IN CY 2020 FINAL HOPPS RULE, CMS FORGES AHEAD WITH CONTESTED CUTS TO PROVIDER-BASED DEPARTMENTS AND 340B DRUGS

Today, the Centers for Medicare and Medicaid Services (CMS) released the **calendar year (CY) 2020 hospital outpatient prospective payment system (OPPS) final rule (fact sheet)** addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs). Of note, the much anticipated hospital price transparency provisions that appeared in the CY 2020 OPPS proposed rule have been stripped from this final rule, and will be published in a separately moving rule, which currently remains pending review at the Office of Management and Budget (OMB).

- **What it is.** This final rule affects payments to approximately 3,800 facilities paid under the OPPS, including hospital outpatient departments (OPDs), as well as ASC payments beginning on Jan. 1, 2020.

- **Why it's important for you.** Despite recent court determinations that CMS exceeded its regulatory authority in previous rulemaking, the agency continues with the implementation of controversial payments cuts to hospitals for clinic visit services furnished at certain off-campus provider-based departments (PBDs) and for certain separately payable drugs or biologicals that are acquired through the 340B program. Specifically, CMS completes the two-year phase in of a 60 percent cut in reimbursements to PBDs and finalizes the continuance of the reduced rate of Average Sale Price (ASP) minus 22.5 percent for 340B drugs, noting that it intends to pursue appeals. Additionally, the rule finalizes its revisions to the Hospital Outpatient and ASC Quality Reporting Programs, revises certain requirements for Organ Procurement Organizations, and announces the availability of residency slots for redistribution following the closure of two teaching hospitals.

  Proposals that would require all U.S. hospitals to publicly post their standard charge information – including negotiated rates for "shoppable" items and services – are not addressed in the final rule, and will be released instead through a separate rule pending review.

- **Potential next steps.** The final rule is effective on January 1, 2020. **Comments are invited by December 2, 2019 on certain provisions** addressing the payment classifications assigned to the interim ambulatory payment classification (APC) assignments and/or status indicators of new or replacement Level II HCPCS codes.

For CY 2020, CMS updates OPPS payment rates by a factor of +2.6 percent (+$6.3 billion) compared with CY 2019 payments. This update factor is based on the projected hospital market basket increase of +3.0

percent minus a -0.4 percentage point adjustment for Multi-Factor Productivity (MFP) required by the Affordable Care Act (ACA).

For the ASC payment system, CMS updates payments by +2.6 percent (+3.0 percent market basket increase minus the -0.4 percentage point adjustment for MFP). The agency estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2020 will be approximately $4.96 billion, (+$230 million over CY 2019 payments). CMS says this policy will help to promote site-neutrality between hospitals and ASCs and encourage the migration of services to the lower cost setting.

Highlights of the OPPS final rule include:

- **<u>Expansion of Site Neutrality</u>** – CMS finalizes several policies intended to reduce payment disparities between inpatient and outpatient settings in Medicare:

    - ***Completion of the Two-Year Phase in for Site Neutral Outpatient Services*** – For CY 2020, CMS finalizes the completion of the two-year phase-in of a 60 percent cut in payments, to achieve a site-neutral rate, for the clinic visit services (billed under HCPCS code G0463) at off-campus provider-based departments (PBDs) excepted from the requirements of Section 603 of the BBA (i.e., those that bill "PO" on claims lines). CMS applied half of this cut in CY 2019, and intends to apply the remaining cut in CY 2020, bringing rates in line with the site-specific Physician Fee Schedule (PFS) rate for the clinic visit service, and saving an estimated $800 million in 2020.

      CMS finalizes this policy, even as it acknowledges that the 30 percent cut applied in CY 2019 was recently vacated by the U.S. District Court for the District of Columbia. The agency says it is working to ensure that affected 2019 claims for clinic visits are paid "consistent with the court's order," but does not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the clinic visit policy, as the Administration is still considering whether to appeal the final judgment. See p. 699 for a detailed discussion.

