Wynne Health Group

Memorandum

December 3, 2020

CY 2021 HOSPITAL OPPS AND ASC PAYMENT FINAL RULE WITH COMMENT PERIOD

The Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2021 hospital outpatient prospective payment system (OPPS) final rule with comment period (fact sheet) addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs). Addenda referred to in the final rule for the OPPS system and the ASC payment system are available here and here, respectively.

- **What it is.** CMS' wide-ranging final rule affects payments to approximately 3,665 facilities paid under the OPPS, including hospital outpatient departments (OPDs) and ASCs, beginning on Jan. 1, 2021.

- **Why it's important for you.** In keeping with the Trump Administration's directives to lower out-of-pocket costs by enacting site neutral payment policies across inpatient, outpatient, and ambulatory settings, the final rule expands the number of reimbursable procedures in the ASC setting and implements a phased elimination of restrictions on procedures that are currently deemed inpatient-only. Though CMS had proposed to further reduce payment for separately payable drugs or biologicals acquired by participating hospitals in the 340B Program, the agency ultimately chose not to apply additional cuts and instead finalizes a rate equal with its current policy of paying Average Sales Price (ASP) minus 22.5 percent. Among other provisions, CMS finalizes several changes to streamline the Overall Hospital Star Rating system methodology; allows physician-owned hospitals with high proportions of Medicaid patients to more easily and frequently expand their facilities; announces a delay in the initiation of the Radiation Oncology (RO) payment model; and introduces new reporting requirements for hospitals related to the impact of acute respiratory illnesses, such as COVID-19 and seasonal influenza, on hospital resources.

- **Potential next steps.** Upon formal publication of the final rule in the *Federal Register*, a 30-day public comment period will apply to the following provisions: the payment classifications assigned to the interim Ambulatory Payment Classification (APC) assignments; and/or status indicators of new or replacement Level II HCPCS codes in this final rule (see p. 196). Additionally, a 60-day comment period will apply to the new provisions addressing reporting requirements for hospitals and CAHs to report acute respiratory illness during the PHE for COVID-19, and to the delay of the Radiation Oncology Model.

Highlights of the OPPS final rule include:

- **OPPS Payment Update** – For CY 2021, CMS increases OPPS payment rates by a factor of +2.4 percent, which represents an increase of +$7.5 billion compared with estimated CY 2020 payments.

This update factor is based on the projected hospital market basket increase of +2.4 percent with a 0.0 percent adjustment for Multi-Factor Productivity (MFP). CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2021 overall will be approximately $83.8 billion. The agency also finalizes the continued implementation of a statutory -2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements. See the full discussion beginning on p. 125.

- **Wage Index Changes** – Beginning on p. 135, CMS finalizes the adoption of revised Office of Management and Budget (OMB) statistical area delineations and related IPPS wage index adjustments in order to calculate the CY 2021 OPPS wage indices. For a complete discussion of the revised OMB delineations, (which stem from OMB Bulletin No. 18–04), the agency refers readers to the FY 2021 IPPS/LTCH PPS proposed rule (p. 32696-32707 and 32717-32728). See also WHG's summary here.

  CMS clarifies that any applicable adjustments for the FY 2021 IPPS post-reclassified wage index (including, but not limited to, the low wage index hospital policy, the one-year 5 percent cap on wage index decreases, the rural floor, and the frontier State floor) will be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. The agency asserts that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is "reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall."

- **Partial Hospitalization Update** – The Partial Hospitalization Program (PHP) is a structured intensive outpatient program consisting of a group of mental health services paid on a per diem basis under the OPPS, based on PHP per diem costs. As proposed, the final rule updates Medicare payment rates for PHP services furnished in hospital OPDs and Community Mental Health Centers (CMHCs). Specifically, CMS uses the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing policy, using updated data for each provider type; and accordingly, calculates the CY 2021 PHP APC per diem rates for HB PHPs and CMHC PHPs based on updated cost and claims data. CMS states that, "given that the final calculated geometric mean per diem costs are much higher than the proposed cost floors, we are not extending the cost floors to CY 2021 and subsequent years." See p. 637.

