2021 Hospital Regulatory Update

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On Dec. 2, 2020, the Centers for Medicare & Medicaid Services (CMS) issued the final rules for the Hospital Outpatient Prospective Payment System (HOPPS or OPPS) for CY 2021. The CY 2021 final rule is 1312 pages in length and located in its entirety online at cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf. Below is information that may be of interest to or may impact oncology specialties. Readers are encouraged to view the document in its entirety for further details.

Payment Rates for Facilities

CMS is increasing payment rates under the outpatient department fee schedule by 2.4 percent to the conversion factor. Utilizing values set as part of the Inpatient Prospective Payment System (IPPS), CMS estimates that the total payments to OPPS providers for CY 2021 will be approximately $1.61 billion compared to CY 2020 OPPS payments. With the increase to the fee schedule payments, it is estimated that urban hospitals will see an increase in payments of approximately 2.6 percent and rural hospitals will see an increase of 2.9 percent.

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. It ensures that 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 hospitals, CMS had proposed in both FY 2021 IPPS and CY 2021 OPPS/ambulatory surgical center rules an adjustment to wage indexes utilizing the Office of Management and Budget updated delineations applied to the IPPS post-reclassified wage index. To limit the potentially significant impact to hospitals where the revised Office of Management and Budget 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 Jan. 1, 2021.

Clinic Visit Reimbursement

In CY 2020 CMS fully implemented changes in reimbursement to code **G0463** (Hospital outpatient clinic visit for assessment and management of a patient) for all off-campus departments, regardless of whether 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 services." To remove any incentivization in billing code **G0463**, the most widely reported outpatient services code, CMS finalized a site-neutral method for reimbursement. For 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. For CY 2021, code **G0463** will continue to be reimbursed at a payment rate of 40 percent of the OPPS rate for any outpatient off-campus hospital setting. For CY 2021 any off-campus provider, excepted and nonexcepted, will be reimbursed $47.50 for code **G0463**, and the on-campus outpatient departments will be reimbursed at a rate of $118.74 for the same code.

Payments of Drugs, Biologics, 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 biologics estimated at a per day administration cost less than or equal to $130—the same rate as CY 2020. The agency 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, biologics and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologics that function as supplies or devices when used in a surgical procedure.

CMS proposed and finalized to continue the policy of making packaging determinations on a drug-specific basis rather than by Healthcare Common Procedure Coding System (HCPCS) code for those codes that describe the same drug or biologic but in different dosages.

For CY 2021, CMS will continue the current payment policy in effect since CY 2013. This payment policy pays for separately payable

drugs and biologics at ASP+6 percent. These separately payable drugs and biologics 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 biologics 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). In CY 2021, CMS will use a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs. For drugs and biologics acquired under the 340B program, the 340B program rate (WAC–22.5 percent) would apply.

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–22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP–22.5 percent of the reference product's ASP.

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 within the Department of Health & Human Services. This program allows participating hospitals and other healthcare providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers.

In the CY 2018 HOPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (does not include drugs on pass-through payment status or vaccines) to be reimbursed at the rate of ASP–22.5 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 that 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.

In response to the initial United States District Court for the District of Columbia findings, which stated that 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 OPPS 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.

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 that 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–28.7 percent for CY 2021.

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 and after it is declared over, CMS is finalizing their alternate proposal of continuing ASP–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, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. In addition, these hospitals 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 biologics acquired under the 340B program and furnished in on-campus hospital departments, excepted off-campus provider-based departments, and nonexcepted off-campus provider-based departments paid under the physician fee schedule will be paid at ASP–22.5 percent. Biosimilar biological products will be paid at –22.5 percent of the biosimilar's ASP, not the reference drug's ASP.

Chimeric Antigen Receptor T-Cell

In CY 2019 the American Medical Association made available four new Category III Current Procedural Terminology (CPT®) codes related to chimeric antigen receptor (CAR) T-cell therapy. At the time CMS assigned each code a status indicator "B" (codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type), these codes were not paid under OPPS. The codes created each describe a step in the process to genetically modify T-cells; the step-by-step process to manufacture a drug or biologic is not something Medicare reimburses.

Commenters proposed a new status indicator be assigned to the CAR T-cell Category III codes (**0537T**, **0538T**, and **0539T**) for CY 2021. CMS did not agree with commenters. The agency did recognize CAR T-cell therapy as unique and as a biologic there is no comparable other therapy with current CPT codes. There is current HCPCS coding approved for CAR T-cell therapies, which includes leukapheresis and dose preparation procedures, and these are included in the manufacturing of the biologics. However, because of their inclusion in the manufacturing, there is no separate payment for these HCPCS codes. Though CMS has not established reimbursement for the Category III codes from the American Medical Association, the agency did indicate that these codes could be reported for tracking purposes. Tables 1 and 2, right, list the CAR T-cell HCPCS and Category III codes, respectively, and their finalized ambulatory payment classification assignments for CY 2021.

