2021 Physician and Freestanding Facility Regulatory Update

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On Dec. 1, 2020, the Centers for Medicare & Medicaid Services (CMS) issued the final rule for the Medicare Physician Fee Schedule (PFS) for CY 2021. The CY 2021 final rule is 2,165 pages in length and located in its entirety at the following link: cms.gov/files/document/12120-pfs-final-rule.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

CY 2021 is the second year in which there is no specific increase to the conversion factor (CF). As part of the Medicare Access and CHIP Reauthorization Act of 2015, 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, and this value is still used for CY 2021 with direct adjustment. CMS must remain budget neutral by maintaining expenditures within $20 million plus or minus each year relative to the increases and/or decreased of the relative value units (RVUs). When it is projected that the impact from any 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 −10.20 percent budget neutral adjustment to the CF; this is a decrease from the proposed adjustment of −10.61 percent. Regardless, the budget neutrality factor adjustment will result in an overall decrease in payments for CY 2021, with a CF value of $32.4085. Table 4, right, outlines the combined impact per specialty of the RVU changes for CY 2021.

Within the final rule, CMS indicated that the most widespread impacts to specialties of the RVU changes resulted from misvalued code adjustments for new and revised codes. Specialties such as endocrinology, rheumatology, family practice, and hematology/oncology will experience increases when compared to other specialties. This is due primarily to the increases in the values for the office/outpatient evaluation and management (E/M) visits. However, there are also increased payments that resulted from the updates to supply and equipment pricing and indirect practice expense (PE) allocations for some office-based services.

The largest impact to the CY 2021 PFS is the restructured E/M visit; these visits currently make up 20 percent of the total PFS spending. Changes to the E/M visits included adjusted values to the different level of office/outpatient codes, the addition of add-on codes for complexity of services, and an add-on code for prolonged service. **Note on December 27, 2020 the Consolidated Appropriations Act, 2021, which included the COVID-relief package, was signed into law reversing many of the payment cuts outlined in MPFS final rule. This includes increasing the conversion factor by 3.75 percent, extending the sequestration waiver, and a moratorium on payment for the new complex services add-on code with evaluation and management visits.

Valuation of Specific Codes for CY 2021

Within the CY 2021 proposed and final rule publications, 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 that the rationale for the proposed changes is based on values recommended by the Relative Value Scale Update Committee (RUC) and other organizations that CMS looks to for assistance in setting appropriate values for codes. These changes include the following.

Radiation Treatment Delivery (CPT Code 77401)

CPT 77401 (Radiation treatment delivery, superficial and/or ortho voltage, per day) has been on the radar for some time regarding valuation. In 2017 this code was identified through the high-volume growth screen for utilization of 10,000 or more, which is an increase of at least 100 percent from 2021 through 2017. In 2019, the RUC recommended the CPT Editorial Panel review this code to better define services associated with the treatment delivery in 2019. CMS proposed refinement of the clinical labor associated with **77401**, reduction of two minutes, to the standard three minutes and did not propose inclusion of requested equipment for "Lead Room." The agency indicated that because the lead-shielded room can be used for other services, it would be considered an indirect PE; therefore, CMS finalized the direct PE inputs without inclusion of the lead-shielded room and at the reduced clinical labor input.

Table 4. Estimated Impact on Total Allowed Charges by Specialty

(A) SPECIALTY	(B) ALLOWED CHARGES (MILLION $)	(C) IMPACT OF WORK RVU CHANGES	(D) IMPACT OF PE RVU CHANGES	(E) IMPACT OF MP RVU CHANGES	(F) COMBINED IMPACT*
Hematology/oncology	$1,707	8%	5%	1%	14%
Radiation oncology and radiation therapy centers	$1,809	−3%	−3%	0%	−5%

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

Proton Beam Treatment Delivery CPT-Codes

CMS reviewed CPT **77522** (Proton treatment delivery; simple, with compensation) and CPT **77523** (Proton treatment delivery; intermediate). Both codes are contractor-priced Category I codes with an estimated 2017 utilization of more than 10,000 services. Even though the RUC determined that these codes should remain contractor priced because of the significant equipment invoice pricing, they were still recommended for survey of PE (practice expense). CMS proposed and finalized that the Medicare Administrative Contractors continue to set contractor pricing per their respective jurisdictions to allow providers and Medicare Administrative Contractors to more easily adapt to and shift reimbursement in response to market-based costs.

