 (Tc-99m) are extremely common in diagnostic medical imaging. Tc-99m is commonly produced in reactors outside the United States using highly enriched uranium (HEU). The US has been promoting elimination of the dependence on the outside reactors to produce medical radioisotopes. To incentivize this, CMS pays an additional $10 for the cost of radioisotopes produced from non-HEU sources. Hospitals would report HCPCS code Q9969 *(Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose)* once per dose along with the imaging code for doses certified to be at least 95 percent produced from non-HEU sources.

CMS received a request to increase the additional payment of $10 since it has not been changed since 2013. After review of comments, CMS is finalizing their proposal to continue to pay an additional $10 for non-HEU sources for CY 2021 and subsequent years when HCPCS Q9969 is billed.

Remote Physiological Monitoring (APC 5741)

Over the last few years there has been an increase in the coding available for remote physiological monitoring. In the hospital setting, CMS uses claims data and cost reporting to set the payment rates for services. Many of the services which are included under the remote physiological monitoring (RPM) category of codes CMS has not separately reimbursed. There are a few with set rates, but most as recent final rules were set as not billable to Medicare Administrative Contractors (MACs) as they were not paid under OPPS or had been adjusted as not recognized under OPPS and may be paid by the MACs.

Requests were made to CMS to adjust some of the RPM codes, for example CPT® 90991, for payment similar to other RPM codes. CMS indicated they needed to further review the code along with all RPM service codes to determine if payable under OPPS. For CY 2021, CMS did make some modifications to a few of the RPM codes, this elevated some codes from not billable to MACs to they can be billed to MACs and any payment is their discretion. Other services will remain as originally established, either not billable to the MACs, up to the MAC for determination, or a G-code which CMS created and does recognize as active and separately reimbursed.

Table 34 Final SI Assignments for the Remote Physiological Monitoring, Virtual Check-ins, E-visits, Telephone E/M, an Medicare Therapy Management Codes can be found in the CY 2021 OPPS final rule with the proposed and finalized payment status indicators.

Multiple Imaging Composite APC

CMS will 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 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 4 within the CY 2021 HOPPS final rule contains the imaging families and multiple imaging procedure for the composite APCs.

Brachytherapy Sources

CMS did not propose any significant changes to how reimbursement for brachytherapy sources is calculated. CMS proposed and finalized to use costs derived from CY 2019 claims data to set the CY 2021 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator (SI) "U". Codes with SI "U" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

CMS will continue to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi).

CMS will continue to assign HCPCS code C2645 (Brachytherapy planar, p-103), a status indicator (SI) "U" (Brachytherapy Sources, Paid under OPPS; separate APC payment) and continue the payment rate for C2645 at $4.69 per mm^2, in the absence of sufficient claims data under their equitable adjustment authority.

Hospitals and other parties are invited to submit recommendations to CMS for new codes to describe new brachytherapy sources. Recommendations can be directed to Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. CMS will continue to add new brachytherapy source codes and descriptors on a quarterly basis.

The following table reflects the estimated national payment by Medicare for a sampling of brachytherapy sources in the on-campus outpatient hospital setting.