Blood Clotting Factors

CMS reimburses blood clotting factors under the same payment methodology as other non-pass-through separately paid drugs and

Table 1. CAR T-Cell Therapies Final APC Assignment for HCPCS Codes Q2041, Q2042, and C9073 for CY 2021

HCPCS CODE	LONG DESCRIPTOR	FINAL CY 2021 APC
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9035
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9194
C9073	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 CAR-positive viable T-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9391

Table 2. CAR-T Preparation and Administration Final SI and APC Assignment for CPT Codes 0537T, 0538T, and 0540T for CY 2021

CPT CODE	LONG DESCRIPTOR	PROPOSED CY 2021 SI	FINAL CY 2021 SI	FINAL CY 2021 APC
0537T	CAR-T therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR T-cells, per day	B	B	N/A
0538T	CAR-T therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage)	B	B	N/A
0539T	(CAR-T) therapy; receipt and preparation of CAR T-cells for administration	B	B	N/A
0540T	(CAR-T) therapy; CAR T-cell administration, autologous	S	S	5694

SI = status indicator; B = codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); S = procedure or service, not discounted when multiple ASP.

biologics under OPPS and includes an additional furnishing fee. CMS proposed to continue to reimburse blood clotting factors at ASP+6 percent along with an updated furnishing fee. CMS did not receive any comments to this proposal, so it was finalized without modification. CMS indicated that the actual figure of the percentage change in the applicable Consumer Price Index and the updated furnishing fee calculation using the Consumer Price Index would be made available on the CMS website.

Blood Not Otherwise Classified Code

Recently the number of blood products available increased and continues to increase compared to the number of products available for use over the last 15 to 20 years. Because of this increase, stakeholders have requested from CMS a way to track and increase utilization of these new blood products through an 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 Jan. 1, 2020, CMS created HCPCS code **P9099** (Blood component or product not otherwise classified) for reporting of unclassified blood products. When the code was created it was assigned a status indicator of "E2" (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. Stakeholder feedback indicated that this created many issues; specifically, the code was not reimbursed,

and it was rejected by CMS when reported on the claim, so the utilization could not be tracked.

Due to stakeholder feedback, CMS is finalizing the alternative proposed. HCPCS **P9099** will be separately reimbursed with assigned status indicator of "R" in CY 2021. The assigned payment rate will equal the lowest paid separately payable OPPS blood product, HCPCS **P9043** (Infusion, plasma protein fraction (human), 5 percent, 50 mL) with a CY 2021 national rate of $7.99 per unit as listed in Addendum B.

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 that 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 that 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. Multiple drug administration services are assigned to this group, including:

- **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.

For CY 2021, CMS proposed and finalized to permanently change the minimum level of supervision for these services to general for the entire services. This would include the initiation, which had previously required direct supervision. CMS does stress that it is at 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 service as appropriate.

Radiation Oncology Model: Waiver of Proposed Rulemaking

On Sept. 18, 2020, CMS released the final rule related to the Radiation Oncology (RO) Model with an expected start date of Jan. 1, 2021, lasting for five years with a set end date of Dec. 31, 2025. Because of 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 that the delay was to ensure that participation in the model during the public health emergency did not further strain participant ability to implement the changes and still effectively treat patients in a safe and efficient manner. The six-month delay is intended to provide participants the opportunity to prepare and more appropriately learn the model components, train staff on the new procedures, and prepare for the new quality measure reporting, which begins in 2022.

The following is a short summary 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, and it is possible that there may be additional changes 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 Dec. 31, 2025. PY1 will be six months, each performance year after that (PY2-PY5) will be 12 months.
- Quality measure reporting: The quality measures requirement will be delayed until PY2 (Jan. 1, 2022, to Dec. 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.
- CMS-approved contractor to administer the Consumer Assessment of Healthcare Providers and Systems Cancer Care Survey for Radiation Therapy is delayed.
- Clinical data element reporting will begin Jan. 1, 2022.
- Quality withhold payments: No quality withhold payment (2 percent) in PY1. Beginning in PY2, a 2 percent withhold will be applied to the trended national base rates after the case mix and historical experience adjustments.
- No quality reconciliation payment amount PY1 for professional and dual participants.
- Advanced Payment Model (APM) status: Expect RO Model to meet criteria for the MIPS (Merit-Based Incentive Payment System) APM under the Quality Payment Program starting PY2. Delay in RO Model start, RO participants will not be eligible for 5 percent APM incentive payment for qualifying APM participants in PY1 based on participation in RO Model. Certified electronic health record technology requirements to begin PY2, Jan. 1, 2022. Annual certification required for PY2 through PY5.