    - ***Changes to the Inpatient Only (IPO) List*** – Beginning on p. 656, CMS finalizes the removal of Total Hip Arthroplasty (THA), six spinal surgical procedure codes which pertain to varying forms of Arthrodesis and Laminectomy for excision or evacuation of intraspinal lesion, and certain anesthesia services from the inpatient only (IPO) list for CY 2020 and subsequent years, making them payable in both inpatient and outpatient hospital settings. CMS also finalizes the assignment of the THA procedure (previously CPT code 27130) to C-APC 5115 with status indicator "J1." Table 49, on p. 674, reflects all final changes to the IPO list for CY 2020.

      Additionally, in response to comments, CMS establishes a two-year (rather than one-year as proposed) exemption from Beneficiary Family Centered Care-Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractors (RACs) and RAC

reviews for “patient status” (i.e. site of service) for procedures removed from the IPO list, such that they could not be counted against a provider in the context of the “two-midnight” rule. See p. 689.

- ***ASC Covered Procedures List*** – CMS finalizes, as proposed, the addition of Total Knee Arthroplasty (TKA), Knee Mosaicplasty, and six coronary intervention procedures to the ASC list of covered surgical procedures, which includes those procedures that pose a low level of risk to beneficiary safety and do not require active medical monitoring via an overnight stay. In addition to what was proposed, CMS also adds twelve procedures with new CPT codes to the ASC covered list of procedures. See the discussion beginning on p. 738, as well as Table 60 on p. 782.

- ***High-Cost/Low-Cost Threshold for Packaged Skin Substitutes*** – In the proposed rule, CMS requested comment on several potential changes to how skin substitutes products could be paid under the OPPS, including eliminating the high and low-cost categories and creating a single payment category and set of procedure codes for the application of all graft skin substitute products. However, as proposed, the agency finalizes its proposal to leave the existing low-cost/high-cost payment groups in place while it considers the comments received and the potential development of an episode-based payment in the future. See p. 567.

- **Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)** – Currently, CMS does not enforce the direct supervision requirement for hospital outpatient services for critical access hospitals (CAHs) and small rural hospitals with 100 or fewer beds. Acknowledging the staffing challenges faced by CAHs and small rural hospitals, CMS finalizes its proposal to change the minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision (i.e. the physician’s presence is not required). On p. 686, CMS notes that providers may require a level of physician supervision for these procedures that is higher than general supervision, and the rule does not preclude hospitals from requiring such as they deem appropriate. See pp. 676-689 for the full discussion.

- **Addressing Wage Index Disparities** – CMS finalizes that the FY 2020 hospital Inpatient Prospective Payment System (IPPS) post-reclassified wage index for urban and rural areas will apply to the wage index for OPPS. On p. 154, CMS describes its methodology to address wage index disparities in the IPPS. This entails: (1) calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural; (2) removing the wage data of urban hospitals that have reclassified as rural from the calculation of “the wage index for rural areas in the State”; (3) increasing the wage index values for hospitals with a wage index below the 25th percentile; and (4) applying a 5-percent cap for FY 2020 on any decrease in a hospital’s final wage index from the hospital’s final wage index in FY 2019.

- **<u>FDA Breakthrough Devices Program</u>** – To expand Medicare beneficiaries' access to new, innovative medical technologies and treatments, CMS finalizes its decision to develop an alternative pathway, under which the "substantial clinical improvement" criterion would not apply, that allows devices approved under the FDA Breakthrough Devices Program to qualify for transitional pass-through status on or after January 1, 2020. As noted on pp.463-464, the Breakthrough Devices Program was established "to expedite the development of, and provide for priority review of, medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions."

    - **<u>Approved Device Pass-through Applications</u>** – For CY 2020, CMS is approving four of seven applications it received for device pass-through payment status: AquaBeam® Robotic System, AUGMENT® Bone Graft, Surefire® Spark Infusion System, Optimizer® Smart System. Additionally, the agency notes it is approving a fifth application, for CustomFlex® ArtificialIris, that was not discussed in the CY 2020 OPPS proposed rule, but has received a Breakthrough Devices designation from the Food and Drug Administration (FDA) and qualifies for the alternative pathway to the OPPS device pass-through substantial clinical improvement criterion. See a summary on p. 470.

