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Regulatory Update: CMS Final Rules for Calendar Year (CY) 2019 – Physician Fee Schedule (PFS) & Ambulatory Surgical Center (ASC) and Outpatient Prospective Payment System (OPPS)

December 3, 2018

Background & Summary

On Thursday, November 1, and Friday, November 2, the Centers for Medicare & Medicaid Services (CMS) issued the annual final rules to update the calendar year (CY) 2019 Medicare payment and policies for the physician fee schedule (PFS), and to update the calendar year (CY) 2019 Medicare payment rates for services payable under the Ambulatory Surgical Center (ASC) and Hospital Outpatient Prospective Payment System (OPPS).

You can find Vizient's detailed summaries on the proposed PFS and OPPS/ASC payment regulations on our Public Policy website. You can find Vizient's comment letters to CMS on the PFS proposed rule here, and the OPPS/ASC proposed rule here. These final payment regulations are effective on January 1, 2019, except when noted otherwise.

PFS Payment Update

The annual update to the PFS conversion factor (CF) is calculated based on a statutory formula. CMS finalized a total increase in PFS payment rates of 0.11 percent in CY 2019. This adjustment results in an estimated conversion factor of $36.0391 for CY 2019, an increase from the CY 2018 conversion factor of $35.9996. The PFS Addenda along with other supporting documents and tables referenced in the final rule are available on the CMS website.

Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

Section 603 of the Bipartisan Budget Act (BBA) of 2015[1] requires that certain items and services – with the exception of dedicated emergency department services – furnished in off-campus provider-based departments (PBDs) that began billing under the Outpatient Prospective Payment System (OPPS) on or after November 2, 2015 are no longer to be paid under the OPPS, but under another "applicable payment system". In the CY 2017 OPPS/ASC final rule with comment period[2], CMS finalized the PFS as the "applicable payment system" for most nonexcepted items and services furnished by off-campus PBDs on or after January 1, 2017. On December 13, 2016, the 21st Century Cures Act was enacted into law, amending Section 603 of the BBA, and providing additional criteria about which off-campus PBDs will be "excepted" (excluded/exempt) from this reduced payment under the law.

In prior rulemaking, CMS established a new set of site-specific payment rates under the PFS to reflect the relative resource cost of furnishing the technical component (TC) of services furnished in nonexcepted off-campus PBDs. The PFS Relativity Adjuster is the percentage of the OPPS payment amount paid under the PFS for a nonexcepted item or service to the nonexcepted off-campus PBD.

For CY 2019, CMS is not making any changes to the "site-neutral" payment rates under the PFS and will continue applying a PFS Relativity Adjuster of 40 percent (of the OPPS amount) for CY 2019 and future years. Additionally, CMS is maintaining policies related to supervision rules, beneficiary cost sharing, and

[1] Bipartisan Budget Act of 2015, Pub. L. No. 114-74.
[2] 81 Fed. Reg. 79713, 79720 through 79729 (Nov. 14, 2016)

geographic adjustments as previously finalized. CMS proposed and finalized a policy for CY 2017 and CY 2018 in which nonexcepted off-campus PBDs continued to bill for nonexcepted items and services on the institutional claim utilizing a new claim line modifier "PN" to indicate that an item or service is a nonexcepted item or service. For CY 2019, CMS is finalizing their proposal to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using the "PN" modifier.

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

Consistent with statute[3], current Medicare Fee For Service (FFS) payments for separately payable drugs and biologicals furnished by providers and suppliers include an add-on of 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the "6 percent add-on"). Although the statute does not specifically state what the 6 percent add-on represents, CMS noted in their proposed rule that "it is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, and storage, as well as additional mark-ups in drug distribution channels."