HCPCS Code	Short Descriptor	2021 APC	2020 National Payment Rate	2021 National Payment Rate	Variance	% Change
A9513	Lutetium lu 177 dotatat ther	9067	$ 259.17	$ 266.59	$ 7.42	2.9%
A9606	Radium ra223 dichloride ther	1745	$ 138.82	$ 140.96	$ 2.15	1.5%
C1717	Brachytx, non-str,hdr ir-192	2646	$ 322.02	$ 334.69	$ 12.67	3.9%
C2616	Brachytx, non-str,yttrium-90	2616	$ 17,091.57	$ 17,397.64	$ 306.07	1.8%
C2634	Brachytx, non-str, ha, i-125	2634	$ 181.91	$ 148.09	$ (33.82)	-18.6%
C2635	Brachytx, non-str, ha, p-103	2635	$ 56.38	$ 45.55	$ (10.83)	-19.2%
C2636	Brachy linear, non-str,p-103	2636	$ 36.03	$ 31.40	$ (4.63)	-12.9%
C2638	Brachytx, stranded, i-125	2638	$ 34.55	$ 37.40	$ 2.85	8.2%
C2639	Brachytx, non-stranded,i-125	2639	$ 35.64	$ 34.10	$ (1.54)	-4.3%
C2640	Brachytx, stranded, p-103	2640	$ 83.60	$ 87.75	$ 4.15	5.0%
C2641	Brachytx, non-stranded,p-103	2641	$ 69.39	$ 69.50	$ 0.11	0.2%
C2642	Brachytx, stranded, c-131	2642	$ 76.71	$ 71.86	$ (4.85)	-6.3%
C2643	Brachytx, non-stranded,c-131	2643	$ 95.72	$ 80.35	$ (15.37)	-16.1%
C2645	Brachytx planar, p-103	2648	$ 4.69	$ 4.69	$ -	0.0%
C2698	Brachytx, stranded, nos	2698	$ 34.55	$ 37.40	$ 2.85	8.2%
C2699	Brachytx, non-stranded, nos	2699	$ 35.64	$ 31.40	$ (4.24)	-11.9%

Payments of Drugs, Biologicals and Radiopharmaceuticals

Each year CMS assesses the drug packaging threshold in accordance with section 1833(t)(16)(B) of the Act. For CY 2021, CMS proposed and finalized to package drugs and biologicals estimated at a per day administration cost less than or equal to $130, in CY 2020 this was also set at $130. CMS also proposed and finalized continuation of separate payment for items with an estimated per day cost greater than $130 with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

Payment rates for HCPCS codes for separately payable drugs and biologicals are published in Addenda A and B Average Sales Price (ASP) data from the first quarter of CY 2020. This published data will be used for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2020. These payment rates will also be updated in the January 2021 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2021. For items that do not currently have an ASP-based payment rate, CMS will recalculate their mean unit cost from all of the CY 2019 claims data.

CMS proposed and finalized to continue the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological, but in different dosages. For all other drugs and biologicals that have HCPCS codes describing different doses, Medicare aggregated the CY 2019 claims data and pricing information at ASP+6 percent for all HCPCS codes that describe each distinct drug or biological. This provided the mean units per day in terms of the HCPCS code with the lowest dosage

descriptor. For other drugs and biologicals that have HCPCS codes describing different doses, CMS multiplied the weighted average ASP+6 percent per unit, across all dosage levels of a specific drug or biological, by the estimated units per day for all HCPCS codes that describe each drug or biological to determine the estimated per day cost of each drug or biological at less than or equal to the CY 2021 drug packaging threshold of $130.

For CY 2021, CMS will continue the current payment policy in effect since CY 2013. This payment policy pays for separately payable drugs and biologicals at ASP+6 percent. These separately payable drugs and biologicals are listed in Addenda A and B to the final rule. CMS will also continue to pay for separately payable non-pass-through drugs acquired with a 340B discount at ASP-22.5 percent, see section on 340B Drug Program for more details.

For drugs or biologicals without sufficient data on sales price during the initial sales period, section 1847A(c)(4) of the Act allows for payments based on Wholesale Acquisition Cost (WAC). The Act defines certain payments must be made with a 6 percent add-on; however, the Act does not require the same add-on amount when utilizing WAC-based pricing. CMS will utilize a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs. For drugs and biologicals acquired under the 340B Program, the 340B Program rate (WAC minus 22.5 percent) would apply.

CMS previously finalized the payment policy for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act in CY 2016 and CY 2017. For CY 2021, CMS will continue the policy finalized in CY 2019 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. CMS will also continue to pay non-pass-through biosimilars acquired under the 340B Program at 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 proposed and finalized to expire pass-through status for several drugs and biologicals on December 31, 2020. These drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2020. A section of Table 36 is provided below detailing drugs and biologicals to be removed from the pass-through list.