- **<u>Prior Authorization Requirements for Certain Outpatient Services</u>** – CMS finalizes its proposal to require prior authorization for "(1) blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation" (pp. 986-989). The agency explains that such requirements would ensure beneficiary access to medically necessary care, prevent overutilization, and increase transparency regarding a patient's financial liability. See Table 64 on pp. 1010-1012 for the final list of outpatient department services requiring prior authorization.

- **<u>Meaningful Measures/Patients Over Paperwork</u>** – CMS finalizes its revisions to the Hospital Outpatient Quality Reporting Programs and the Ambulatory Surgical Center Quality Reporting Program.

    - ***Hospital Outpatient Quality Reporting (OQR) Program*** – CMS finalizes its change to eliminate the external beam radio therapy (ERBT) for Bone Metastases (OP-33) measure, "beginning with January 2020 encounters used in the CY 2022 payment determination and for subsequent years" (pp. 850-851).

      In the proposed rule, CMS requested comments on the potential addition to the Hospital OQR program of four measures from the Ambulatory Surgical Center (ASC) quality reporting program: ASC-1: patient fall, ASC-2: patient burn, ASC-3: wrong site, wrong side, wrong procedure, wrong implant and ASC-4: all-cause hospital transfers/admissions (p. 851). CMS notes that public comments, which were overall supportive of these additions, (summarized on pp. 859-861) will be taken into consideration as the agency deliberates these measures.

Finally, CMS proposes to apply the reduction of the outpatient department (OPD) fee increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQP Program requirements for the CY 2020 annual payment update factor (pp. 874-875).

- ***Ambulatory Surgical Center Quality Reporting (ASCQR) Program*** – The ASCQR program requires ASCs to meet quality reporting requirements or receive a reduction of 2.0 percentage points in their annual fee schedule update if requirements are not met. CMS does not propose to eliminate any existing measures and add one new measure. CMS finalizes the addition of ASC-19: Facility-Level 7-day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers beginning in the CY 2024 payment determination. See discussion beginning p. 879.

- **CY 2020 OPPS Payment Methodology for 340B Purchased Drugs** – CMS finalizes its proposal, without any changes, to continue paying the Average Sales Price (ASP) minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B program, including when they are furnished in nonexcepted off-campus PBDs paid under the PFS. See discussion beginning on p. 542.

  This payment methodology has been the subject of litigation in the case of *American Hospital Association et al v. Azar et al*, in which the court concluded the Secretary “exceeded his statutory authority” by adjusting the Medicare payment rates for that year. CMS states on p. 548 that it respectfully disagreed with the court’s decision. In the event that the court rules on the administration’s appeal unfavorably, CMS states that public comments collected in the CY 2020 proposed rule will inform a potential remedy for CY 2018 and 2019 payments under the CY 2021 rulemaking cycle. In the proposed rule, CMS sought comments on recommendations on alternative payment rates and the appropriateness of potentially paying a rate of ASP plus 3 percent in such an event, as well as how to structure such a remedy. A summary of these comments begins on p. 552.

  Other policies implemented in CY 2018 and 2019 are retained in the CY 2020 final rule, including those that excepted rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment.

- **Update to the Per Diem Rate for Partial Hospitalization Programs (PHP)** – CMS finalizes its proposal to maintain the unified rate structure established in CY 2017 for Partial Hospitalization Program (PHP) services furnished in hospital outpatient departments and Community Mental Health Centers (CMHCs). PHPs are structured intensive outpatient programs consisting of a group of mental health services paid on a per diem basis under the OPPS, based on PHP per diem costs. The unified rate structure involves a single PHP APC for each provider type for days with three or more services per day. CMS will use the CMHC and hospital-based PHP geometric mean per diem costs, consistent with existing policy, but with a cost floor equal to the CY 2019 final geometric mean per diem costs. Discussion begins on p. 609.

