

# compliance

## Highlights from the CY 2020 PFS and OPFS Proposed Rules

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### Medicare Physician Fee Schedule Proposed Changes

#### Payment Rates

Calendar year (CY) 2020 begins the transition in the Medicare physician fee schedule (PFS) payment system away from fee-for-service reimbursement, which is affected by the changing conversion factor, to a payment system that is set with potential changes related to budget neutrality. As part of the Medicare Access and CHIP Reauthorization Act of 2015, beginning in CY 2020 the conversion factor is frozen at the CY 2019 rate with no increases through CY 2025.

The budget of the Centers for Medicare & Medicaid Services (CMS) must be maintained within \$20 million, plus or minus, each year. When the impact of any relative value unit (RVU) changes is projected to fall outside the expected budget, a budget neutrality factor is applied to the conversion factor to bring the budget back into range and maintain budget neutrality. CMS is proposing a positive 0.14 percent adjustment to the CY 2019 conversion value, which will result in an overall increase in proposed payments for CY 2020, with a proposed value of \$36.09. The overall impact for CY 2020 on hematology/oncology and radiation oncology (and radiation therapy centers) of the proposed positive adjustment to the conversion factor is expected to be 0 percent.

#### RVUs

Malpractice RVUs reflect the premium liability insurance rates paid by providers under the various specialties by state. These data are used to set values relative to the risk

inherent in the different procedures specific to the specialty. The geographic practice cost index values account for the cost of living and providing services in a specific geographic location and are updated once every three years. Prior to CY 2015, malpractice RVUs were updated every five years; however, in the CY 2016 PFS final rule, CMS changed this update to every three years.

The data used by CMS for both malpractice RVUs and the geographic practice cost index are the same. For CY 2020, CMS is proposing that the valuation of the malpractice RVUs and malpractice geographic practice cost index be coordinated because the malpractice premium data used to update the malpractice geographic practice cost index are the same as those used to determine the risk levels of the specialties. Thus, CMS believes that any changes to the malpractice RVUs would be aligned and relative to the changes in the malpractice geographic practice cost index. This change would implement the next mandated review in CY 2023.

Beginning in CY 2020, CMS will recognize two new specialties for which the agency will calculate specific values related to practice expense RVUs: medical toxicology and hematopoietic cell transplantation and cellular therapy. CMS recognized both specialties in 2018, and each will have values related to the direct practice expense categories (clinical labor, medical supplies, and medical equipment) and the indirect expense categories (administrative labor, office expense, and all other expenses) valued into their procedure codes.

### Reimbursement and Proposed Valuation of Codes

In the CY 2020 proposed PFS rule, CMS addresses a few of the misvalued and/or proposed value changes to specific series of CPT® codes. The agency explains the rationale for the proposed changes, values recommended by the Relative Value Scale Update Committee and other organizations to which CMS looks for assistance in setting appropriate values for codes.

The only oncology-specific codes that CMS addresses for proper valuation are the radiation oncology G-codes (**G6001-G6017**) for treatment delivery and image-guided radiation therapy. These codes have been in place since January 1, 2015, and are set to expire on December 31, 2019, when they were slated to be replaced with an alternative payment model under the PFS. In early July 2019 CMS released a proposed rule on the Radiation Oncology Payment Model, but within this model CMS continues to list the G-codes as applicable codes in CY 2020.

Under the PFS, CMS is proposing to continue using the G-codes for treatment delivery and image-guided radiation therapy and continue to use the current work RVUs, direct practice expense inputs, and the practice expense methodology to include a utilization rate of 60 percent for the IMRT accelerator.

### Evaluation and Management Guidelines

With the CY 2019 PFS final rule, CMS made clear the agency's intent to make sweeping changes to evaluation and management (E/M) guidelines. Most of the changes were

slated for CY 2021 to give stakeholders time to prepare, and the American Medical Association (AMA) time to accept that change was coming and align its guidelines with CMS.