- **Cancer Hospital Payment Adjustment** – CMS finalizes its proposal to continue providing additional payments to cancer hospitals, such that their payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals. Using the most recently submitted or settled cost report data, and accounting for a Cures Act-required -1.0 percent adjustment, CMS specifies that the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital. See p. 129 for discussion, and Table 5 on p.164 for estimated hospital-specific payment adjustments.

- **ASC Payment Update** – Beginning on p. 771, CMS updates payment rates under the ASC payment system by 2.4 percent for those ASCs that meet the quality reporting requirements under the

ASCQR Program. The finalized increase is based on a hospital market basket percentage increase of +2.4 percent with a multifactor productivity adjustment of 0.0 percent. Based on this update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2021 will be approximately 5.42 billion, which represents an increase of approximately 120 million compared to estimated CY 2020 Medicare payments.

- **Phased Elimination of Inpatient Only (IPO) List** – CMS finalized its proposal to eliminate the current IPO list of 1,740 services (i.e., services typically provided only in an inpatient setting and, hence, not paid for by Medicare under the OPPS) over a three-year transition period begging in CY 2021, with the full list eliminated in its entirety by CY 2024. CMS proposed to begin this process with the elimination of 266 musculoskeletal services from the IPO list, citing technological and surgical care advances for these services, as rationale for the removal of this clinical service grouping. See Table 48 on p. 709 for the final procedures, along with the corresponding CPT/HCPCS codes, that are removed from the IPO list for CY 2021.

  CMS indicated that procedures removed from the IPO list that might otherwise be subject to "2-midnight rule" medical review activities will be exempted from these rules for a two-year period, and that procedures removed from the IPO list in CY 2021 will be indefinitely exempted from Part A site-of-service claim denials. CMS noted that the exemption allows CMS to collect claims data showing that these procedures are more commonly performed in the outpatient (v. inpatient) setting, in addition to giving providers time to gain experience billing for claims that were previously paid on an inpatient-only basis.

- **Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A (2-Midnight Rule)** – CMS finalized its proposal to exempt procedures that have been removed from the inpatient only (IPO) list beginning on January 1, 2021 from eligibility for referral to Recovery Audit Contractors for noncompliance with the "2-Midnight rule" and subsequent RAC site of service "patient status" reviews for an indefinite period rather than the two-year period proposed. The agency notes that the indefinite exemption period will last "until the procedure is more commonly performed in the outpatient setting then the inpatient setting." CMS further explains that termination of the exemption for a specific procedure will require "Medicare claims data indicating that procedure was performed more than 50 percent of the time in the outpatient setting." CMS states that future rulemaking may extend the exemption period for procedures removed from the IPO list prior to January 1, 2021 and/or modify the duration of the exemption period. See p. 740.

- **340B-Acquired Drugs** – CMS ultimately opted to continue its current policy of paying Average Sales Price (ASP) minus 22.5 percent for drugs and biologicals acquired under the 340B program, including when furnished in nonexcepted off-campus PBDs paid under the PFS. CMS continues to exempt rural sole community hospitals (Rural SCHs), PPS-exempt cancer hospitals and children's hospitals from the 340B payment reductions. The exempted hospitals would continue to be paid at ASP plus 6 percent and would continue to report 340B-acquired drugs using the "TB" modifier.

Recall that, in the proposed rule, CMS outlined an option that, if finalized, would have *further* reduced net payment by more than 6 percent (to ASP minus 28.7 percent) in CY 2021. The proposed further 340B payment reduction was predicated on CMS' recent hospital acquisition cost survey data, which reflected a rate of ASP minus 34.7 percent plus a 6 percent add-on amount for overhead and handling costs for 340B-acquired drugs. However, following stakeholder feedback, CMS says it believes that maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs is "appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs." The agency also notes that doing so affords CMS additional time to "conduct further analysis of hospital survey data for potential future use for 340B drug payment." See the discussion that begins on p. 538 of the final rule.

