Association of Community Cancer Centers
CY 2021 MPFS and HOPPS Proposed Rule Highlights
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Medicare Physician Fee Schedule (MPFS) Proposed Changes

Payment Rates

CY 2021 marks the second year in which there is no specific increase to the conversion factor (CF) as it is frozen and CY 2020's CF, pending any adjustments due to budget neutrality. As part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), beginning in CY 2020 the CF is frozen at the previous year's value with no increases for the next five years. The CY 2020 CF is $36.0896, this value is still used for CY 2021 with direct adjustment.

The Center for Medicare and Medicaid Services (CMS) budget must be maintained within $20 million plus or minus each year. When it is projected the impact from any Relative Value Unit (RVU) changes will be outside the expected budget, a budget neutrality factor is applied to the CF to bring it back into range and maintain budget neutrality. CMS is applying a minus 10.61 percent budget neutral adjustment to the CF, which will result in an overall decrease in payments for CY 2021, with a CF value of $32.2605.

Table 88 from the proposed ruling outlines the projected impacts:

CY 2021 Conversion Factor		**36.0896**
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.61 percent (0.8939)	
CY 2021 Conversion Factor		**32.2605**

This significant decrease is not proposed to impact all specialties the same. Impacts to the CF are predominantly related to changes associated to misvalued codes, phasing in of Direct Practice Expense equipment value changes, and largely to the increases in valuation for evaluation and management (E/M) services, which will be discussed later in this summary. To account for increases impacting some specialties, monies must be reallocated from other specialties to cover and maintain budget neutrality.

The following table outlines the combined impact per specialty including Radiation Oncology and Radiation Therapy Centers, Hematology/Oncology, and Radiology regarding RVU changes for CY 2021.

TABLE 90: CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact**
Hematology/Oncology	$1,702	9%	5%	1%	14%
Radiation Oncology and Radiation Therapy Centers	$1,803	-3%	-3%	0%	-6%

** Column F may not equal the sum of columns C, D, and E due to rounding.

Proposed Valuation of Specific Codes for CY 2021

Within the CY 2021 proposed rule publication, CMS addressed quite a few of the misvalued and/or proposed value changes to specific series of new and established Current Procedural Terminology (CPT®) codes. CMS explains the rationale for the proposed changes are based on values recommended by the Relative Value Scale Update Committee (RUC) and other organizations which CMS looks to for assistance in setting appropriate values for codes.

One of the new codes for CY 2021 is 7615X, *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist).* This code appears to be tied to radiation oncology with the specific indication of the medical physicist and dosimetrist within the definition, but it is listed under the radiology section of codes as it is outside the 77xxx series specific to radiation oncology. This new code is a practice expense (PE) only code, which means it is technical only. Per CMS this code is a stand-alone code, the medical physicist works independently from a physician. A PE survey was developed by the specialty societies to assist with establishing values for the code.

Additional review for valuation were provided for radiation therapy treatment delivery codes 77401 for superficial radiation therapy and proton therapy codes 77520, 77522, 77523, and 77525.

CPT® 77401, *Radiation treatment delivery, superficial and/or ortho voltage, per day,* has been addressed over the last few years due to significant changes in the definition and bundling of services into the treatment delivery code. Code 77401 was identified through the screen for high-volume growth with 10,000 or more billed 77401 services in 2017 for Medicare beneficiaries, which increased by at least 100 percent from 2012 to 2017.

After review of the code, CMS is proposing for direct PE refinements to include a reduction of 2 minutes for clinical labor, to the standard 3 minutes. CMS is also proposing to not include the "Lead Room" in the equipment direct PE evaluation due to lack of information on what this specific equipment includes and is requesting additional information.

CMS also reviewed CPT® 77522, *Proton treatment delivery; simple, with compensation,* and CPT® 77523*, Proton treatment delivery; intermediate,* both of which are contractor-priced Category I codes with an estimated 2017 utilization of over 10,000 services. Even though it was determined by the Relative Value Upscale Committee's (RUC) Relativity Assessment Workgroup (AWP) these codes should remain contractor priced, due to the significant equipment invoice pricing.

CMS received invoices for proton treatment delivery equipment pricing which ranged from $19,001,914 and $30,400,000. CMS compared these values to other linac-based treatment delivery machines, such as the SRS Linac invoices recently submitted to CMS for roughly $4,233,825. CMS also noted in the invoices submitted for proton treatment machines was the inclusion of building construction costs. CMS indicated these external costs are building maintenance or office rent under the indirect PE, rather than a direct PE, and should not be included.