Therefore, CMS is finalizing their proposal that, effective January 1, 2019, in the case of a drug, biological or biosimilar during an initial sales period in which data on the prices for sales (ASP) is not yet available from the manufacturer, WAC-based payments for Part B drugs will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. Once the ASP information is available, the standard Part B reimbursement rate of ASP plus 6 percent will become effective. CMS notes this payment reduction will not apply to single source drugs or biologicals that are required under law that a 6 percent add-on be applied regardless of whether WAC or ASP is less.

CMS is also finalizing changes to permit Medicare Administrative Contractors (MACs) to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs and biologicals. In the near future, CMS plans to issue Claims Processing Manual instructions that will address the application of the add-on to payment determinations made by MACs.

Modernizing Medicare Physician Payment – Communication Technology-Based Services

CMS is finalizing the proposals to modernize Medicare physician payment for "communication technology-based services", which would not be subject to limitations on Medicare telehealth services in section 1834(m) of the ACA because CMS does not consider them to be Medicare telehealth services. Instead, like other physicians' services, they would be paid under the PFS. CMS notes that in furnishing these services, practitioners need to comply with any applicable privacy and security laws, including the HIPAA Privacy Rule.

CMS is creating coding and finalizing their proposals to make separate payment under the PFS for two of these services. The first is for brief communication technology-based "check-in" services between providers and patients. The code will be described as Healthcare Common Procedure Coding System (HCPCS) G2012 "(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion)." CMS is also finalizing their proposal to limit this service to established patients. The second is for providers' remote evaluation of recorded video and/or images submitted by the patient. The code will be described as HCPCS G2010 "(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment)." CMS is also finalizing their proposal to limit this service to established patients. Only physicians or other qualified health care professionals who are eligible to bill for E/M services (the providers) may bill for virtual check-ins and remote evaluations.

[3] Section 1847A of the Social Security Act (SSA), as established in the Medicare Modernization Act of 2003 (MMA)

Medicare Telehealth Services & Adding to the List of Services

Beginning in CY 2019, CMS is finalizing the addition of two codes to the list of Medicare telehealth services for prolonged preventive services that extend beyond the typical service time of the primary procedure and require direct patient contact. Additionally, CMS is finalizing that for CY 2019 and onward, they will extend the timeline for accepting requests to add services to the list of Medicare telehealth services through February 10, consistent with the deadline for receipt of code valuation recommendations from the Relative Value Scale Update Committee (RUC). In other words, to be considered during PFS rulemaking for CY 2020, requests to add services to the list of Medicare telehealth services must be submitted and received by February 10, 2019.

Interprofessional Internet Consultation Services & Payment

Recognizing the shift and proliferation of team-based approaches to care that are often facilitated by electronic medical record technology, CMS is finalizing proposals to make a separate payment for six current procedural terminology (CPT) codes that describe interprofessional internet consultations by a consulting physician. CMS reiterates concerns about how these services can be distinguished from activities undertaken for the benefit of the practitioner, such as information shared as a professional courtesy or as continuing education – and notes that consultations must be performed for the benefit of a specific patient, not for the general benefit of the physician.

CMS is finalizing separate payment for CPT codes 99451, 99452, 99446, 99447, 99448, and 99449 describing interprofessional consultation services. Additionally, the agency is finalizing a policy to require the patient's verbal consent that is noted in the medical record for each service. CMS notes that cost sharing will apply for these Interprofessional services, and that these services may be billed only by practitioners that can bill Medicare independently for evaluation and management (E/M) services.

Streamlining Evaluation and Management (E/M) Payment and Reducing Clinician Burden

Under the PFS, physicians and other practitioners bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) – which distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. In the CY 2018 PFS rulemaking, CMS requested stakeholder feedback on potential changes to the E/M documentation rules – but deferred making any changes to the E/M coding itself in order to focus more immediately on the revision of E/M guidelines to "reduce unnecessary administrative burden." In the CY 2019 PFS proposed rule, CMS made several major proposed changes to current E/M coding and documentation, as well as payment (see Vizient summary here). The agency discussed at length their proposed policies and belief that the E/M visit code set is outdated and needs to be revised and revalued. CMS also reiterated their belief that E/M documentation changes were inextricably linked to PFS payment policies.

