Wynne Health Group

Memorandum

July 29, 2019

SUMMARY OF THE CY 2020 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) PROPOSED RULE

Today, the Centers for Medicare and Medicaid Services (CMS) released the **calendar year (CY) 2020 hospital outpatient prospective payment system (OPPS) proposed rule (fact sheet)** addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs).

- **What it is.** CMS' wide-ranging proposed 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 is important for you.** CMS makes significant proposals that would apply to all hospitals operating in the United States, which are designed to implement directives in President Trump's Executive Order on "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (details). Specifically, the rule outlines the parameters of the requirement that all hospitals publicly post their standard charge information, including negotiated rates, for "shoppable" items and services.

  The rule proposes to complete the two-year phase in of a 60 percent cut in reimbursements for clinic visit services furnished at certain off-campus provider-based departments (PBDs), and puts forward several additional policies designed to advance site neutrality across Medicare payment settings and services. Despite litigation, CMS proposes to continue paying for certain separately payable drugs and biologics acquired through the 340B Program at the reduced rate of Average Sale Price (ASP) minus 22.5 percent. Comments are solicited on an appropriate remedy in and alternative 340B payment rate, in the event that CMS cannot successfully appeal in that litigation.

- **Potential next steps.** Comments on the proposed rule are due by **Sept. 27, 2019**.

For CY 2020, CMS proposes to increase OPPS payments rates by a factor of +2.7 percent (+$6 billion) compared with CY 2019 payments. This update factor is based on the projected hospital market basket increase of +3.2 percent minus a -0.5 percentage point adjustment for Multi-Factor Productivity (MFP) required by the Affordable Care Act (ACA). See Table 41 beginning on p. 740 for a detailed break-out of estimated impacts by hospital type.

Similarly, CMS proposes to increase payment rates under the ASC payment system by +2.7 percent (+3.2 percent market basket increase minus the -0.5 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 would be approximately $4.89 billion, (+$200 million over CY 2019

Medicare payments). CMS says that 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 proposed rule include:

- **Price Transparency for Hospital Standard Charges** – In order to apply proposed transparency requirements to all hospitals operating in the United States, the proposed rule outlines the following:

    - ***Proposed Definition of 'Hospital'*** – CMS proposes to broadly define a "hospital" as an institution in any State in which State or applicable local law provides for the licensing of hospitals, (1) is licensed as a hospital pursuant to such law or (2) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing." Examples of institutions that meet this definition include critical access hospitals, inpatient psychiatric facilities, sole community hospitals, and inpatient rehabilitation facilities. In addition, CMS notes that the proposed definition of hospital excludes ambulatory surgical centers (ASCs) or other non-hospital sites of care, such as those that provide ambulatory surgical services or laboratory/imaging services. See pp. 581-584.

    - ***Proposed Definition of 'Standard Charges'*** – Based on stakeholder feedback collected through RFIs issued in 2018, CMS proposes to define "standard charge" as "gross charges" and "payer-specific negotiated charges." See pp. 592-594 for a brief summary of public comments.

      Beginning on p. 595, CMS proposes to define a "gross charge" to mean "the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts." On p. 598, CMS proposes to define a "payer-specific negotiated charge" to mean "the charge that the hospital has negotiated with a third party payer for an item or service." In addition, CMS proposes to define "third party payer" as "an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service." CMS notes that "gag clauses" between hospitals and third party payers prohibiting hospitals from disclosing negotiated rates prevents consumers from determining potential out-of-pocket costs before receiving a health care service. See discussion beginning on p. 598 for the agency's rationale for the proposed definition.

    - ***Proposed Definition of Hospital 'Items and Services'*** – CMS proposes to define "items and services" furnished by hospitals as "all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge." Examples include supplies, procedures, room and board, use of the facility, and the services provided by physicians and non-physician practitioners. CMS notes that the proposed definition includes both individual items and

services as well as "service packages," defined as "an aggregation of individual items and services into a single service with a single charge."

To potentially address the issue of surprise medical billing, CMS is considering including in the proposed definition services furnished by physicians and non-physician practitioners who are not employed by the hospital but who furnish services at the hospital. However, CMS notes that because these independent practitioners set their own charges for services and receive payment for their services, the services that they provide are not considered services "by the hospital." Therefore, these services fall outside the scope of services required to be publicly reported in a hospital's chargemaster. In addition, CMS proposes to define "chargemaster" as "the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge." See pp. 587-591.