Due to this, CMS is proposing the Medicare Administrative Contractors (MACs) continue to set contractor pricing per their respective jurisdictions to allow providers and MACs to more easily adapt to and shift reimbursement in response to market-based costs.

Service Description		TOTAL NON-FACILITY RVUs	
HCPCS	**DESCRIPTION**	**2020 RVU Totals**	**2021 RVU Totals**
7615X	Med physic dos eval rad exps	-	24.89
77401	Radiation treatment delivery	0.69	1.29
77520	Proton trmt simple w/o comp	0.00	0.00
77522	Proton trmt simple w/comp	0.00	0.00
77523	Proton trmt intermediate	0.00	0.00
77525	Proton treatment complex	0.00	0.00

Evaluation and Management (E/M) Guidelines

Evaluation and Management (E/M) visits comprise nearly 40 percent of allowed charges for Physician Fee Schedule (PFS) services, and office/outpatient E/M visits make up nearly 20 percent of the allowed PFS charges. Nearly all specialties utilize and bill for E/M visits, for some this comprises the bulk of their charges. For other specialties that are more procedural based, like radiation oncology, the bulk of services billed are not E/M. Due to the volume of E/M visits billed each year and the fact the guidelines had not been updated since 1995 and 1997, CMS and the AMA have been working to revamp the outpatient new and established patient visits.

After publication of the CY 2019 MPFS final rules, it was clear CMS was making sweeping changes to Evaluation and Management (E/M) guidelines. Most of the changes were slated for CY 2021 as a means to give stakeholders time to prepare and the AMA time to jump on board and align their guidelines with CMS.

In the CY 2020 MPFS proposed ruling, CMS outlined cancelation of most if not all of the proposed changes and adjusted to the initial updates for E/M released by the AMA for CY 2021. CMS indicated they received many thousands of comments to the CY 2020 proposed ruling specific to E/M changes.

CMS is not proposing new changes to the outpatient E/M visits from what was finalized in the CY 2020 final rule, but they did clarify the use of two new E/M related codes for 2021, GPC1X (complex visit code) and 99xxx (prolonged services code). The full definitions of the codes are as follows:

- GPC1X - *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)*
- 99xxx - *Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)*

CMS indicated code GPC1X recognizes the resources involved when practitioners furnish services best-suited to the patients' ongoing care, needs, and evolving illness. The specialty code is only available to certain specialties and it would not be expected as a routine code billed in addition to the E/M visit. Instead it reflects the time, intensity, and practice expense that practitioners will utilize when furnishing services to build long standing relationships, and not just those with chronic conditions or single high-risk issue, over longer periods of time.

Per CMS, "*add-on code GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals.*"

Code 99xxx, for prolonged services, is billed in addition to level 5 new or established patient visit codes, 99205 and 99215. CMS clarified the expectation and application of this code from a time threshold standpoint. For example, code 99215, level 5 established outpatient visit, the time range is 40-54 minutes. According to CMS, if the billing practitioner spent 55 minutes with the patient, they could not bill the prolonged services code in addition to the level 5 visit code. They indicated if they allowed this, the practitioner would be double dipping their time as the prolonged services code represents 15-minute increments. In the scenario presented, the practitioner would be double counting 14 minutes, the last 14 minutes to meet the top threshold for 99215 and the first 14 minutes of the prolonged service to meet the additional 15 minutes.

CMS is proposing that 99xxx for prolonged services, when the practitioner uses the time-based method, the code could be selected when the outpatient office visit level 5 is exceeded by at least 15 minutes on the date of service of the actual visit. The following tables reflect the application of this add-on code with the proposed changes by CMS.