After considering stakeholder comments, CMS is finalizing several of their documentation proposals in order to provide "significant and immediate burden reduction…." including 1) eliminating the requirement to document the medical necessity of a home visit in lieu of an office visit; 2) allowing providers to document only what has changed since an established patient's last visit or pertinent items that have not changed; and 3) clarifying that for new and established patients, providers do not need to re-enter in the medical record information that was already entered by ancillary staff or the beneficiary. These new policies are effective on January 1, 2019.

For CY 2019 and 2020, CMS will continue the current coding and payment structure for E/M office/outpatient visits. Thus, "practitioners should continue to use either the 1995 or 1997 versions of the E/M guidelines to document E/M office/outpatient visits billed to Medicare for 2019 and 2020" (with the exception of their final policy to eliminate redundant data recording).

In the final rule, CMS acknowledges significant stakeholder feedback, specifically regarding the time it takes for practitioners and stakeholders to implement significant payment and coding changes. Therefore, CMS is finalizing modified changes in payment coding, and associated documentation rules for E/M office/outpatient visits for 2021. At that time, there will be a significant reduction in the current payment variation in office/outpatient E/M visit levels with CMS paying a single rate for E/M office/outpatient visit levels 2, 3, and 4 (one for established and another for new patients). CMS is not finalizing the inclusion of E/M office/outpatient level 5 visits in the single payment rate based on stakeholder feedback that level 5 visits are critical to account for the care and needs of complex patients.

Additionally, CMS is not finalizing aspects of the original proposals that would have: "reduced payment when E/M office/outpatient visits are furnished on the same day as procedures, established separate podiatric E/M visit codes, or standardized the allocation of Practice Expense Relative Value Units (PE RVUs) for the codes that describe these services." For CY 2021, CMS is finalizing a policy to "adopt add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of specialized medical care." These add-on codes will only be reportable with E/M office/outpatient level 2 through 4 visits – and generally, their use will not impose new per-visit documentation requirements. CMS states that these codes are neither required nor restricted by physician specialty. The agency acknowledges, however, that "like many other physicians' services for which payment is made under the PFS, they are specifically intended to describe services that clinicians practicing in some specialties are more likely to perform than those in other specialties." For CY 2021, CMS is also finalizing a policy to "adopt a new 'extended visit' add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient."

Beginning in CY 2021, for E/M office/outpatient levels 2 through 5 visits, CMS will allow for flexibility in how visit levels are documented. Specifically, practitioners have the choice to use the 1995 guidelines[4], 1997 guidelines[5], time, or Medical Decision-Making (MDM) to determine the E/M level. Additionally, for E/M office/outpatient level 2 through 4 visits, CMS will apply a "minimum supporting documentation standard associated with level 2 visits when practitioners use the current framework or MDM to document the visit." The agency intends to continue to engage stakeholders to further refine these policies via future notice and comment rulemaking.

OPPS Payment Update

After accounting for inflation and other adjustments required by law, the final rule would increase outpatient operating payment rates by 1.35 percent in calendar year (CY) 2019. Based on this update, CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 will be approximately $74.1 billion, an increase of approximately $5.8 billion compared to estimated CY 2018 OPPS payments. CMS is continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services (i.e., a fee schedule increase factor of -0.65 percent).

Method to Control Unnecessary Increases in Volume of Outpatient Services

CMS continues to be concerned with the rate of increase in program expenditures under the OPPS. Furthermore, CMS is "concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making." If there are lower-cost sites-of-service available, CMS believes that "beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons." CMS believes that the higher payment rates under OPPS as compared to PFS incentivizes providers to furnish care in the former versus latter site of service – something the agency considers unnecessary if a beneficiary can safely receive care in a higher cost setting.