- **Radiation Oncology Model** – Beginning on p. 1179, CMS effectuates its intent to delay the Radiation Oncology Model (RO Model) due to stakeholder concerns around implementing the model during the PHE. Specifically, stakeholders are concerned about revenue losses for RO participants due to decreased patient volume and lay-offs due to the PHE. To ensure that participation in the RO model does not further strain RO participants' care capacity, CMS is delaying the start of the model until July 1, 2021. Additional modified RO Model policies can be found on p. 1181. **CMS invites comments on these provisions for 60 days following publication of the rule.**

- **Reporting Requirements for COVID-19 Therapeutic Inventory and Usage and Acute Respiratory Illness During the Public Health Emergency** – Beginning on p. 1190, CMS notes that March guidance required hospitals and CAHs to report "important data critical to support the fight against COVID-19" and the conditions of participation (CoP) for the Medicare and Medicaid programs require that hospitals report this information in accordance with a frequency and format specified by the Secretary of HHS. However, as new COVID-19 therapeutics emerge, CMS notes that the agency lacks real-time and real-world understanding of the usage patterns of each new therapeutic to properly allocate the therapies to areas of need. Therefore, CMS is amending the CoP reporting requirements to now require hospitals and CAHs to report the following information:

    - Current inventory supply of any COVID-19 related therapeutics that have been distributed and delivered to a hospital under the authority and discretion of the Secretary; and
    - Current usage rate for any COVID-19 related that have been distributed and delivered to the CAH under the authority and direction of the Secretary

  Additionally, CMS will now require hospitals and CAHs to report information on Acute Respiratory Illness, such as influenza, influenza-like illness, and severe acute respiratory infection. Such data elements could include diagnoses, admissions, and counts of patients currently hospitalized with diagnoses of Acute Respiratory Illness. CMS asserts that this data will allow the agency to better prepare for the planning, monitoring, and resource allocation during the PHE. **CMS invites comments on these provisions for 60 days following publication of the rule.**

- **Packaging of Payment for Non-Opioid Alternatives –** Beginning on p. 99, CMS discusses its ongoing evaluation of potential payment disincentives for non-opioid alternatives (e.g., surgical injections, neuromodulation) as stipulated by the SUPPORT Act.

  The agency reiterates its CY 2020 analysis that had supported its decision to unpackage payment for Exparel in the ASC setting only. The agency says it does not believe re-running the analysis would yield different evidence that "would prompt us to change our payment policies under the OPPS or ASC payment system." Thus, it finalizes its policy without modification to unpackage and pay separately for non-opioid pain management drugs in the ASC setting but not the hospital OPD setting.

  Responding to public comments, CMS says it does not believe there is "sufficient evidence" that non-opioid pain management drugs should be paid separately in hospital OPDs at this time and says commenters did not provide "convincing evidence" that the OPPS packaging policy is impeding utilization. See p. 101-103, with CMS also noting plans for ongoing data-monitoring for potential future rulemaking.

  On p. 107, CMS addresses comments on separate payment for spinal cord stimulators. The agency says it has not found "compelling evidence" for non-opioid alternatives to be paid separately, although indicates it will take comments into consideration for future rulemaking and agrees with commenters that incentives to avoid opioid prescriptions "may be one of several strategies for addressing the opioid epidemic." The agency elaborates that it encourages providers to use non-opioid alternatives when medically appropriate.

- **Device Pass-Through Payment Applications** – As discussed beginning on p. 378, CMS approves five devices for pass-through status, including three with breakthrough designations. The agency notes that two had been previously approved during the quarterly review process (CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope) and automatically included in the CY 2021 process.

- **Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals** – CMS finalizes a change that will pay for drugs with expiring pass-through status on a packaged basis if their estimated per-day cost is less than or equal to the OPPS packaging threshold (i.e., $130 for CY 2021). Otherwise, the drug will be paid separately at the applicable relative ASP-based amount of ASP plus six percent for non-340B drugs. See Table 36 on p. 492 for a list of drugs and biologics with expiring pass-through status in CY 2021.