TABLE 22: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient	
CPT Code(s)	**Total Time Required for Reporting***
99205	60-74 minutes
99205 x 1 and 99xxx x 1	89-103 minutes
99205 x 1 and 99xxx x 2	104-118 minutes
99205 x 1 and 99xxx x 3 or more for each additional 15 minutes	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 23: Proposed Prolonged Office/Outpatient E/M Visit Reporting - Established Patient	
CPT Code(s)	**Total Time Required for Reporting***
99215	40 -54 minutes
99215 x 1 and 99xxx x 1	69-83 minutes
99215 x 1 and 99xxx x 2	84-98 minutes
99215 x 1 and 99xxx x 3 or more for each additional 15 minutes	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

Telehealth Services After the End of the Public Health Emergency

In response to COVID-19 and as part of the Public Health Emergency (PHE), CMS expanded telehealth services to be more broadly accepted and applicable than the system was prior to the pandemic. As part of the waivers and expansion, CMS has allowed for telehealth services to be provided in various settings, including office settings and the patient's home. As part of the Interim Final Rule released in both March and April 2020, CMS indicated when the PHE ends the waivers and expansions would also end and services would revert back to pre-PHE days. As of the release of the CY 2021 MPFS Proposed Rule, there is no definitive end date to the PHE in sight. Health and Human Services (HHS) Secretary Alex Azar extended the PHE for another 90 days effective July 25, 2020. This would, at the very least, extend waivers and expansions through October 23, 2020.

Due to the uncertainty, and the fact that even when the PHE is declared over the effects of COVID-19 and the response of patients in their lack of comfort to return back to a semblance of "normal" may still linger, CMS is proposing a phased-in end to the waivers and expansions for some items rather than a hard-and-fast stop.

Specifically, CMS is proposing several changes to telehealth services moving forward which include the following:

- Proposing to create a Category 3 level of telehealth, this would allow for the services which meet the Category 1 and 2 telehealth services criteria to be added temporarily on an interim final basis as necessary and in response to this or another PHE
- Proposing any service added to Category 3 would remain on the Medicare telehealth services list through the calendar year in which the PHE ends
    - Proposed services to be designated Category 3 through the year when the PHE ends can be found in Table 10 of the proposed rule
- Proposing most of the services added during the PHE to be removed as CMS, in review of the codes, did not find they met the Category 2 criteria already established for telehealth services. CMS is seeking comments from stakeholders if these services should be added to the Category 3 designation.
    - Seeking comments on code 77427, *Radiation treatment management, 5 treatments*, and whether it should be added as a Category 3 code
- Proposing to amend language that, when a code is deleted and replaced with a new CPT®/HCPCS code that describes the same clinical services of a code currently on the Medicare telehealth services list, the new code would be considered a successor to the old code and updated accordingly.

TABLE 12: Summary of CY 2021 Proposals for Addition of Services to the Medicare Telehealth Services List	
Type of Service	**Specific Services and CPT Codes**
1. Services we are proposing for permanent addition to the Medicare telehealth services list	• Group Psychotherapy (CPT code 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334-99335) • Home Visits, Established Patient (CPT codes 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT code 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X) • Prolonged Services (CPT code 99XXX) • Psychological and Neuropsychological Testing (CPT code 96121)
2. Services we are proposing as Category 3, temporary additions to the Medicare telehealth services list.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99336-99337) • Home Visits, Established Patient (CPT codes 99349-99350) • Emergency Department Visits, Levels 1-3 (CPT codes 99281-99283) • Nursing facilities discharge day management (CPT codes 99315-99316) • Psychological and Neuropsychological Testing (CPT codes 96130-96133)
3. Services we are not proposing to add to the Medicare telehealth services list but are seeking comment on whether they should be added on either a Category 3 basis or permanently.	Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Psychological and Neuropsychological Testing (CPT codes 96136-96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161-97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521-92524, 92507) • Initial hospital care and hospital discharge day management (CPT 99221- 99223; CPT 99238-99239) • Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT 99468-99472; CPT 99475-99476) • Initial and Continuing Neonatal Intensive Care Services (CPT 99477-99480) • Critical Care Services (CPT 99291-99292) • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962) • **Radiation Treatment Management Services (CPT 77427)** • Emergency Department Visits, Levels 4-5 (CPT 99284-99285) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324-99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Initial and Subsequent Observation and Observation Discharge Day Management (CPT 99217- 99220; CPT 99224- 99226; CPT 99234-99236)

Telehealth Services Technology Requirements

During the PHE, CMS removed language and allowed for telehealth expanded services to be provided by *"multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner".* This allowed for the use of smartphones to be utilized by practitioners and patients when communicating with audio and video capability. CMS is proposing to update the last sentence of the Medicare telehealth services regulation which states: "*prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services."* The regulation which prohibits the use of telephones could be confusing when a smartphone and the capabilities for the audio and video are used for the visit. By removing this verbiage, outdated references to technology would no longer be present and potentially create confusion.