Acknowledging stakeholders' concerns related to the release of identifiable negotiated charges, CMS seeks comment on potential unintended consequences and alternative methods for making such information publicly available. See discussion beginning on p. 602 for alternative definitions for types of standard charges under consideration.

- ***Proposed Requirements for Making Public All Standard Charges for All Items and Services*** – CMS proposes to require hospitals to make standard charges publicly available through "a comprehensive machine-readable file that makes public all standard charge information for all hospital items and services." Beginning on p. 610, CMS proposes the following standardized data elements to ensure uniformity and meaningful use by consumers: description of each item or service; the corresponding gross charge; the corresponding payer-specific negotiated charge, the accounting or billing code; and revenue code, as applicable. See discussion beginning on p. 614 for proposed filed format requirements, location and accessibility requirements, frequency of updates, and requirements for making public separate files for different hospital locations.

- ***Proposed Requirements for Making Public Consumer-Friendly Standard Charges for a Limited Set of 'Shoppable Services'*** – CMS proposes to require hospitals to make negotiated charges for "shoppable services" publicly available in a consumer-friendly format (i.e., in plain language). The agency explains that information is consumer friendly if "the shoppable service charge is displayed along with charges for ancillary services the hospital customarily provides with the primary shoppable service, and that the consumer can easily search for and find charges for the shoppable services based on the service description, by the code associated with the shoppable service, or by payer." See discussion beginning on p. 621.

  CMS defines a "shoppable services" to mean "a service package that can be scheduled by a health care consumer in advance." An "ancillary service" is defined as "an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service." They include laboratory, radiology, drugs, delivery room, operating room, hospital fees, room and board charges, and charges for employed professional services.

CMS proposes that hospitals form a public list of payer-specific negotiated charges for as many of the 70 CMS-specified shoppable services listed on Table 37 (see pp. 627-629) in additional to other shoppable services identified by the hospitals to reach a total of at least 300 shoppable services. See discussion beginning on p. 632 for proposed required corresponding data elements, display format, location and accessibility requirements, and frequency of updates.

- ***Proposals for Monitoring and Enforcement*** – CMS proposes to implement monitoring methods to assess compliance that may include evaluation of complaints made by individuals or entities to CMS as well as review of individuals' or entities' analysis of noncompliance. On pp. 641-644, CMS discusses proposed actions to address noncompliance with requirements to make standard charges publicly available. They include issuing a written warning and requiring submission and subsequent implementation of a corrective action plan. In addition, CMS proposes to impose civil monetary penalties for noncompliance. See discussion beginning on p. 644.

- **Expansion of Site Neutrality** – CMS proposes 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*** – CMS confirms in the proposed rule that it will complete in CY 2020 the two-year phase-in of a policy finalized last year to pay a site-neutral rate for the clinic visit service, as described by 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). Specifically, CMS finalized a 60 percent overall payment reduction to the OPPS rate, half of which was applied in CY 2019. In CY 2020, the remaining cut will be implemented, bringing rates in line with the site-specific Physician Fee Schedule (PFS) rate for the clinic visit service. The agency estimates this will result in $810 million in savings for 2020. CMS refers readers to the CY 2019 PFS final rule and the CY 2020 PFS proposed rule for further discussion.

  - ***Changes to the Inpatient Only List*** – Beginning on p. 407, CMS proposes to remove Total Hip Arthroplasty (THA) from the inpatient only (IPO) list for CY 2020 and subsequent years. The IPO list is an annually reviewed list of procedures typically provided only in inpatient settings and not paid for under the OPPS; therefore, the change would make the procedure eligible to be reimbursed in both inpatient and outpatient hospital settings. CMS proposes to assign the THA procedure (currently CPT code 27130) to C-APC 5115 with status indicator "J1," and invites comment.

    In Table 23, CMS solicits comment on whether to remove six additional codes from the IPO list, which it says have been recommended for removal over the years by various stakeholders. This includes CPT Codes 22633, 22634, 63265, 63266, 63267, 63268 which pertain to varying forms of Arthrodesis and Laminectomy for excision or evacuation of

intraspinal lesion. See p. 413. The complete CY 2020 proposed IPO list is included as Addendum E to the proposed rule, which is available on the CMS website here.