Table 36.– Drugs and Biologicals for Which Pass-Through Payment Status Would Expire December 31, 2020

CY 2020 HCPCS Code	CY 2020 Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2020

Medicare finalized several drugs and biologicals to continue pass-through payment status for CY 2021. For CY 2021, CMS will continue to pay for pass-through drugs and biologicals at the ASP+6 percent and continue to update pass-through payment rates on a quarterly basis through the CMS website. A section of the HOPPS Table 37 is provided below detailing the drugs and biologicals commonly utilized within oncology or hematology

which are expiring pass-through status for CY 2021. Table 38 identifies the drugs which are continuing pass-through status in CY 2021.

Table 37 –Drugs and Biologicals with Pass-Through Payment Status Expiring During CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass Through Payment Effective Date	Pass Through Payment End Date
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
A95950	A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021

Table 38 – Drugs and Biologicals with Pass-Through Payment Continuing Through CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass Through Payment Effective Date	Pass Through Payment End Date
C9060	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
N/A	C9068	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9387	01/01/2021	12/31/2023

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.

HRSA calculates the ceiling price for each covered outpatient drug, which is the average manufacturer price (AMP) minus the unit rebate amount (URA). This ceiling price represents the maximum price a drug manufacturer can charge a covered entity for the drug. It is noted, covered entities have the option to participate in HRSA's Prime Vendor Program (PVP), which may allow for negotiation of additional discounts (known as "subceiling prices").

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 the implementation of the drastic reduction in reimbursement for drugs purchased under 340B program (ASP-22.5 percent) lawsuits have been filed alleging CMS does not have the authority to make these changes. Recent litigation concluded, for CY 2018, Secretary Azar "*exceeded his statutory authority*" by adjusting the reimbursement rate to ASP-22.5 percent.

The United States District Court for the District of Columbia concluded the Health and Human Services (HHS) Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. HHS disagreed with this ruling but moved forward

with surveying hospitals which are part of the 340B program. During this time, CMS appealed the final judgement entered on July 10, 2019 and on July 31, 2020 the D.C. Circuit reversed the district court's earlier judgement.

In response to the initial district court findings which stated CMS could base Medicare payment amount on average acquisition cost of drugs purchased under the 340B Program, CMS announced through the Federal Register they intended to conduct the survey for certain quarters within CYs 2018 and 2019.

The survey was sent to 100 percent of the hospitals that acquired drugs under the 340B Programs and were paid for the drugs under HOPPS in fourth quarter 2018 and/or first quarter 2019. The survey, which closed May 15, 2020, provided two options for responding, Detailed Survey or Quick Survey.

Results of the survey included:

- 7 percent responded and completed the Detailed Survey
- 55 percent responded and completed the Quick Survey
- 38 percent did not respond to either option

When a hospital did not have cost data for a particular drug to report as part of the Detailed Survey, because they did not administer it during the survey timeline, or for those hospitals that did not respond, CMS utilized 340B ceiling prices.

In response to the results of the survey, CMS determined a single reduction amount to average sales price (ASP) was the better option than calculating individual cost acquisition amounts for 340B-acquired drugs. This also ensured the confidentiality of the data obtained through the survey and protected the sensitive pricing information.

After applying several factors to determine the reduction, CMS also utilized the same ASP+6 percent factor applied to all drugs with pass-through status. CMS theorized all drugs were afforded the same ASP+6 percent factor regardless of how they were purchased. This final adjustment resulted in a proposed 340B Drug Program discount of ASP minus 28.7 percent for CY 2021.