Communication Technology-Based Services (CTBS)

As part of the CY 2019 MPFS Final Rule, CMS created several G-codes for services furnished via telecommunications technology. These services are not considered telehealth services but use telecommunications technology between the practitioner and patient. Two of the codes created include,

- G2010 - *Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*

- G2012 - *Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*

Both of these codes may be billed by nonphysician practitioners (NPPs). CMS is also proposing two new codes to be added effective January 1, 2021. These new codes would also be billable by NPPs, consistent with their scope of practice, for those who cannot bill independently for E/M services. The value of these codes would match G2010 and G2012 respectively.

- G20X0 – *Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment*.
- G20X2 – *Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*

Audio-only Visits

Prior to the PHE CMS did not provide coverage for telephone services codes, 99441-99443. In large part, this is due to the fact the codes can be provided to the patient, parent, or guardian. CMS does not typically cover services or codes that are not directly provided to the patient themselves. However, as part of the PHE and feedback by stakeholders that most beneficiaries did not want to, know how to, or have the capabilities to use video technology for visits, CMS approved their coverage.

Telecommunication codes available prior to the PHE were only the short duration G-codes referenced above and CMS noted, for some patients, a longer telephone visit is needed. CMS is **not** proposing to recognize the telephone codes under MPFS after the PHE has ended. This is due to the requirement for telehealth services, moving forward after the PHE, audio/video capabilities are required. However, CMS is seeking comments on whether a service similar to the check-in visit should be created that covers a longer period of time for the visit. CMS is also seeking comments whether the audio-only visits should remain under provisional coverage until the end of year the PHE ends or if they should be part of the permanent MPFS payment policy.

Physician Supervision for Telehealth Services

CMS, for the duration of the PHE, has redefined direct supervision under MPFS to be provided through interactive real-time audio-video telecommunication technology. This allows the physician to provide real-time assistance and direction throughout a procedure or service by allowing them to see and interact with the staff member and patient without adding any unnecessary exposure. It is important to note, the supervision adjustments are meant as a minimum requirement. There may be circumstances in which the physical presence of the physician with the patient in the same location is necessary and more appropriate, for example administration of certain drugs or therapies. CMS stressed in these types of scenarios the physician and facility must make the best decision given the situation, even if this means potential exposure due to the nature of the scenario.

CMS is proposing to extend direct supervision expansion under MPFS to end later in the calendar year in which the PHE ends or December 31, 2021. This will allow, along with other waivers and extensions, an easement to the change in supervision than immediate pending the end of the PHE and for physicians and practices to prepare for the change back to the in-person requirement. CMS did note, if the PHE ends before the CY 2021 MPFS Final Rule is released, it is set to end October 23, 2020, the ability to use real-time audio and video technology to provide direct supervision would end during the period the PHE ends and the final rule is published.

CMS did clarify, the use of real-time audio and video technology to provide direct supervision under MPFS does not mean the physician must be actively observing and using the technology throughout the entire procedure. Instead the supervising physician is immediately available to engage via the real-time audio and video technology (excluding audio-only) throughout the procedure.

CMS has also received requests for clarification for when a physician and patient are at the same physical location, but the visit is provided using telecommunications technology if this can be billed as a telehealth visit. CMS did provide clarification for this in the Second Interim Final Rule released April 30, 2020. CMS states, "…*if audio/video technology is used in furnishing a service when the beneficiary and the practitioner*

are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements."

Physician Supervision of Physician Assistant (PA) Services

Requests were made to CMS to allow for PAs to practice medicine without the required supervision by the physician, to align their roles and the regulations similar to those of NPs and CNSs. The scope of work provided by PAs has changed over the years and many provide and deliver health care more broadly than ever before. Many of these changes have resulted in changes to the scope of work and laws in different states. Some states have relaxed their requirements related to the necessary supervision while others have yet to make any changes.

Currently, physicians and NPPs can order diagnostic testing when the results are used by them to manage the patient related to a specific problem. Supervision of diagnostic services has been limited to physicians only as the services are paid under the Medicare Physician Fee Schedule (MPFS) and the minimum levels of supervision are assigned to the code. Supervision does not apply to NPs or Clinical Nurse Specialists (CNSs) as authorized under state law, but CMS is of the understanding in these scenarios the NP or CNS is working in collaboration with the physician.