CMS Most Favored Nation Model Interim Final Rule

On Nov. 20, 2020, CMS announced the Most Favored Nation (MFN) Model, a new Medicare payment model related to payments for Part B drugs. This model is in response to President Trump's Sept. 13, 2020, Executive Order on Lowering Drug Prices by Putting America First. This model tests the method of lowering drug costs by paying no more than the lowest price drug manufacturers receive in other similar countries, specifically any country in the Organisation for Economic Co-operation and Development (OECD) that has a gross domestic product (GDP) per capita that is at least 60 percent of the U.S. GDP per capita.

Drug spending in the United States has steadily increased and significantly outpaces spending on other Part B services, and U.S. drug prices surpass those of other countries. Per the Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Medicare Part B

fee-for-service drug spending per enrollee for 2006-2017 grew 8.1 percent. This is more than twice the per capita spending on Medicare Part D, which is 3.4 percent and almost three times the overall retail prescription per capita drug spending, which is 2.9 percent. It is expected that per capita spending on Medicare Part B physician-administered drugs and separately payable hospital outpatient drugs will grow at a similar annual rate of 8 percent between 2020 and 2027, not including potential increases related to the COVID-19 pandemic.

Drug acquisition costs in the United States also exceed those in Europe, Canada, and Japan based on an Assistant Secretary for Planning and Evaluation analysis completed in October 2018. The analysis compared U.S. drug acquisition costs for Part B physician-administered drugs to those in 16 other developed countries, including Austria, Belgium, Canada, Czechia, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom. The study focused on 27 drugs, which accounted for 64 percent of total Medicare Part B spending in 2016. In general, the U.S. acquisition costs were 1.8 times higher. One drug was identified to be comparable to that in other countries; however, the U.S. had the highest drug prices for 19 of the 27 drugs evaluated. In some instances, the U.S. prices were up to seven times higher than international prices. A similar study in 2018 supported that ASP rates were at least 2.05 times higher than those in other OECD countries with a GDP of 60 percent.

The model was scheduled to go into effect Jan. 1, 2021; however, on December 23, a federal court issued a temporary restraining order blocking CMS from implementing the MFN Interim Final Rule. If implemented, the model is considered a nationwide, mandatory model and will include the following key elements.

Included Drugs

The drugs included within the model focus on a Medicare Part B drugs that result in a high percentage of Part B spending. There are 50 single-source drugs and biologics (including biosimilar biological products) included within the first year based on 2019 spending.

Some drugs have been excluded from the model, including drugs used at home, as well as certain vaccines, oral drugs, multiple source drugs, intravenous immune globulin, compounded drugs, radiopharmaceuticals, and drugs with an emergency use authorization or U.S. Food and Drug Administration approval to treat COVID-19. Drugs without specific HCPCS codes will also be excluded, specifically those billed under "not otherwise classified" codes, such as **J3490**.

In addition, drugs billed with an HCPCS code to which generic drugs are assigned will be excluded. These are excluded because they are already subject to a competitive market, and pricing is already reflective of generic product pricing. To encourage the use of biosimilars, CMS is not excluding biosimilar biological products from the MFN Model; however, because of the relative lower annual Medicare Part B spending for HCPCS codes for separately payable biosimilar biological products through 2019, only one biosimilar biological product is included for PY1.

The model focuses on separately payable Medicare Part B drugs; therefore, payment for products bundled into another procedure or service will not be affected by the model. This concept does not exclude drugs that are packaged under one Medicare payment system, while separately payable in another setting, because the inclusion of a particular drug is based solely on those receiving separate payment.

For future years, CMS will maintain approximately 50 drugs in the model during the seven-year model period. It is expected that changes will be necessary to add drugs to the model on an annual basis. These will coincide with drugs that move to the top 50 drugs based on updated annual Part B spending. CMS believes that this will identify potential shifts in utilization to drugs that have not yet been included within the model. Drugs already included in the model will continue to be part of the model for future years unless the drug is withdrawn from the U.S. market, if the HCPCS code is deleted without replacement, or if a drug is excluded due to one of the accepted exclusion criteria.