- **Supervision of Outpatient Therapeutic Services in Hospitals and CAHs** – CMS finalized its proposal to make permanent its policy changing the minimum default supervision level for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire duration of the service, including the initiation portion. This flexibility to the minimum required supervision level for all NSEDTS was initially promulgated in the March 31st IFC. Prior to the pandemic, direct supervision was required during the initiation portion. See p. 729.

CMS also finalized its proposal to allow direct supervision of pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services via interactive audio and video technology "subject to the clinical judgment of the supervising physician." This flexibility to the minimum required supervision level for the aforementioned rehabilitation services was initially promulgated in the March 31st IFC. See p. 413. The agency had proposed to make this flexibility permanent but noted that more information on the issues involved with direct supervision via interactive audio and video technology is needed before making the flexibility permanent. See p. 733.

- **Changes to the List of ASC Covered Surgical Procedures** – Beginning on p. 820, CMS finalized its proposal to eliminate five of the general exclusions at 42 CFR 416.166(c)(1) through (5). They are surgical procedures that:

  (1) Generally result in extensive blood loss;
  (2) Require major or prolonged invasion of body cavities;
  (3) Directly involve major blood vessels;
  (4) Are generally emergent or life-threatening in nature; and
  (5) Commonly require systematic thrombolytic therapy.

  Due in part to this change, CMS finalized its proposal to modify its approach to updating the ASC Covered Procedures List (ASC-CPL). Specifically, CMS is establishing a notification process to allow the public to notify the agency about surgical procedures that meet the requirements to be covered but are not currently on the ASC-CPL.

  CMS finalized its proposal to add 11 procedures to the ASC-CPL using current regulatory safety criteria. See Table 59 on pp. 851-852. In addition, CMS will add 267 procedures to the ASC-CPL based on other finalized changes to the definition of covered surgical procedures.

- **Comprehensive APCs (C-APCs)** – CMS finalizes its proposal to create two new C-APCs: C-APC 5378 (Level 8 Urology and Related Services) and C-APC 5465 (Level 5 Neurostimulator and Related Procedures). See a discussion beginning on p. 57.

- **Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs** – Although CMS is not adding or removing any measures for either program, it is revising and codifying previously finalized administrative procedures. Specifically, CMS finalizes its decision to codify the statutory authority for the Hospital OQR program, as well as a policy finalized in the 2009 OPPS/ASC rule requiring hospitals sharing the same CCN to combine data collection and submission of clinical measures across their campuses for public reporting purposes.

  For both the Hospital OQR and ASCQR programs, CMS is expanding its review and corrections policy to include measure data submitted via the CMS web-based tool starting with data submitted for the CY 2023 payment determination. Under the finalized policy, hospitals and ASCs will have

an opportunity to enter, review, and correct data for web-based measures that would run concurrently with the data submission period. Hospitals and ASCs will not be allowed to change these data after the submission deadline.

Previously in its proposed rule, CMS stated it also seeks to develop a comprehensive set of quality measures for informed decision-making and quality improvement in the ASC setting. The agency said it is interested in measures that would facilitate meaningful comparisons between ASCs and hospitals and invites public comment on measures to consider that address quality of care in ASCs as well as other measures that could enable comparison of the care provided in ASCs and hospitals. CMS responds to the comments it received on potential new measures that could facilitate such comparisons beginning on p. 945.

- **Overall Hospital Quality Star Ratings** – Starting on p. 963, CMS notes that it is using the CY 2021 OPPS/ASC rule to finalize changes to the methodology for the Overall Star Rating even though it includes hospital inpatient measures, due to timeline constraints related to calculating and distributing results in time for hospitals to preview the ratings in advance. Accordingly, CMS plans to reference policies for the Overall Star Rating in the FY 2022 IPPS rule.

  Beginning with the Overall Star Rating in CY 2021, CMS proposes several methodological changes for calculating the rating (see p. 992) to simplify interpretation, and improve predictability and comparability, including:

  - Regrouping measures into five groups, rather than seven, due to the removal of measures resulting from the Meaningful Measure Initiative;
  - Using an average of measure scores to calculate measure group scores;
  - Stratifying the Readmission measure group scores by the proportion of dual-eligible patients at each hospital;
  - Requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating; and
  - Peer grouping hospitals that provide acute inpatient and outpatient care based on number of measure groups.