Personal Protective Equipment CPT Code 99072

The CPT Editorial Panel released code **99072** after the release of the 2021 PFS proposed rules. During the comment period, stakeholders reached out to CMS for immediate consideration of valuation of code **99072** because of the expenditures incurred by providers in response to COVID-19. Specifically, stakeholders requested valuation of direct PE inputs for supplies and clinical staff time beyond the services provided with the code. Because of the increased costs incurred by stakeholders, CMS finalized on an interim basis an increase in pricing for several supplies based on submitted invoices for code **99072**. These supplies included N95 masks, surgical masks, and face shields. CMS did not finalize any RVUs for code **99072**; it is considered a bundled code.

E/M Guidelines

These visits comprise nearly 40 percent of allowed charges for 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 code comprises the bulk of their charges. For other specialties that are more procedural based, the bulk of services billed are not E/M.

CMS had proposed a new code to account for complexity of services provided to new and established patients. CMS indicated that it believes that the updated definitions for CPT **99202-99215** reflect the work provided in a "typical" office outpatient visit; however, for some specialties these codes do not adequately capture the resources associated with patient care. CMS proposed a Healthcare Common Procedure Coding System (HCPCS) add-on code: temporary code **GPC1X**. CMS finalized the add-on code as:

- **G2211**: Visit complexity inherent to E/M 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 complex condition. Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established.

This code is for use by any specialty for the ongoing care needs of the patient and potentially evolving illness.

The care provided would be distinctly separate from existing services represented by preventative and care management services. Instead HCPCS add-on code **G2211** "reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time." CMS believes that the addition of this code could bolster comprehensive and longitudinal care in the rural setting. The PFS 2021 national rate, facility and non-facility, for code **G2211** is $15.88.

CMS did indicate that there would also be circumstances in which it would *not* be appropriate to bill HCPCS G2211: *"... there are many visits with new or established patients*

where HCPCS add-on code G2211 would not be appropriately reported, such as when the care furnished during the office/outpatient E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature, such as a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, initial onset gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or and when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time."

In addition, CMS stated that **G2211** would not be reported when the office/outpatient E/M visit is reported with a payment modifier, such as –25. In these instances, there are already separate and distinct services provided to the patient beyond the E/M visit, which would preclude the use of the add-on code.

Documentation to support the ongoing relationship between the practitioner and patient could be represented by the patient relationship codes **X1**, **X2**, **X3**, **X4**, and **X5** established under the Medicare Access and CHIP Reauthorization Act of 2015. Each of the patient relationship modifiers defines the relationship between the patient and practitioner at the time the item or service is furnished.

For CY 2021 the American Medical Association created this new CPT code:

- **99417**: 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 additional 15 minutes (List separately in addition to CPT codes **99205**, **99215** for office or other outpatient evaluation and management services).

This code is billable with time-based reporting for office/outpatient visit codes that have reached the threshold for a level 5 visit (**99205** and **99215**).

In the 2021 PFS proposed rule, CMS indicated that it did not agree with the time thresholds for the level 5 office/outpatient codes to be able to bill for a prolonged service code as outlined by the American Medical Association. For example, code **99215**, level 5 established outpatient visit, the time range is 40 to 54 minutes. According to CMS, if the billing practitioner spent 55 minutes with the patient, he or she could not bill the prolonged services code in addition to the level 5 visit code. The agency indicated that if it allowed this, the practitioner would be double dipping his or her time because 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 believes that when the practitioner uses the time-based method, the prolonged services 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. For example, code **99215** as described above has a time threshold of 54 minutes, and to bill for prolonged services, CMS believes that the visit must last at least 69 minutes. This number is 15 more minutes than the top threshold of 54 minutes and is completely separate time from time counted for the actual visit level.