Drugs for which the ASP was unavailable, CMS proposed an adjustment for 340B drugs using the Wholesale Acquisition Cost (WAC) minus 34.7 percent plus 6 percent for the drug's WAC, except where policy directs the WAC is plus 3 percent. Drugs paid at Average Wholesale Price (AWP) would continue with the similar logic as in the past, payment 95 percent AWP first reduced by 6 percent which would align with ASP and WAC pricing. This would result in 63.90 percent of AWP.

After consideration of stakeholder feedback and to maintain consistent and known payment for drugs acquired under 340B Program for the remainder of the public health emergency (PHE) and after it is declared over, CMS is finalizing their alternate proposal of continuing ASP minus 22.5 percent. This would continue the payment policy that has been in effect since 2018 and include continued reporting of modifier JG on claims with drugs purchased under the program.

CMS will continue to exempt rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. In addition, they would still be required to report modifier TB for 340B-acquired drugs on claim forms and paid at ASP+6 percent. CMS would continue to pay for drugs not

purchased under the 340B program at ASP+6 percent. Drugs and biosimilar biologicals acquired under 340B program and furnished in on-campus hospital departments, excepted off-campus provider-based departments, and nonexcepted off-campus provider-based departments paid under MPFS will be paid at ASP minus 22.5 percent. Biosimilar biological products will be paid at minus 22.5 percent of the biosimilar's ASP, not the reference drug's ASP.

Changes to Supervision of Non-Surgical Extended Duration Therapeutic Services

There are specific non-surgical services identified by CMS that have an extended duration, meaning they may run several hours to complete, like drug administration. Some of these services will have an initial supervision level assigned, and when it is determined the patient is stable and the remainder of the service can be provided under general supervision, the level is changed. These services have had a hybrid level of supervision and are termed non-surgical extended duration services (NSEDTS). Multiple drug administration services are assigned to this group including:

HCPCS Code	Short Descriptor
96365	Ther/proph/diag iv inf init
96367	Tx/proph/dg addl seq iv inf
96368	Ther/diag concurrent inf
96369	Sc ther infusion up to 1 hr
96371	Sc ther infusion reset pump
96374	Ther/proph/diag inj iv push
96375	Tx/pro/dx inj new drug addon

To maintain alignment with the general supervision guidelines established by CMS in 2020 for all therapeutic services and in response to the public health emergency (PHE) for COVID-10, CMS also adjusted the initial period of nonsurgical extended duration therapeutic services (NSEDTS) to general supervision. This allowed physicians to provide the services as necessary in response to COVID-19 without being tied up in other services which could be conducted under general supervision.

For CY 2021, CMS proposed and finalized to permanently change the minimum level of supervision for NSEDTS to general for the entire services, this would include the initiation which had previously required direct supervision. CMS does stress this is to the discretion of the hospital, whether or not the change to general supervision for a given scenario is in the best interest of the patient. This change allows for flexibility of the hospital on a case-by-case basis but provides hospitals the opportunity to also require direct supervision during any part of the NSEDTS as appropriate.

Final Payment for Therapeutic Radiopharmaceuticals

New drugs, biologicals and radiopharmaceuticals are granted pass-through status by Medicare as a means of establishing a transitional payment until enough data is acquired to determine if the new agent is to be paid separately or packaged into an APC. For CY 2021, CMS will continue providing payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on average sales priced (ASP)

methodology, as CMS considers these to be drugs under HOPPS. The ASP methodology is the ASP +6 percent; however, if no ASP data is available, CMS is proposing to provide pass-through payment at whole acquisition cost (WAC) of +3 percent, which is 3 percent less than currently paid. If that is not available, then payment will be 95 percent of average wholesale price (AWP). CMS will also continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021.

Radiation Oncology (RO) Model – Waiver of Proposed Rulemaking

On July 10, 2019 the Centers for Medicare and Medicaid Services (CMS) released the proposed rule *Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures,* which outlined payment models for radiation oncology and end-stage renal disease treatment choices. This summary will only focus on the radiation oncology model (RO Model).