In the CY 2020 PFS proposed rule, CMS revisits changes to E/M codes it finalized in the 2019 PFS rule. Most of these changes, slated to go into effect in 2021, are now removed. For CY 2020 CMS proposed to align E/M changes with those of the AMA. The agency is now proposing the following, effective January 1, 2021. Discontinued payment or recognition for AMA deleted code **99201** (office or other outpatient visit for the evaluation and management of a new patient); deleted CMS finalized times assigned to the code levels, including all of the time spent on the date of the visit; and eliminated the ability to use the history and exam or time in combination with the medical decision making to select the final code level.

After release of the CY 2019 final PFS, CMS held several stakeholder meetings. Much of the feedback the agency received was related to the single payment rate for levels 2-4 of the outpatient office visits. Many voiced concerns that paying the same amount regardless of level would incentivize providers to spend as little time as necessary or the minimum to qualify for payment, rather than spend more time as beneficial for patients. Other feedback included requests that time be the only tool for determining the level of visit because these data are easy to audit, document, consistently interpret, and apply to the levels and better account for complexity levels.

The AMA has published an estimate of anticipated burden reduction relative to its policies online [ama-assn.org/cpt-evaluation-and-management](https://ama-assn.org/cpt-evaluation-and-management). Given the information and feedback the AMA received when conducting its surveys, CMS is now proposing the following for CY 2021:

- Assign separate reimbursement amounts to each visit code level instead of one rate for levels 2-4, except code **99201**, which will be deleted in CY 2021.
- Recognize and reimburse the new prolonged visit add-on code (**CPT® code 99XXX**) and allow for this code to be used with levels 2-4 as well as level 5.

- Delete the HCPCS add-on code for extended visits: **GPRO1**.
- Eliminate history and/or physical exam in determining billable code level.
- Remove requirement for the number of body systems reviewed to be documented; only include as pertinent to the visit itself.
- Establishing level 1 visits (**99211**) to describe or include those visits performed only by clinical staff for established patients.
- Code for visit levels based on medical decision making or time (both face-to-face and non-face-to-face on same date as visit) personally spent by billing provider.
- Consolidate and revalue primary care and non-procedural medical care codes (**GPC1X** and **GCG0X**).
- Adopt the prefatory language and interpretive guidance framework established by the AMA ([ama-assn.org/cpt-evaluation-andmanagement](https://ama-assn.org/cpt-evaluation-andmanagement)) to assist with conformity and reduce burden to providers.

### Utilization of State Scope of Practice Requirements for Non-Physician Practitioners

CMS recognizes that the scope of work provided by non-physician practitioners has greatly changed since 1965 when the Medicare program was signed into law. At that time, nurses predominantly provided assistance to physicians. Today, other specialties, such as nurse practitioners (NPs) and physician assistants (PAs), also known as non-physician practitioners (NPPs), assist physicians. Due to these changes, CMS is proposing to adjust language regarding how these NPPs provide assistance.

Some of the proposed changes will allow for NPPs to provide services in Medicare-certified facilities within their scope of practice as defined by the state where the services are provided. For beneficiaries receiving hospice care, this means that a patient could select his PA as his attending physician. Historically, PAs working in the hospice setting could not write scripts for medications or orders for care without intervention by a physician. CMS is proposing to amend this language to allow for hospice to accept drug orders from

a physician, NP, or PA. Similar to NPs, PAs must have within their state scope of practice the ability to do so, and they must be designated as the patient's attending physician and not contracted with the hospice itself.

### Physician Supervision of 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 clinical nurse specialists. As mentioned previously, the scope of work provided by PAs has changed over the years, and many provide and deliver healthcare 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; whereas others have yet to make any changes.

Currently CMS requires general supervision of the PA by the physician. CMS is seeking comments to fully understand the roles of PAs and how the current supervision requirements impede or constrict a PA's ability to provide services to beneficiaries.

CMS is proposing to amend the physician supervision requirements of PA services. Specifically, CMS is proposing to allow PAs to provide services in alignment with the state law and scope of practice for where the services are provided. These services would need to be performed under the necessary medical direction and appropriate supervision as outlined by the state. If there are no state laws that address supervision of PA services, the supervision would need to be documented in the medical record to support the PA's work with the physician in furnishing the services. This documentation would need to be available upon request.