CMS states that "capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed." Therefore, for CY 2019, CMS proposed to "apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by Healthcare Common Procedure Coding System (HCPCS) code G0463", when provided at previously excepted (grandfathered) off-campus PBDs (departments that bill the modifier "PO" on claim lines). CMS cites that they are making this proposal "given the unnecessary increases in the volume of clinic visits in hospital outpatient departments." In other words, CMS is proposing to pay for clinic visit (i.e., evaluation and management

[4] CMS 1995 Documentation Guidelines for Evaluation and Management Services.
[5] CMS 1997 Documentation Guidelines for Evaluation and Management Services.

(E/M)) services in excepted off-campus PBDs at the same rate they are paid in nonexcepted off-campus PBDs – which is 40 percent of the OPPS payment rate (the “PFS equivalent” payment rate).

CMS will phase in the application of the reduction in payment for code G0463 in excepted off-campus PBDs of a hospital over 2 years. The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2019. Based on a 2-year phase-in of this policy, half of the total 60 percent payment reduction, a 30 percent reduction, will apply in CY 2019. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service. **In other words, these departments will be paid 70 percent of the OPPS rate for the clinic visit service in CY 2019.** The final payment rates are available in Addendum B to the final rule with comment period (available on the CMS website). In CY 2020 and subsequent years, these departments will be paid the site-specific PFS rate for the clinic visit service. **In other words, these departments will be paid 40 percent of the OPPS rate for the clinic visit in CY 2020 and subsequent years.** Under this policy, an excepted off-campus PBD will continue to bill HCPCS code G0463 with the “PO” modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 when billed with modifier “PO” will be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier “PN”.

As a result of this finalized policy, CMS estimates decreases of 0.6 percent to both urban and rural hospitals, with the “estimated effect for individual groups of hospitals depending on the volume of clinic visits provided at the hospitals’ off-campus PBDs.” Taking into consideration the comments regarding a potential disproportionate impact to rural hospitals, CMS believes “that implementing this policy with a 2-year phase-in will help to mitigate the immediate impact […].” The agency “may revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.” Additionally, CMS will implement this policy in a non-budget neutral manner, resulting in an estimated decrease in total payment under the OPPS in CY 2019 at $380 million – with Medicare OPPS payments decreasing by $300 million and beneficiary copayments decreasing by $80 million.

Expansion of Clinical Families of Services at Excepted Off-Campus Provider-Based Departments (PBDs) of a Hospital

In addition to capping the OPPS payment at the PFS-equivalent rate for clinic visit services, CMS solicited public comments on how to expand the application of the Secretary’s statutory authority to “additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization.” For CY 2019, CMS proposed that if an excepted off-campus PBD furnished items and services from a clinical family of services from which it did not furnish items and services (and subsequently bill for those items and services) during a baseline period, services from the new clinical family of services would not be covered OPD services. Instead, these items and services would be nonexcepted and paid under the PFS at 40 percent of the OPPS amount. While CMS is not finalizing this proposal at this time, the agency intends to monitor the expansion of services in excepted off-campus PBDs, and the public comments the agency received will be considered for future rulemaking.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

In order to develop data to assess the extent to which OPPS services are shifting to off-campus PBDs, CMS will be implementing – through the subregulatory HCPCS modifier process – a new modifier effective beginning January 1, 2019. Details will be released via the agency’s OPPS transmittal sometime in December. CMS is creating a HCPCS modifier (ER—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. The modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals (CAHs) would not be required to report this modifier.