  CMS finalizes its proposal to include voluntary measure data from CAHs, and to include quality measure data from Veterans Health Administration hospitals (VHA hospitals) beginning in CY 2023. Noting that the addition of VHA hospitals has no direct influence on CMS-administered programs, but that it would influence national results, the agency states it will provide more information about the implications of adding VHA hospitals to the Overall Star Rating in future rulemaking.

  Although it will continue to publish the Overall Star Rating once a year, CMS moving forward will use measure results on Hospital Compare or a successor website from a quarter within the prior year instead of the same or previous quarter – e.g., July or October 2020 for a January 2021 Overall Star Rating release. See p. 995 for more.

- **Addition of New Service Categories for HOPD Prior Authorization Process** – Beginning on p. 1108, CMS finalizes the addition of the following categories of services to the prior authorization process: (1) cervical fusion with disc removal; and (2) implanted spinal neurostimulators. The agency also finalizes that the effective dates for these service categories begin on or after July 1, 2021. CMS explains that these categories were added to the prior authorization list because the agency has determined that there has been an unnecessary increase in volume of these services. Table 72 on p. 1116 details that finalized list of additional outpatient services that would require prior authorization under these two categories and Table 73 contains the 2020 final list of services that require prior authorization.

- **Clinical Laboratory Date of Service (DOS) Policy** – Beginning on p 1146, CMS finalizes the exclusion of cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the OPPS packaging policy and adds them to the laboratory date of service (DOS) provision. CMS notes that MAAAs are not typically performed in the outpatient setting and have a similar clinical pattern of use as other tests that are not paid under the OPPS. Under the finalized proposal, Medicare will pay for cancer-related protein-based MAAAs (such as CPT codes 81500, 81503, 81535, 81536, 81539, and 81490) under the clinical laboratory fee schedule (CLFS) and the performing lab would bill Medicare directly.

- **Physician-Owned Hospitals** – Beginning on p. 1158, CMS finalizes a provision to allow physician-owned "high Medicaid facilities" to request an exception to the prohibition on expansion of facility capacity at any time, provided it has not submitted an exception for which the agency has not issued a decision. Specifically, the agency finalized the removal of the cap on the number of additional operating rooms, procedure rooms, and beds that can be approved in an exception and the restriction that the expansion must occur only in facilities on the hospital's main campus.

  Additionally, CMS clarified that the agency defers to state law with respect to the determination of whether a bed is licensed as of a certain date for the purposes of determining "baseline number of operating rooms, procedure rooms, and beds." To make this explicit, CMS finalizes the revision of the definition of "baseline number of operating rooms, procedure rooms, and beds" to include a statement that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure. See the full discussion beginning on p. 1171.

- **Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots** – In accordance with section 5506 of the Affordable Care Act, CMS announces on p. 1175 that as a result of the recent closure of two teaching hospitals – Astria Regional Medical Center of Yakima, WA and Westlake Community Hospital of Melrose Park, IL – direct graduate medical education (DGME) and indirect medical education (IME) resident cap slots are available for redistribution. The final rule serves as notice of the closures and initiates an application and selection process for the available slots, which is detailed on p. 1178. Applications are due March 7, 2021 and applying hospitals must submit a section 5506 slot application in hard copy. CMS has not established a deadline by when the agency will issue a final determination of the slots.

- **Summary of Costs and Benefits** – Table 79 on p. 1234 provides the estimated impact of the finalized changes for the OPPS. CMS estimates that payments to all facilities will increase by 2.4 percent for CY 2021. CMS also estimates that payments to rural hospitals will increase by 2.5 percent while payments to urban hospitals will increase by 2.4 percent. Additionally, CMS estimates that the proposed update of the wage indexes would result in a 0.2 percent increase for urban hospitals and a 0.4 percent increase for rural hospitals.