The CY 2020 PFS proposed rule is located in its entirety online at: [s3.amazonaws.com/public-inspection.federalregister.gov/2019-16041.pdf](https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16041.pdf). To submit comments, refer to file code **CMS-1715-P**. Comments must be received **no later than 5 pm EST September 27, 2019**. CMS encourages electronic submission ([regulations.gov](https://www.regulations.gov)). Follow the instructions under the "submit a comment" tab.

## Hospital Outpatient Prospective Payment System Proposed Changes

### Payment Rates

CMS is proposing an increase of payment rates under the Outpatient Prospective Payment System (OPPS) with a 2.7 percent increase to the CY 2019 conversion factor. For CY 2020, CMS is proposing a conversion factor of \$81.4; however, for hospitals that fail to meet the Hospital Outpatient Quality Reporting Program requirements, the agency proposes a conversion factor of \$79.7. Based on the proposed updates to the payment rates, CMS is projecting that CY 2020 OPPS expenditures will be approximately \$79 billion, an increase of approximately \$6 billion compared to projected CY 2019 OPPS payments.

CMS is proposing to maintain the rural adjustment factor of 7.1 percent to the OPPS payments to certain rural sole community hospitals, including essential access community hospitals for CY 2020 and subsequent years. This payment adjustment will continue to exclude separately payable drugs, biologicals, and devices paid under the pass-through payment policy. CMS proposes a target payment-to-cost ratio of 0.89 to determine the CY 2020 cancer hospital payment adjustment to be paid at cost report settlement.

CY 2020 will mark the second and final adjustment year based on CY 2019 finalized changes to how the clinic visit, represented by code **G0463**, is reimbursed in all off-campus departments. Due to the high volume of reporting for the outpatient clinic visit billed with code **G0463**, CMS finalized reimbursement adjustments to the most widely reported code under the OPPS for what is seen as “unnecessary increases in the volume of outpatient service.”

For CY 2019, CMS finalized a site-neutral method for reimbursement of code **G0463**. In any setting considered off-campus (i.e., more than 250 yards from the main buildings of the hospital), either excepted or nonexcepted, CMS set a site-neutral rate. This means that in either off-campus location (excepted or nonexcepted) the reimbursement for code **G0463** would be 40 percent of the on-campus outpatient reimbursement.

Due to the high rate change, CMS must implement these cuts over a two-year period, rather than all at once.

For CY 2019, code **G0463** was to be reimbursed at 40 percent of the OPPS payment rate, which is a reimbursement decrease of 60 percent. To phase in this 60 percent cut, the decrease was divided in half for implementation over two years. Thus, in CY 2019 reimbursement rates for **G0463** in all off-campus provider-based departments were decreased by 30 percent. The remaining 30 percent will be applied in CY 2020, bringing the overall total reimbursement down 60 percent, so that payment will be at 40 percent of the hospital OPPS rate.

### Payment Policy for Drugs, Biologicals, and Radiopharmaceuticals

For CY 2020, CMS is proposing to increase the drug packaging threshold to \$130 per day, up from the current \$125. Any drugs, biologicals, or radiopharmaceuticals that are reimbursed at a value greater than \$130 will be reimbursed separately. Those that fall under the threshold will be packaged into the services provided and not separately paid.

CMS is proposing to continue reimbursing drugs and biologicals with pass-through status at average sales price (ASP) + 6 percent. The agency proposes to continue to reimburse drugs and biologicals with non-pass-through status and those acquired with the 340B drug discount at ASP - 22.5 percent; however, CMS is asking for comments on how to address recent and pending litigation for CYs 2018 and 2019.

For 2020, CMS is proposing to implement wholesale acquisition cost (WAC) + 3 percent in place of WAC + 6 percent when WAC-based pricing is used for any drug or biological. For any drugs or biologicals purchased under the 340B program, the rate would also continue to be WAC - 22.5 percent.

