

# compliance

## Change of Course for Some 2021 Payment Rates and Policies

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One of the many lessons we learned in 2020 was that anything can happen and if it was related to regulatory changes, it was likely to change or be delayed, and 2021 has not disappointed. The end of December 2020 brought a flurry of activity for the Centers for Medicare & Medicaid Services (CMS), the Medicare Physician Fee Schedule (PFS), the Hospital Outpatient Prospective Payment System (OPPS), and ambulatory surgical centers (ASCs). Changes were also made to the Most Favored Nation (MFN) drug payment policy and the Radiation Oncology Model (RO Model), and the public health emergency (PHE) was extended yet again.

### 2021 PFS Updates

As previously reviewed in *Oncology Issues*,<sup>1</sup> a 14 percent increase to reimbursement for hematology/oncology and 5 percent decrease for RO under the PFS was anticipated for CY 2021. This was largely due to the dramatic changes to the evaluation and management coding and reimbursement for outpatient and office visit Current Procedural Terminology codes **99202-99215** for new and established patient visits. Many specialties were opposed to the reimbursement. After considerable pushback and lobbying by various specialty societies for Congress to change the finalized reimbursement values specific to the PFS, changes were made.

On Dec. 27, 2020, the Consolidated Appropriations Act, 2021, was signed into law by the president. The changes outlined in the Act, also referred to as the COVID relief package, adjusted the finalized 10.2 percent decrease to the PFS with an overall 3.3 percent increase. The changes in reimburse-

ment values were not strictly applied to the conversion factor, which changed from the finalized \$32.4085 to \$34.8931 but also resulted in changes to the relative value units for physician work, practice expense, and malpractice of nearly every Current Procedural Terminology and Healthcare Common Procedure Coding System (HCPCS) service. In addition to the payment increase, the Act included several other provisions, including:

- A 3.75 percent increase in PFS payments for CY 2021.
- Suspension of the 2 percent payment adjustment (sequestration) through March 31, 2021.
- Reinstatement of the 1.0 floor on the work Geographic Practice Cost Index through CY 2023.
- Delayed implementation of the inherent complexity add-on code for evaluation and management services (**G2211**) until CY 2024.
- Delay of the RO Model to start no sooner than Jan. 1, 2022.

The increase in the conversion factor and changes to relative value units mean that instead of a 14 percent increase overall for hematology/oncology, the combined impact for 2021 is now a 13 percent increase. Instead of a 5 percent decrease, radiation oncology now has a combined impact of a 1 percent increase; this percentage still includes the decrease in stereotactic radiotherapy equipment valuation, which is being applied over a four-year phase-in period.

In response to what CMS believed was not an appropriate acknowledgment of the complexity of some evaluation and

management services provided to patients by some specialties, the agency created **HCPCS G2211**: Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed healthcare services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established.) Because reimbursement of this code affected the overall negative impact to healthcare, CMS placed a moratorium on the code until 2024. In other words, though it was not deleted, it will not be recognized by Medicare or Medicare Administrative Contractors until 2024. As a G-code, commercial payers are not required to accept this code regardless of the moratorium. Review of payer policy is necessary in the interim.

The 2 percent sequestration payment adjustment was placed on hold due to the April 2020 PHE; it was supposed to end Dec. 31, 2020. The sequestration was adjusted to extend through March 31, 2021, but due to the ongoing and uncertainty of just how long the PHE will last, there is some discussion that the sequestration may be extended through the end of 2021.

One of the other big changes was the delay of the RO Model. In the Dec. 1, 2020, release of the PFS final rule, the RO Model was officially delayed until July 1, 2021, under an interim final rule. This would have created a 4.5-year RO Model payment policy and delay some of the quality reporting and payments until the first full 12-month performance year. The Act delayed the RO

Model, stating that it cannot start prior to Jan. 1, 2022. It is uncertain at this time whether the full length of the model will be increased from the now four-year model to at least five years, which was the initial intent. It is also uncertain whether the randomly selected core-based statistical areas will need to change. When the RO Model was delayed initially to July 1, 2021, CMS indicated that it was not necessary to select new participants due to the six-month delay. With the additional delay, attention will be focused on the participants and whether this means a new selection of core-based statistical areas.