CMS has indicated the potential to include other types of products in future years, such as blood related, plasma derived, and human tissue products. CMS is also considering a potential exclusion of other drugs; for instance, gene and cell therapies, such CAR-T products. The drugs included within the model for PY1 are published in table 2 of the Interim Final Rule. CMS will publish the MFN Model Drug HCPCS Codes List quarterly on the MFN Model website: innovation.cms.gov/initiatives/most-favored-nation-model.

Model Drug Payment

Currently separately paid Part B drugs are paid based on the manufacturer's ASP plus an add-on fee related to overhead costs associated with drugs and biologics. This amount is calculated quarterly based on manufacturer-submitted data. In this model, the CMS payment will be based on a blended formula that includes the lowest adjusted international price, known as the "MFN price," and the ASP for the specific drugs included in the model. The MFN price will be based on the lowest GDP-adjusted price paid by an OECD member country with a GDP per capita that is at least 60 percent of the U.S. GDP.

The MFN price will be phased in at 25 percent per year over a four-year period, specifically the first four years of the seven-year model. Years 4 to 7 of the model will be at 100 percent of the MFN price. Table 3, page 14, outlines the schedule for this phased-in approach.

The MFN price and the blended formula will not allow for the model payment amount to exceed the ASP. CMS has stated that the phased-in approach may be accelerated during the initial four years if the U.S. prices rise faster than inflation. Illustrative MFN drug payment amounts per unit billed are provided within the Interim Final Rule in table 6. This table outlines the illustrative price for each drug selected to be included in the model, along with the corresponding HCPCS code, code dosage, ASP amount, model payment amount, and corresponding MFN OECD country.

CMS will continue to calculate MFN drug payment amounts on a quarterly basis

Table 3. Phase-In of MFN Prices by Performance Year

	BLEND OF THE ASP AND MFN PRICE FOR AN MFN MODEL DRUG AT THE HCPCS CODE LEVEL
Year 1	75 percent applicable ASP and 25 percent MFN price
Year 2	50 percent applicable ASP and 50 percent MFN price
Year 3	25 percent applicable ASP and 75 percent MFN price
Year 4	100 percent MFN price
Year 5	100 percent MFN price
Year 6	100 percent MFN price
Year 7	100 percent MFN price

utilizing the most recent ASP and international drug pricing information. Because of reporting timelines of ASP data by manufacturers, there will be a two-quarter lag between the ASP data and the use of that data within the Medicare payment calculation.

ASP Add-on Payment

Currently Part B drugs are paid based on the ASP+6 percent; however, the MFN Model will replace this amount with a flat payment per dose that is uniform across all drugs included within the model. CMS defines dose as "the number of HCPCS billing units reported on a claim line."

This rate was calculated using 6.1224 percent of the 2019 spending on drugs designated to be included in the first year of the model. CMS then increased the amount to equal 6 percent post-sequestration and applied an inflation factor. The per dose add-on payment will be calculated once at the beginning of the model and will not be recalculated again. For future quarters, updates to the add-on payment will be achieved through use of the cumulative inflation factor. The per dose add-on for the first quarter of 2021 will be $148.73.

The estimated impact by specialty related to the add-on payment is provided in table 8 of the Interim Final Rule. Hematology/oncology ranks the highest in the percentage of MFN Model drug spending, equating to 29.2 percent. Other specialties defined as high spending include rheumatology, medical oncology, hematology, and gynecology/oncology. Based on 2019 data, all but 9 of the top 35 specialties impacted by the MFN Model will see increases in add-on revenue on average compared to 4.3 percent of the applicable ASP with a single payment amount. The nine specialties impacted are expected to be hematology/oncology, medical oncology, neurology, hematology, gastroenterology, gynecological/oncology, infectious disease, hematopoietic cell transplantation and cellular therapy, and dermatology.

Specific to drugs acquired under the 340B program, the MFN drug payment amount cannot exceed the non-model drug payment amount for a drug submitted with the JG modifier (identifies drugs purchased under the 340B program). If policy related to payment for 340B drugs at ASP–22.5 percent continues, the MFN drug payment amount will be capped at ASP–22.5 percent and the MFN participant will receive the per dose add-on payment amount.

In efforts to continue support for reduction in out-of-pocket drug costs and to minimize confusion for beneficiaries, CMS will waive the coinsurance and deductible amounts for the add-on payment. Beneficiary cost-sharing will be waived for the per dose add-on amount, and Medicare will pay the entire allowed payment amount for the alternative add-on payment.