CMS is proposing to continue the policy in which all biosimilar biological products are eligible for pass-through status and not just the first biosimilar product of a reference product. For biosimilar biologicals purchased under the 340B program, the agency would also continue applying the ASP - 22.5 percent methodology to the biosimilar's ASP and not the reference product for those not granted

pass-through status. However, in light of pending litigation, CMS is seeking comments about the proposed reimbursement policy change in which biosimilar products purchased under 340B drug program are reimbursed at ASP + 3 percent of the reference product's ASP.

Since implementation of the drastic reduction in reimbursement for drugs purchased under 340B program (ASP - 22.5 percent), which began in CY 2018, lawsuits have been filed alleging that CMS does not have the authority to make these changes. After a request by CMS for a final judgment, so that the agency could file an appeal, the district court entered a final judgment on July 10, 2019. Recent litigation concluded that in the OPPS final rule for CY 2018 Secretary Azar “exceeded his statutory authority” by adjusting the reimbursement rate to ASP - 22.5 percent. CMS is taking steps to appeal and create a policy that would address what the court sees as overstepping, and for reimbursement of monies back to hospitals and adjustment to beneficiary cost sharing. The agency is seeking public comment on how to proceed with reimbursement for drugs purchased under the 340B program for CY 2020 and beyond outside of any changes or policies that may need to be adopted pending the ongoing litigation.

Any repayment of monies back to hospitals and impacts to beneficiary cost sharing could have far-reaching effects. A few of the highlights for how CMS plans to do this and the comments the agency is seeking to assist with this plan include:

- CMS operates in a budget-neutral system; reversal of the rates would impact approximately 3,900 facilities reimbursed for outpatient services and beneficiary cost sharing to an estimated sum of \$1.7 billion for CY 2018 alone. Savings from the program were distributed across all other specialties by increasing reimbursement and decreasing beneficiary expenses. This would have to be paid back to hospitals and beneficiaries may be required to pay additional monies due to the reduced rates for CYs 2018 and 2019, which would be corrected and as part of their 20 percent responsibility.

- Proposing to continue paying ASP - 22.5 percent for drugs and biosimilar biologics acquired under 340B program and furnished in nonexcepted off-campus provider-based departments paid under the PFS.
- Seeking comments for an OPPS rate for drugs acquired under 340B program of ASP + 3 percent would be appropriate and a remedial payment amount for CY 2020 and for determining how to rectify CYs 2018 and 2019.
- Seeking comments on how to structure CYs 2018 and 2019 and the potential payback scenario. For example, should payback be retrospective on a claim-by-claim basis or prospective by adjusting future claims to account for the underpayments. Also, how to address hospitals that do not acquire drugs under 340B program, while respecting the need to remain budget neutral and what those adjustments may mean.
- Potentially addressing each hospital that can demonstrate harm from the underpayment and CMS would make a one-time calculated payment through their Medicare Administrative Contractor. This would be done by identifying claims submitted with modifier JG for CYs 2018 and 2019. Rather than reprocessing every claim, this payment would be outside the normal claims processing approach.
- Seeking comments on advantages and disadvantages to spreading out over future years a budget-neutral adjustment depending on the amount that is calculated as underpaid and the outcome of the appeal.
- Seeking comments on the most appropriate way to address the impact to the Medicare beneficiary and the cost-sharing responsibilities for whichever solution is selected.

### **Proposed Changes to Supervision of Therapeutic Outpatient Services**

Since April 2000, CMS has required direct supervision of therapeutic services in the outpatient setting. In CYs 2009, 2010, and 2011, CMS continued to clarify what direct supervision means and the expectations for meeting the requirements. During that time, critical access hospitals and many rural hospitals pushed back, citing hardship in

recruiting staff or hiring appropriate physicians for all therapeutic services to meet the requirement. Many stakeholders specifically cited difficulties with finding appropriately trained physicians for specialty services, such as radiation oncology, for the more rural locations.

In response to stakeholder concerns, over the years CMS has enforced, and then not enforced, the need for direct supervision of all therapeutic services in critical access hospitals and, most recently, in rural hospitals with 100 or fewer beds. The current enforcement exception for critical access hospitals and rural hospitals with 100 or fewer beds is set to expire December 31, 2019. With this deadline quickly approaching, the agency has decided on an across-the-board review of the direct supervision requirement for all hospitals regardless of size or location.