## 2021 Hospital OPPS and ASC Updates

Following closely on the heels of the changes published to the PFS were payment updates under OPPS for outpatient hospital settings and ambulatory surgical centers. The reasoning behind the changes is not as dramatic, and as sometimes happens, there are errors in the reimbursement data published by CMS, so adjustments (correction notices) are published. Reimbursement changes under OPPS were primarily for HCPCS codes related to drugs and biologics. Many included an increase from the final rule publication, whereas others saw no or minimal change. Reimbursement for ASCs included a decrease to nearly every code, surgical service, and ancillary service covered.

## Public Health Emergency Extension

On Jan. 31, 2020, the first PHE due to COVID-19 was declared by Alex M. Azar II, secretary of Health and Human Services (HHS). It is important to note that when a public health emergency is declared it does extend for 90 days. Since that first declaration, the PHE was subsequently renewed on April 21, 2020; July 25, 2020; and Oct. 23, 2020. The latest PHE was scheduled to end on Jan. 21, 2021; however, on Jan. 7, 2021, it was renewed and is currently scheduled to end April 21, 2021. There is discussion that the PHE may also continue through the end of 2021 because of the uncertainty of COVID-19 and to provide some consistency to healthcare providers.

The continued PHE means that the extensions and waivers finalized in March and April 2020 will continue, including:

- The extension of services available as telehealth.
- The place of service for the patient and provider.
- Payment of telehealth services as if provided in-person.
- Changes in direct supervision for therapeutic services in the office setting.

Once the PHE does end, some services will discontinue immediately, and others will be phased out to ensure that patients and providers are confident and prepared to return to in-person visits. Continued access to telehealth services for all patients and providers, not just the providers or traditional telehealth services in place prior to the PHE, is expected, and there is work being done to push for this continuation.

## MFN Drug Payment Policy Delay

On Nov. 20, 2020, CMS announced the MFN Model, a new Medicare payment model related to the reimbursement of Medicare Part B drugs. This model is in response to an executive order issued on Sept. 13, 2020, on lowering drug prices by putting America first. This model would test 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 Organization for Economic Cooperation and Development that has a gross domestic product per capita that is at least 60 percent of the U.S. gross domestic product per capita.

The premise was to create a payment model based on the 50 most costly single-source drugs and biologics (including biosimilars) in the United States, excluding certain drugs based on various criteria, and pay for the drugs in some equivalency to what other countries pay for the same drug. The MFN Model would be in place for seven years and payments would be phased in over the first four years to reach the full model design. The impact of the model reimbursement would be most widely felt by providers who purchase the drugs and not the drug manufacturers themselves. Because the

payment change was provided to the purchaser, it did not incentivize the seller to lower the drug rates in the United States. Due to the burden the MFN Model would create for providers and the fact the model was not put through an official rulemaking process, it has been delayed from the Jan. 1, 2021, start date.

On Feb. 8, 2021, CMS posted an update to the MFN Model regarding several court orders filed following the publication of the interim final rule. A temporary restraining order was filed by ACCC on Dec. 23, 2020, which temporarily restrained HHS from implementing the model. This restraining order expired on Jan. 20, 2021. On Dec. 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction in *Biotechnology Innovation Organization v. Azar*. This prohibited HHS from implementing the model as planned for Jan. 1, 2021. On Feb. 4, 2021, CMS stated, "Given this preliminary injunction, the MFN Model was not implemented on January 1, 2021 and will not be implemented without further rulemaking."<sup>2</sup>

At this time, until additional rulemaking is published with the ability for stakeholders to comment, it appears that the MFN is on hold. This is a theme with some of the last-minute policymaking changes pushed through at the end of 2020 and very beginning of 2021, prior to the switch to the new administration. It is possible that more changes or halts in policy will be made in 2021 to allow the usual chain in command the opportunity to vet and allow for stakeholder input prior to implementing new policies. Stay tuned: 2021 is proving to be another exciting year! 🎉

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## References

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2. Centers for Medicare & Medicaid Services. Most favored nation model. Available online at: [innovation.cms.gov/innovation-models/most-favored-nation-model](https://innovation.cms.gov/innovation-models/most-favored-nation-model). Last accessed February 17, 2021.