- **<u>Revision to the Organ Procurement Organization Conditions of Coverage (CfCs)</u>** – Currently, Organ procurement organizations (OPOs) are required to meet two out of the three outcome measures: (1) the OPOs donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the national mean for this rate; (2) the observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 month of data; and (3) the OPO data reports, averaged over the four years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

  Beginning on p. 927, CMS finalizes its proposal to revise the definition of "expected donation rate" used in the second measure to align with the Scientific Registry of Transplant Recipients (SRTR) definition, which adjusts for different hospital and population characteristics. The proposed definition will state that the "expected donation rate" per 100 eligible deaths is the expected rate for an OPO based on the national experience for OPOs serving similar eligible donor populations. However, to allow OPOs time to comply with the change, CMS will temporarily suspend the requirement that OPOs meet two out of three outcome measures, instead requiring that they meet only one (the donation rate of eligible donors measure or the aggregate donor yield measure) for the 2022 recertification cycle only.

- **<u>Request for Information: Potential Changes to the Organ Procurement Organization and Transplant Center Regulations</u>** – In the proposed rule, CMS sought comment on what revisions may be appropriate as the agency considers a comprehensive update to current OPO CfCs and current transplant center Conditions of Participation (CoPs). Additionally, CMS sought public comment on the addition of two potential OPO outcome measures: (1) the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation; and (2) the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. Responses to the RFI, which CMS says it will consider for future rulemaking, are discussed beginning on p. 932.

- **<u>Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy</u>** – In the proposed rule, CMS solicited comments on potential revisions to the laboratory date of service (DOS) policy under the Clinical Laboratory Fee Schedule (CLFS). CMS notes that when certain conditions are met under a previously finalized exception, the DOS is considered the date of test performance, rather than the date of specimen collection, "which effectively unbundles the test from the hospital outpatient encounter." This means the test performed is not considered a hospital outpatient service for which the hospital must bill Medicare and for which the performing laboratory must seek payment from the hospital, but rather a laboratory test under the CLFS for which the performing laboratory must bill Medicare directly. Beginning at p. 948, CMS describes three potential changes to the existing DOS exception and requests comment. Overall, commenters discouraged CMS from pursuing these changes, citing concerns of beneficiary access to such laboratory testing. The agency is not finalizing any of these changes.

- **Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals** – Beginning on p. 1032, CMS finalizes its proposal to allow grandfathered children's hospitals-within-hospitals (HwHs) to increase the number of beds without resulting in the loss of grandfathered status. CMS says, given the low number of Medicare claims submitted by children's hospitals, and the minimal level of Medicare payment to them relative to the payments they receive from other payers, that the change will allow these hospitals to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments.

- **Notice of Teaching Hospital Closures and Availability of Residency Slots** – In light of the closures of Hahnemann University Hospital in Philadelphia, PA and the Ohio Valley Medical Center in Wheeling, WV, CMS uses the final rule as a vehicle to initiate two 90-day application processes to redistribute the full-time equivalent (FTE) residency slots previously apportioned to the closed hospitals. The process by which the slots can be reallocated was statutorily defined by Section 5506 of the Affordable Care Act (ACA) for teaching hospitals that closed on or after March 23, 2008, and was further outlined by CMS in the FY 2013 IPPS/LTCH PPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

  The closure of Hahnemann University Hospital constitutes the 16th Round of the Sec. 5506 application and selection process, and the closure of Ohio Valley Medical Center initiates the 17th Round. Tables 66 and 67 (p. 1036-1037) delineate the identifying information and IME and DGME FTE resident caps for the respective closed teaching hospitals.

  Hospitals that wish to apply for slots from the hospitals' FTE resident caps, must submit applications directly to the CMS Central Office no later than 90 days following the date of the publication of this rule in the Federal Register, placing the deadline on or around February 10, 2020. CMS directs interested applicants to the Direct Graduate Medical Education (DGME) website where you can access the Application Form. The agency does not commit to a deadline by which it will issue the final determinations.