Outside of the public health emergency (PHE) response to COVID-19, CMS requires general supervision of the PA by the physician. Due to the need to free up physicians and offer flexibility, CMS finalized, on an interim basis (for the duration of the PHE), the ability for NPs, CNSs, PAs, or Certified Nurse-Midwife (CNMs) to provide physician services as if the physician provided them. In addition, this flexibility will allow for payment under Medicare Part B as provided directly and "incident to" their own professional services, within the allowance of their state scope of practice. This specifically will allow NPs, CNSs, PAs, or CNMs to order, furnish directly, and supervise the performance of diagnostic tests as allowed under their state law for the duration of the PHE.

CMS is proposing to make the modifications permanent. This would allow for NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. CMS is also proposing that diagnostic tests performed by a PA in accordance with their scope of practice and state law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians would continue to apply. In addition, CMS is proposing to make permanent the removal of the parenthetical, which was part of the COVID-19 Interim Final Rule, that required general supervision by the physician for diagnostic tests performed by the PA.

National Coverage Determination Removal

CMS is proposing to utilize to continue a process established in CY 2013 of criterion to regularly identify National Coverage Determinations (NCDs) which need to be removed as they no longer contain clinically pertinent and current information. These would be services which are no longer the current medical practice or services used infrequently by beneficiaries. By removing an NCD that once covered certain services, the removal would mean those services would no longer be covered automatically by CMS; however, those services which may have been previously denied could now be covered. This would be due the Medicare Administrative Contractors (MACs) would now be responsible for setting coverage determinations related to the NCDs removed, if the MAC determined it was appropriate to do so.

It has been 5 years since CMS last evaluated older NCDs for removal. CMS recognizes the technology fast out paces the regulations and by being proactive to remove broad coverage determinations, this can open limitations and restrictions to new technologies for stakeholders and CMS. CMS is proposing to remove nine NCDs, two of them specific to medical oncology/hematology include:

- NCD #110.14 Apheresis (Therapeutic Pheresis) (7/30/1992)
    - CMS believes the MACs can make better decisions for coverage and meeting the needs of Medicare beneficiaries
- NCD #110.19 Abarelix for the Treatment of Prostate Cancer (3/15/2005)
    - CMS believes this technology is obsolete and no longer marketed

<u>Medicare Part B Drug Payment for Drugs Approved as Part of Food, Drug and Cosmetic Act</u>

Medicare Part B covers drugs on a limited drug benefit of specific drugs and biologicals. These drugs and biologicals are in one of three categories and typically paid at Average Sales Price (ASP) plus six percent:

- Drugs and biologicals furnished incident to a physician's services,
- Drugs and biologicals administered via a covered item of durable medical equipment (DME), and
- Other drugs and biologicals specified by statute

Payments for separately payable Part B drugs and biologicals are defined using methodology established within section 1847A of the Act, which involves assigning payable drug products to either a multiple source or single course drug code for the purpose of payment. Drugs (does not include biologicals or biosimilar biological products defined in section 1847A of the Act) fit into one of two mutually exclusive categories, multiple source drugs and single source drugs. The definition of multiple source drug is for a calendar quarter "there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations") are pharmaceutically equivalent and bioequivalent, as determined by the FDA; and are sold or marketed in the United States during the quarter." CMS provides the following example, "a sterile injectable drug product that had been sold as a lyophilized powder in a vial and was then approved for sale as a concentrated liquid in a vial, as well as a ready-to-use IV bag". A single source drug is defined as "a drug which is not a multiple source drug."

When assigning payment to newly marketed drug products, CMS assesses if an existing multiple source code descriptor describes the new drug product and if the active ingredient(s), drug name, and portions of the prescribing information coincide with existing products already assigned and paid under a multiple source drug code. CMS interprets this to mean if there is an existing HCPCS code that includes two or more drug products which are rated to be therapeutically equivalent, and meet the remaining conditions of multiple source drug code, the billing and payment is for a multiple source drug code. It is important to note, CMS does not assign all drug products from section 505(b)(2) (Food, Drug and Cosmetic Act) to existing multiple source drug codes. If a drug product is not described by an existing code or it is not suitable for billing and payment, it is not assigned. CMS can also assign other multiple source drug products to the identified multiple source drug code for the purpose of payment.