CY 2019 Final OPPS Payment Methodology for 340B Purchased Drugs

Last year, CMS finalized its proposal to pay for separately payable, non pass-through drugs and biologicals (other than vaccines) purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5 percent, rather than the current rate of ASP plus 6 percent, effective January 1, 2018. Excluded from this payment adjustment in CY 2018 were rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals. Additionally, this policy change did not apply to drugs on pass-through payment status, which are required to be based on the ASP methodology – or vaccines, which are excluded from the 340B Program. In other words, CMS will continue to exclude Medicare Part B drugs or biologicals that are vaccines (assigned status indicator “L” or “M”) and drugs

with OPPS transitional pass-through payment status (assigned status indicator "G"). For CY 2019, CMS is finalizing their proposal to continue all of the 340B Program policies that were implemented in CY 2018 – with the exception of the way the agency calculates payment for 340B-acquired biosimilars, which will be outlined in more detail below.

Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

Nonexcepted off-campus PBDs are not subject to the payment changes that apply to hospitals and PBDs paid under the OPPS, and thus were not subject to the payment reductions (ASP minus 22.5 percent) for drugs purchased through the 340B Drug Pricing Program finalized in CY 2018 – which apply to hospitals and PBDs paid under the OPPS. In the proposed rule, CMS stated the agency believes that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments – excepted off-campus PBDs versus nonexcepted off-campus PBDs – creates an incentive for hospitals to move drug administration services for these drugs (i.e., to nonexcepted off-campus PBDs to receive a higher payment amount). Thus, for CY 2019, CMS proposed changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program. CMS elected to finalize this proposal.

These payment policies are consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS. Additionally, CMS established two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction, but which do acquire drugs under the 340B Program. CMS implemented the modifiers such that they are required for drugs that were acquired under the 340B Program. Effective January 1, 2019, nonexcepted off-campus PBDs that are paid under the PFS are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug for the payment adjustment (reduction). Rural SCHs, children's hospitals and PPS-exempt cancer hospitals are required to report informational modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP plus 6 percent. Because they are excluded from the OPPS, critical access hospitals (CAHs) are not included in these 340B policy changes.

Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

For CY 2019, CMS is making payment for separately payable drugs and biologicals that do not have pass-through payment status and are not acquired under the 340B Program at wholesale acquisition cost (WAC) plus 3 percent instead of WAC plus 6 percent if ASP data are not available. CMS will continue its current policy and pay for separately payable drugs and biologicals furnished by providers and suppliers to include an add-on of 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition cost (WAC) for the drug or biological (the "6 percent add-on"). Consistent with a similar policy in the CY 2019 Physician Fee Schedule (PFS) proposal, CMS is finalizing that effective January 1, 2019, in the case of a drug or biological during an initial sales period in which data on the prices for sales (ASP) is not yet available from the manufacturer, WAC-based payments for Part B drugs will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. Additionally, CMS is finalizing their proposal to apply this policy to specified covered outpatient drugs (known as SCODs).

The actual payment rates for drugs and biologicals with ASP information for January 2019 will be determined through the standard quarterly process. ASP data submitted by manufacturers for the third quarter of CY 2018 (July 1, 2018 through September 30, 2018) will be used to set the payment rates that are released for the quarter beginning in January 2019, near the end of December 2018. If WAC data are not available for a drug or biological product, CMS will continue their current policy to pay separately payable drugs and biological products at 95 percent of the average wholesale price (AWP). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent, or 69.46 percent of AWP) will continue to apply.

Biosimilar Biological Products

CMS is finalizing their proposal to pay for non pass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's own ASP, rather than ASP minus 22.5 percent of the reference product's ASP – beginning in CY 2019. CMS made this proposal based on feedback received from stakeholders that the "current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program." Additionally, CMS is finalizing

the proposal to continue current payment policy for biosimilar products. That is, all biosimilar biological products are eligible for pass-through payment – and not just the first biosimilar biological product for a reference product. CMS is also finalizing that Medicare will continue to pay for biosimilars with pass-through payment status their own ASP plus 6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program will also continue to be paid their own ASP plus 6 percent of the reference product's ASP.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring regulatory developments that impact our members. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback these policies. We encourage you to reach out to our office if you have any questions or regarding any aspects of this final regulation – both positive reactions and provisions that cause you concern.