On September 18, 2020 CMS released the final rule related to the RO Model with an expected start date of January 1, 2021, lasting for five years with a set end date of December 31, 2025. Due to stakeholder feedback about the significant challenges in beginning the new payment model in early 2021, CMS released notification of intention to delay the start date to July 1, 2021.

Within the CY 2021 OPPS final rule CMS officially delayed the start of the RO Model and outlined the changes within performance year one (PY1) as a result of the delay. CMS indicated the delay was to ensure participation in the model during the PHE did not further strain participant ability to implement the changes will still effectively treating patients in a safe and efficient manner. The 6-month delay is intended to provide participants the opportunity to prepare and more appropriately learn the model components, to train staff on the new procedures, and prepare for the new quality measure reporting which begins in 2022.

The following is a succinct list of the changes to the RO Model as finalized in the CY 2021 OPPS final rule. As the start date approaches CMS is conducting webinars and additional education on the model, it is possible there may be additional changes add to the RO Model not identified or published at this time.

- Start date of July 1, 2021 ***will not*** require a re-randomization of ZIP Codes selected to participate and posted to CMS website
- RO Model will be a 4.5-year model beginning July 1, 2021 and ending December 31, 2025.
    - PY1 will be 6 months, each performance year after that (PY2-PY5) will be 12 months
- Due to delay in model start, CMS predicts the savings will still be able to reach the 3.75 percent threshold
- Low-volume opt-out eligibility for each PY will be determined as follows:
    - PY3 eligibility will be determined by a mix of both episodes (first 6 months of 2021) and RO episodes (last 6 months of 2021)
    - PY4 and PY5 will be determined by RO episodes
- Quality measure reporting
    - Quality measures requirement will be delayed until PY2 (January 1, 2022 – December 31, 2022), RO participants must report quality data measures for PY2 in March 2023
    - Quality measures finalized in the RO Model final rule will continue to be the quality measures reported, unless CMS specifies different individual measure specifications
    - Three measures will be pay-for-performance

        - (1) Plan of Care for Pain;
        - (2) Screening for Depression and Follow-Up Plan; and
        - (3) Advance Care Plan
    - Fourth measure will be pay-for-reporting measure
        - Treatment Summary Communication—Radiation Oncology
        - Data collected will be used to propose a benchmark and re-specify as pay-for-performance measure for PY4
- CMS-approved contractor to administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy delayed
    - Original start date April 2021, will be delayed beginning October 2021
- Clinical data element (CDE) reporting
    - CDE collection will begin January 1, 2022
    - Frist submission of CDEs for January 1, 2021 – June 30, 2022 due in July 2022
- Quality payment withholds
    - No quality payment withhold (2 percent) in PY1
    - Beginning PY2 2 percent withhold will be applied to the trended national base rates after the case mix and historical experience adjustments
- Reconciliation Payments
    - No quality reconciliation payment amount PY1 for Professional and Dual participants
        - Payment reconciliation based solely on incorrect episode payment amount and any stop-loss amount if applicable
- Advanced Payment Model (APM) Status
    - Expect RO Model to meet criteria for both Advanced APM MIPS (Merit-based Payment System) APM under Quality Payment Program (QPP) staring PY2
    - Delay in RO Model start, RO participants will not be eligible for 5 percent APM Incentive Payment for Qualifying APM Participants (QPs) in PY1 based on participation in RO Model
- Certification of individual practitioner list
    - PY1 all requirements will still be in effect to certify participants
    - PY1 the list will only be used for QPP to assign automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants
    - PY2 individual practitioner list used to identify relevant eligible clinicians in determining QP determinations related to QPP
    - Dual and Professional participants must certify the individual practitioner list within 30 days of receipt
- Certified Electronic Health Record Technology (CEHRT) requirements
    - To begin PY2, January 1, 2022
    - Annual certification required for PY2 – PY5