If the product is assigned to an existing multiple source drug code, payment is based on the volume-weighted average ASP of all products assigned to the code, rather than based solely on its own ASP. As a

result, a multiple source drug code may include generic and branded drug products within an individual HCPCS code. A new single payment is determined based solely on its own ASP.

When assigning classification of services, CMS believes in maintaining consistency of payment by paying similar amounts for similar services. CMS has identified a number of section 505(b)(2) drug products that are described by an existing multiple source drug code; however, are priced significantly higher than the comparable products. For example, two recently introduced products are 10 times higher, than those in the existing multiple source code. CMS is concerned the potential abuse of the system when drug products are assigned unique separate HCPCS codes despite being described by a multiple source drug code. CMS believes that assigning these drug products described by existing multiple source HCPCS codes is a method to curb drug prices and limits opportunity to "game the regulatory process and the patent system in order to unfairly maintain monopolies."

CMS is proposing to continue to assign certain drug products to existing multiple source drug codes if the products, as part of the Food, Drug and Cosmetic Act, are described by an existing multiple source drug codes and consistent with the interpretation of the definition of multiple source drug code.

Planned 30-day Delayed Effective Date for the Final Rule

CMS is adjusting the timeline in which the final rules will be released. Historically CMS has been required to provide 60 days before implementation of specific payment rules. Due to efforts in prioritizing the response related to COVID-19, CMS stated the rules will be completed 30 days prior to implementation. In addition, there will not be a 30-day delay in the effective date of the final rule because it is not presented with 60 days to prepare for implementation. In summary, the expected release date for CY 2021 MPFS Final Rules will be December 1, 2020 instead of the traditional date of November 1, 2020.

Hospital Outpatient Prospective Payment System (HOPPS) Proposed Changes

Payment Rates

CMS is proposing an increase of payment rates under the Outpatient Department (OPD) fee schedule with a 2.6% increase to the conversion factor of CY 2020. The CY 2021 conversion factor is proposed to be $83.697; however, for hospitals that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements, CMS is proposing a conversion factor of $82.065. To determine this payment rate, CMS utilized data released in the inpatient prospective payment system (IPPS) proposed ruling for FY 2020 which reflected a proposed 3.0 percent increase for inpatient services, minus 0.4 percent for the multifactor productivity (MFP) adjustment.

Based on the proposed updates to the payment rates, CMS is projecting CY 2021 HOPPS expenditures will be approximately $83.9 billion, an increase of approximately $7.5 billion compared to projected CY 2020 HOPPS payments.

CMS is proposing to maintain the rural adjustment factor of 7.1% 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 is proposing to 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. There are changes to the wage index values proposed as part of the IPPS FY 2021 proposed rules, which are relative population changes between urban and rural located hospitals. Overall CMS believes the updates to the wage index values will result in an estimated 0.2 percent increase for urban hospitals and an estimated 0.4 percent increase for rural hospitals.

Cancer Hospital Payment Adjustment

CMS is proposing in CY 2021 to continue additional payments to cancer hospitals. The payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data.

Beginning CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1.0 percentage point. CMS is proposing no change to the CY 2020 PCR and instead use the proposed target PCR of 0.89 to determine the CY 2021 cancer hospital payment adjustment to be paid at cost report settlement. The following table reflects the 11 designated cancer hospitals and the proposed estimated increase in payments for CY 2021.

TABLE 5.—ESTIMATED CY 2021 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2021 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	32.8%
050660	USC Norris Cancer Hospital	11.2%
100079	Sylvester Comprehensive Cancer Center	12.8%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.5%
220162	Dana-Farber Cancer Institute	35.8%
330154	Memorial Sloan-Kettering Cancer Center	39.4%
330354	Roswell Park Cancer Institute	13.6%
360242	James Cancer Hospital & Solove Research Institute	12.7%
390196	Fox Chase Cancer Center	10.4%
450076	M.D. Anderson Cancer Center	41.9%
500138	Seattle Cancer Care Alliance	44.8%

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 cost. 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 is proposing to continue using Healthcare Common Procedural Coding System (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 is proposing use of the proposed 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 2019 and carried into 2020, CMS 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, either excepted or nonexcepted, CMS had finalized to reimburse for 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 is proposed to continue to be reimbursed a payment rate of 40% of the HOPPS rate. The proposed rate for G0463 in 2021 is $120.88. Any off-campus provider, excepted and nonexcepted, is proposed to only be paid $48.35 for code G0463, while on-campus outpatient departments would be paid $120.88 in 2021.