CMS expressed concern that currently there are two tiers to supervision for the same services. General supervision is applied for critical access hospitals and rural hospitals with 100 or fewer beds; direct supervision is required for all other hospitals. Additionally, the agency indicated that it is not aware of any data or information that would lead it to believe that the application of only general supervision in the designated areas has affected the services or care of patients. To alleviate these differences, CMS is proposing one supervision standard (general supervision) for all hospital outpatient therapeutic services provided in hospitals and critical access hospitals.

Per the proposed OPPS rule, general supervision is defined as “procedure is furnished under the physician’s overall direction and control, but that the physician’s presence is not required during the performance of the procedure.” Direct supervision “means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.” Additionally, the physician must be able to respond without interval of time and not be providing another service that he or she cannot step away from.

CMS emphasizes, however, that if the requirement were changed to general supervision this would not prevent any of the hospitals from providing services under direct supervision when the physician administering that service determines that it is appropriate to do so. There are many therapeutic services provided in the outpatient setting that are highly complex and need the direct supervision of the qualified physician.

CMS also stated that it is specifically seeking comments on whether specific types of services, like chemotherapy administration or radiation therapy services, should be excepted from this proposed change of supervision level. If these services were excluded, direct supervision would be required as it is currently, and there would be no change, except, possibly, for critical access hospitals and rural hospitals with 100 or fewer beds, which might see enforcement of the direct supervision requirement.

### **Proposed Requirements for Transparency**

For CY 2020, CMS is proposing to require hospitals to make public a list of standard charges. The Public Health Service Act, Sec 2718 “Bringing Down the Cost of Health Care Coverage,” requires hospitals to make public a list of the hospital’s standard charges for items and services—and even diagnosis-related groups—used for inpatient services. This concept of publishing charges for services is not new and was reclarified for reporting effective January 1, 2019, but there are some proposed changes to ensure compliance and conformity to the published data.

The items and services that CMS is proposing for public listing include supplies, procedures, room and board, professional services of employed physicians and non-physician practitioners, and any other services for which the hospital has a charge. The standard charges are defined as “gross charges” and “payer-specific negotiated charges.”

CMS also proposes that the charges be displayed in a format that is easily accessible by the public without the need for further processing or special software. The agency states that acceptable formats include, but

are not limited to, XML, JSON, and CSV. The agency does not consider PDF an acceptable format because most consumers would have to purchase or have access to software to download or review the file. CMS considered mandating the use of XML but did not want to be overly prescriptive.


In addition, CMS is proposing that all hospitals make public payer-specific negotiated charges for 70 CMS-selected shoppable services (listed in table 37 of the proposed rule). Included among these are E/M services, laboratory and pathology services, radiology services, and medical and surgical services. In addition to the 70 CMS-selected shoppable services, each hospital must also select at minimum another 230 shoppable services (identified by primary CPT®, HCPCS, and diagnosis-

related group codes) to make public to reach a total of 300 services.

The proposed rule states that though hospitals can select these services, they must be among those with high utilization or billing rates over the past year. Hospitals would be required to update the information at least once every 12-month period. Though the proposal gives hospitals the ability to decide where to place this information on their website, the agency requires that the information be easy to find, “displayed prominently,” and not require login or personal information for consumer access so that the public is not dissuaded from downloading the information.

CMS is seeking feedback on monitoring compliance. For those hospitals failing to meet the proposed standard, civil monetary

penalties would be imposed, but hospitals would have the opportunity to take corrective action first. The proposed maximum daily dollar penalty, regardless of how egregious or the number of violations identified, would be \$300.

The full CY 2020 OPPS proposed rule is available at [s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf](https://www.federalregister.gov/2019-16107). To submit comments, refer to file code **CMS-1717-P**. Comments must be received **no later than 5 pm EST Sept. 27, 2019**. CMS encourages electronic submission ([regulations.gov](https://www.regulations.gov)). Follow the instructions under the “submit a comment” tab. 

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