To remedy the discrepancies in reporting for prolonged services with office/outpatient visits, CMS created this HCPCS add-on code:

- **G2212**: Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services).

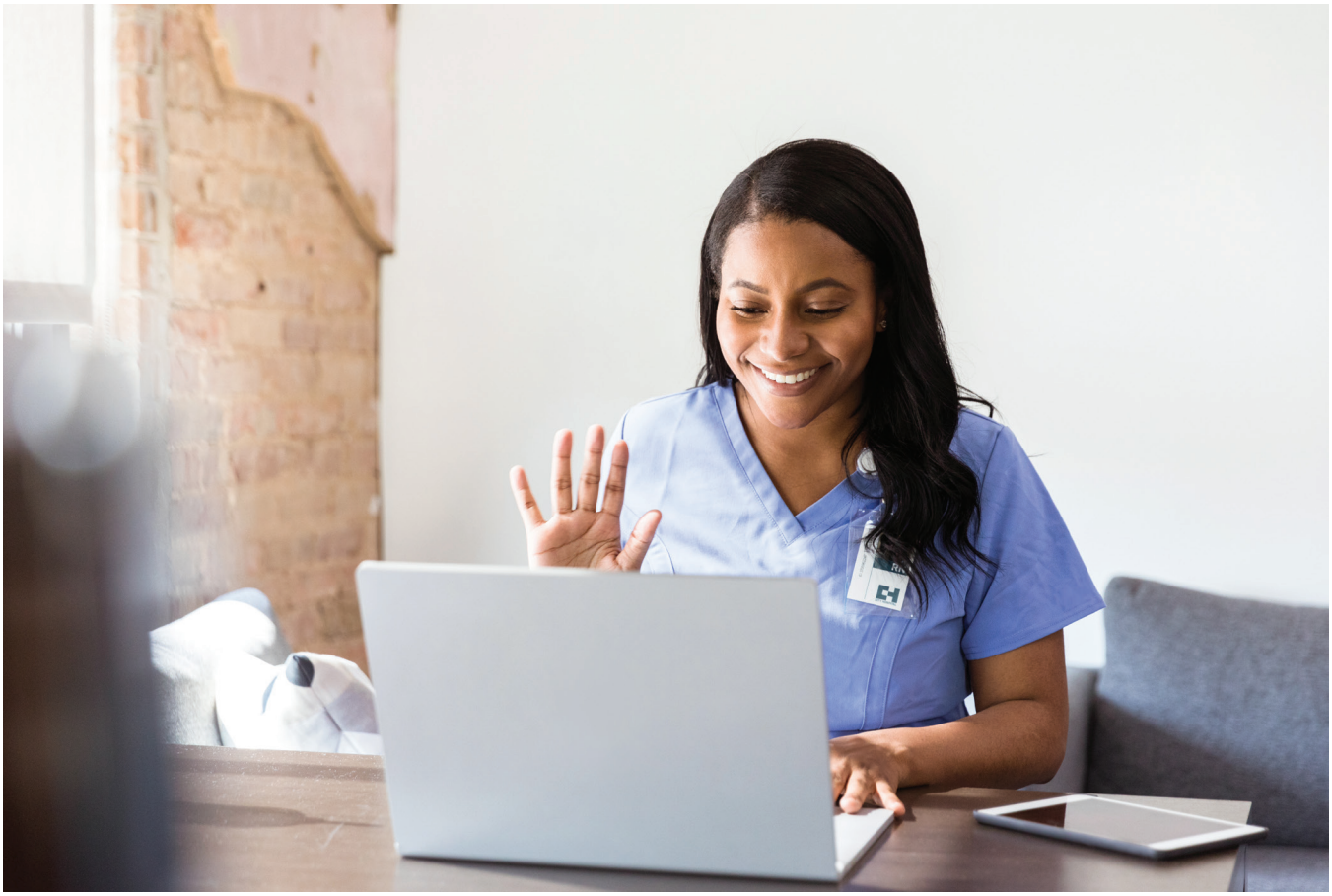
In addition, CMS states, "Do not report **G2212** on the same date of service as **99354**, **99355**, **99358**, **99359**, **99415**, **99416**. Do not report **G2212** for any time unit less than 15 minutes."