<u>New CPT® Codes for CY 2021</u>

CMS indicated in the CY 2021 proposed ruling it did receive timely notification of the CPT® coding changes by the American Medical Association (AMA). This allowed CMS to propose values for the new codes effective for January 1, 2021. CMS did not list the codes within the context of the rule itself but provided them in an addendum. The following table is a partial representation of Addendum O, with the long descriptors and codes with placeholders of codes that could be related to, directly or indirectly, radiology and oncology service lines. The full code will be released by the AMA in late August/early September 2020.

One code to watch for more information from the American Medical Association (AMA) is, technical only, 7615X, *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)* This is a new code for 2021 and even though is lists medical physicist and dosimetrist in the definition, the code beginning with -76 indicates it is not solely a

radiation oncology code. Medicare has proposed to group it into APC 5611 with a national rate of $129.86 for CY 2021. Other codes in this same APC include 77280, 77299, 77300, 77332, 77332, 77333, 77336, 77370, and 77399.

Addendum O: Long Descriptors for New CPT® and C and G Level II HCPCS Codes Effective January 1, 2021	
CPT® codes and descriptions only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.	
CY 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code	**Long Descriptor**
7615X	**Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)**
99XXX	Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)

NOTE: Following the release of the proposed rules, the AMA did release the CPT® code updates for 2021. Per the updates, the full codes mentioned above in table Addendum O from CMS are 76145 and 99417.

Proposed 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 is proposing to continue providing payment for diagnostic and therapeutic radiopharmaceuticals that are 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%; however, if no ASP data is available, CMS is proposing to provide pass-through payment at whole acquisition cost (WAC) of +3%, which is 3% less than currently paid. If that is not available, then payment will be 95% of average wholesale price (AWP). CMS is also proposing to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021.

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 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 to continue to pay separately 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 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 proposed 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. The drugs and biologicals for which would apply in CY 2021 are displayed in Table 25 below.

Table 25.– HCPCS Codes to Which the CY 2021 Drug-Specific Packaging Determination Methodology Would Apply

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 40 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
C9257	Injection, bevacizumab, 0.25 mg	N

For CY 2021, CMS is proposing to 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 is proposing to pay for separately payable non-pass-through drugs acquired with a 340B discount at ASP-28.7 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 28.7 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 is proposing to 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 28.7 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 28.7 percent of the reference product's ASP.

CMS has also proposed to expire pass-through status of twenty-eight (28) 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 21 is provided below detailing drugs and biologicals to be removed from the pass-through list.

Table 21.– 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
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017
J3316	Injection, triptorelin, extendedrelease, 3.75 mg	G	9016	01/01/2018
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018

Medicare also proposed forty-six (46) 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 Table 22 is provided below detailing the drugs and biologicals commonly utilized within oncology or hematology which are expiring pass-through status for CY 2021. Table 23 identifies the drugs which are continuing pass-through status in CY 2021.

Table 22 – Proposed Drugs and Biologicals with Pass-Through Payment 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
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	03/31/2021
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells	G	9035	04/01/2018	03/31/2021
Q2042	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells	G	9194	04/01/2018	03/31/2021
Q5104	Q5104	Injection, infliximababda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Q5105	Injection, epoetin alfaepbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfaepbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
J9204	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

Table 23 – Proposed 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
J0642	J0642	Injection, levoleucovorin, 1 mg	G	9334	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimabrwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastimjmdb, biosimilar,	G	9173	04/01/2019	03/31/202
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastimcbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022

J1303	J1303	Injection, ravulizumabcwvz,10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hcl (belrapzo), 1 mg	G	9313	04/01/2019	06/30/2022
J9210	J9210	Injection, emapalumablzsg,1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J9311	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q5107	Q5107	Injection, bevacizumabawwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumabanns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022
C9053	C9053	Injection, crizanlizumab-tmca, 1 mg	G	9342	04/01/2020	03/31/2023
C9057	C9057	Injection, cetirizine hydrochloride, 1 mg	G	9344	04/01/2020	03/31/2023
Q5114	Q5114	Injection, Trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	C9058	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023

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.