Participants

Participation in the model will be mandatory for Medicare-participating providers and suppliers that receive Part B fee-for-service payment. This includes physicians, non-physician practitioners, supplier groups, and hospital outpatient departments, including 340B covered entities, ambulatory surgical centers, and other providers that receive separate Part B payments for the included drugs. It is expected that claims from these participants will make up approximately 88 percent of the annual Medicare Part B spending on drugs.

Participants are not required to enroll in the model, because participation will be effectuated by the submission of a claim inclusive of an MFN Model drug. Participants will continue to bill separately payable MFN Model drugs, and they will be responsible for collecting beneficiary cost sharing amounts as normal.

Exclusions to mandatory participation do apply for cancer hospitals, children's hospitals, critical access hospitals, rural health clinics, federally qualified health centers, and Indian Health Service facilities. Exclusions also apply to participants of other Innovation Center models testing fully

capitated or global payments for outpatient hospital services and Part B drugs. Examples of this exclusion include the Maryland Total Cost of Care Model and the Pennsylvania Rural Health Model. This type of exclusion applies to the first and second quarters of the first performance year, and further continuation of the exclusion will be determined based on the ability for those models to incorporate savings on Part B drug spending.

Exclusions also apply to community mental health centers, comprehensive outpatient rehabilitation facilities, outpatient rehabilitation facilities, and other providers and suppliers that do not submit claims for Medicare Part B drugs or are not paid separately for Medicare Part B drugs. CMS is also excluding Part B drugs that are furnished in the inpatient setting, administered through durable medical equipment, orally administered, or paid under the End-Stage Renal Disease Prospective Payment System.

The model also offers a financial hardship exemption for model participants whose revenue is significantly affected by the model. To be eligible for a financial hardship exemption, the MFN participant must submit a request for a financial hardship exemption to CMS. The submission process will be in accordance with the instructions CMS will post on the MFN Model website prior to Oct. 1, 2021. Requests must be submitted to CMS within 60 calendar days following the end of the performance year for which the MFN participant seeks a financial hardship exemption.

If the financial hardship exemption is granted, CMS will provide a reconciliation payment for the previous performance year. CMS does not foresee many MFN participants that will qualify for the reconciliation payment for PY1 due to the phased in approach.

Beneficiaries

The model includes beneficiaries who are furnished an MFN Model drug by a MFN participant, while enrolled in Medicare Part B. This includes only beneficiaries with Medicare as the primary payer and does not include Medicare Advantage or other group health plans. In the event that a beneficiary receives outpatient hospital services, including MFN Model drugs, during the three days immediately preceding a hospital admission, the outpatient hospital services are treated as inpatient services if the beneficiary has Medicare Part A coverage. As a result, the services are not separately payable under Medicare Part B. This policy will continue to apply under the MFN Model; therefore, if a beneficiary receives an MFN Model drug in an hospital outpatient department that is an MFN participant and is admitted to this hospital within three days, those services, including drugs, will be treated as inpatient services (in accordance with Medicare inpatient payment policies) and will not be separately payable under the MFN Model.

Claim Submission

CMS has published model-specific claims submission instructions, which include reporting of a new model-specific HCPCS code (**M1145**: MFN drug add-on, per dose). This code will be required to be submitted on a separate claim line for the MFN Model drugs included on the claim with the corresponding number of units for the number of doses separately payable. CMS has clarified that MFN participants will count the number of claim lines with an HCPCS code that are included within the model and the units field will be utilized to report the number of doses of a separately payable MFN Model drug. This will exclude the number of claim lines billed with the JW modifier indicating wastage. MFN participants will continue to bill for drug waste on separate claim lines with the JW modifier.

Quality Measures

The model intends to be inclusive of quality measures to include potential measures related to the following areas.

- Patient experience
- Medication management
- Medication adherence
- Patient access and utilization.

CMS has indicated that the model will include robust monitoring activities, such as analysis of claims data, patient survey data, and site visits to identify any negative consequences and to ensure that beneficiaries' access to medication is not impacted. CMS is cautious of over-burdening MFN Model participants; therefore, only one quality measure will be required, which focuses on patient experience. This will be accomplished via patient survey, which will be fielded by CMS and initiated in PY1. The agency has indicated that if the patient experience of care quality measure and claims-based monitoring strategies are found to be insufficient to adequately measure the quality of care that MFN beneficiaries are receiving or MFN participants are providing, CMS may specify additional measures to monitor quality.

Resources

CMS has published and made available additional resources, information, and regulations on the Most Favored Nation Model website: innovation.cms.gov/initiatives/most-favored-nation-model. The agency has indicated that additional information and technical documentation will be posted on this website and updated on a quarterly basis. OI