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. As part of these waivers and expansion, CMS 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 that when the PHE ends the waivers and expansions would also end and services would revert to pre-PHE days.

Because of the uncertainty of how long the PHE will last 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 to a semblance of "normal" may linger, CMS has finalized a phased-in end to the waivers and expansions for some items rather than a hard-and-fast stop.

Specifically, CMS proposed and finalized several changes to telehealth services moving forward. Any of the newly added services to the Category 3 level of telehealth as part of the PFS final rule will remain on the Medicare telehealth services list through the calendar year in which the PHE for COVID-19 ends. Unfortunately, this does not include code **77427**: Radiation treatment management, 5 treatments, because this code was added as part of the waivers list of temporarily added telehealth services related to the COVID-19 response. CPT **77427** will end as a telehealth service on Jan. 21, 2021. Commenters stated that because most radiation oncology practices were able to secure adequate PPE, it was no longer necessary for the radiation treatment management code to be available as telehealth and CMS agreed. In addition, CMS was concerned that the components of code **77427** could not be adequately provided by real-time audio-video capabilities.



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 practitioners and patients to the use smartphones when communicating with audio and video capability. CMS finalized an update to the last sentence of the Medicare telehealth services regulation that stated: "prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services." The regulation prohibited the use of telephones and could be confusing when a smartphone and its capabilities for audio and video are used for the visit. By removing the term "telephones," outdated references to technology no longer present and potentially create confusion.

Communication Technology-Based Services

As part of the CY 2019 PFS 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. Codes **G2250** and **G2251**, proposed and finalized by CMS, may be billed by nonphysician practitioners. These new codes would also be billable by nonphysician practitioners, 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.

- **G2250**: 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 seven days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
- **G2251**: 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 seven days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5 to 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 because

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 patients 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 that, for some patients, a longer telephone visit is needed. CMS finalized that the agency will not recognize the telephone codes **99441**-**99443** under the PFS after the PHE has ended. Once the PHE ends, the agency will assign the status "B" for "bundled" to the codes. Instead, CMS believes that the communication technology-based services above should be reported for patients after the PHE ends.

On an interim basis, CMS created an HCPCS code for an extended audio-only assessment service. This code has been designed for those patients who even after the PHE has ended are still reluctant to return for in-person visits to their practitioner. This will also allow CMS to determine whether this code should be made permanent. Effective for CY 2021, this HCPCS code is available for use:

- **G2252**: 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 seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11 to 20 minutes of medical discussion.

This code was cross-walked to code **99442** for valuation. HCPCS code **G2252** is not a replacement for in-person visit; instead, it is meant to assess whether one is needed. The only technological requirement for this service is that the communication technology must be synchronous, happening in real-time. As with other similarly defined services, if it results from an E/M service in the previous seven days or in an E/M or other service within the next 24 hours or soonest available appointment, it is bundled into the in-person service.

Physician Supervision for Telehealth Services

For the duration of the PHE, CMS has redefined direct supervision under the PFS 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 him or her to see and interact with the staff member and patient without adding any unnecessary exposure. It is important to note that 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 that 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 finalized to extend direct supervision expansion under the PFS to end later in the calendar year in which the PHE ends or on Dec. 31, 2021. This allows, along with other waivers and extensions, an easement to the change in supervision and for physicians and practices to prepare for the change back to the in-person requirement

CMS Most Favored Nation Model Interim Final Rule

On Nov. 20, 2020, CMS announced the Most Favored Nation 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 that drug manufacturers receive in other similar countries, specifically any country in the Organisation for Economic Co-operation 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. For information on included drugs, drug payments, participation and beneficiary requirements, claims submission, and quality measures, turn to pages 12-15 in the CY 2021 Hospital Regulatory Update. OI

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