They 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.

In calculating the amount of the discount proposed for 2021, CMS took a conservative approach. The data reflected the 340B discount if using the arithmetic mean an average ASP discount would have been 66.3 percent, the mean would have resulted in 70.4 percent, and the geometric mean would have meant 58.3 percent. Because CMS tends to utilize the geometric mean when establishing payment rates under HOPPS already, they used the 58.3 percent as a starting point and made adjustments from there.

From the 58.3 percent geometric mean, CMS applied various other factors and arrived at ASP minus 34.7 percent. These factors included volume weighting to mirror the drug utilization in OPPS for CY 2018 and CY 2019. Specifically, commonly used drugs, such as an oncology drug, were assigned a higher weight than less common drugs, such as snake anti-venom. The average discount was utilized to establish a caseweighted average for each HCPCS code. HCPCS codes may also represent multiple different drugs with different NDCs for the same drug; therefore, CMS analyzed the effects of averaging all NDCs

acquisition costs for a given HCPCS. CMS determined to utilize the highest acquisition cost NDC for each HCPCS code. CMS also determined to exclude penny priced drugs that may be outliers and may distort the average discount.

CMS then determined an additional factor was needed. Because drugs with pass-through status are paid as ASP+6 percent, CMS also applied this to the 340B discount. Therefore, all drugs are afforded the same ASP+6 percent factor regardless of how they were purchased. This final adjustment results in a proposed 340B Drug Program discount of ASP minus 28.7 percent for 2021. Hospitals would continue to report modifier JG for drugs purchased under the 340B Program.

Drugs for which the ASP is unavailable, CMS proposes 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.

CMS is proposing to 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 TB modifier 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 would be paid at ASP minus 28.7 percent. Biosimilar biological products would be paid at minus 28.7 percent of the biosimilar's ASP, not the reference drug's ASP.

<u>Blood Products</u>

Blood Clotting Factors

CMS provides reimbursement for blood clotting factors under the same payment methodology as other nonpass-through separately paid drugs and biologicals under HOPPS and includes an additional furnishing fee. CMS is proposing to continue to reimburse blood clotting factors at ASP+6 percent along with an updated furnishing fee. At the time of the proposed rule release the data necessary to calculate the furnishing fee, which is also applied to the blood clotting factor payment in the office setting, was not available. CMS indicated the actual figure for the furnishing fee would be made available on the CMS.

Blood Not Otherwise Classified (NOC) Code

Recently the number of blood products available has increased and continues to increase compared to the couple of products available for use over the last 15-20 years. Due to this, stakeholders have requested from CMS a way to track and increase utilization of these new blood products a HCPCS code to allow for payment of unclassified blood products. Typically, unclassified procedures are assigned the APC with the lowest payment level of the family; however, blood products are generally assigned their own individual APC.

Beginning January 1, 2020 CMS created HCPCS code P9099, *Blood component or product not otherwise classified*, for reporting of unclassified blood products. When it was created it was assigned a status

indicator of "E2", *Not payable by Medicare when submitted on an outpatient claim*, for CY 2020. Feedback from stakeholders is this created many issues, no payment and it was rejected by CMS when reported on the claim so the utilization could not be tracked.

For CY 2021, CMS is proposing to package the cost of unclassified blood products into the primary procedure but assigning status indicator "N". Even though this is packaged, Medicare still requires hospitals to bill packaged services on the claim form for tracking and utilization. CMS is also seeking comment on an alternative payment, HCPCS code P9099 would be separately payable with the equivalent rate to that of the lowest clot blood product, HCPCS code P9043, *Infusion, plasma protein fraction (human), 5 percent, 50 ml*. If the alternative was selected the status indicator would not be E2" or "N", instead it would be "R", *blood and blood products, paid under OPPS*.

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 for 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 is proposing 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.

Planned 30-day Delayed Effective Date for the Final Rule

CMS is adjusting the timeline in which the final rules will be released. Historically CMS has been required to provide 60 days before implementation of specific payment rules. Due to efforts in prioritizing the response related to COVID-19, CMS stated the rules will be completed 30 days prior to implementation. In addition, there will not be a 30-day delay in the effective date of the final rule because it is not presented with 60 days to prepare for implementation. In summary, the expected release date for CY 2021 HOPPS Final Rules will be December 1, 2020 instead of the traditional date of November 1, 2020.