Additionally, CMS proposes that for a one-year period after a procedure's removal from the IPO list, such procedures would not be eligible for referral to the Recovery Audit Contractor (RAC), nor would they be subject to Beneficiary Family Centered Care-Quality Improvement Organization (BFCC-QIO) reviews of short-stay inpatient claims that could be counted against a provider in the context of the "two-midnight" rule. The agency intends that the one-year moratorium would allow providers time to gain experience applying the two-midnight rule to these procedures and to update their billing systems. See p. 424.

- ***ASC Covered Procedures List*** – As depicted in Table 32 on p. 468, CMS proposes to add 8 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. Proposed additions to the list include a total knee arthroplasty (TKA) procedure and a knee mosaicplasty procedure (see the discussion beginning on p. 462), as well as six coronary intervention procedures (see p. 469).

- ***High-Cost/Low-Cost Threshold for Packaged Skin Substitutes*** – Beginning on p. 349, CMS proposes to continue a policy established in CY 2018 to assign skin substitutes to a low-cost or high-cost group, which was done in order to ensure adequate resource homogeneity among Ambulatory Payment Classification (APC) assignments for skin substitute application procedures. However, on p. 357, CMS seeks comment on several potential changes to how these 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. The agency additionally welcomes new ideas on how to pay for these products, noting that "a more equitable payment rate for graft skin substitute procedures could substantially reduce the amount Medicare pays for these procedures." Table 19 on p. 362 displays the proposed CY 2020 cost category assignment for each skin substitute product.

- ***Device Pass-through Applications*** – Device pass-through applications are submitted to CMS through the quarterly sub-regulatory process, with the applications then subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Beginning on p. 195, CMS says it is evaluating seven applications it received by the quarterly deadline for device pass-through payments. Each of these are described beginning on p. 201. CMS seeks public comment on whether these applications meet the criteria for device pass-through payment status.

- **CY 2020 OPPS Payment Methodology for 340B Purchased Drugs** – Beginning with the CY 2018 OPPS/ASC final rule, CMS implemented an adjusted Medicare Part B drug payment methodology for 340B hospitals of Average Sales Price (ASP) minus 22.5 percent, in order to better reflect the hospital acquisition costs for these drugs, they asserted (see p. 337). This change 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. 370, that it respectfully disagreed with the court's decision and proposes for CY 2020 to continue paying the 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.

However, CMS solicits recommendations on alternative payment rates for CY 2020 and an appropriate remedy for CY 2018 and 2019 in the event of a court ruling unfavorable to CMS (see p. 345). Specifically, the agency seeks comment on 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.

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

- **Addressing Wage Index Disparities** – CMS proposes that the FY 2020 hospital Inpatient Prospective Payment System (IPPS) post-reclassified wage index for urban and rural areas apply to the wage index for OPPS. As noted on p. 111, CMS proposes to: (1) calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural; (2) remove 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) increase the wage index values for hospitals with a wage index below the 25th percentile; and (4) apply 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."

- **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 proposes to change the minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision. See pp. 415-420.

- **FDA Breakthrough Devices Program** – To expand Medicare beneficiaries' access to new, innovative medical technologies and treatments, CMS proposes an alternative pathway that allows devices approved under the FDA Breakthrough Devices Program to qualify for "device pass-through payment under the OPPS for pass-through payment applications received on or after January 1, 2020." As noted on p. 279, 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."

- **Proposed Prior Authorization Requirements for Certain Outpatient Services** – On p. 691, CMS proposes to require prior authorization for "(1) blepharoplasty; (2) botulinum toxin injections; (3) panniculectomy; (4) rhinoplasty; and (5) vein ablation." The agency explains that such

requirements would ensure beneficiary access to medically necessary care, prevent improper use of Medicare Trust Funds, and maintain the medical necessity documentation requirements for providers.

- **Meaningful Measures/Patients Over Paperwork** – CMS proposes to eliminate one measure from the Hospital Outpatient Quality Reporting Programs and add one new measure the Ambulatory Surgical Center Quality Reporting Program.

    - ***Hospital Outpatient Quality Reporting (OQR) Program*** - For the CY 2022 program year, CMS is proposing to eliminate the external beam radio therapy (ERBT) for Bone Metastases (OP-33) measure. CMS suggests the removal of this measure because the cost of the measure exceed the benefit (p. 507). Table 34 on p. 511 summarizes the proposed measures for Hospital OQR program for CY 2022. CMS is also requesting comment 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. 512). 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 (p. 530).

    - ***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 proposes to add 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 p. 538).

- **Revision to the Organ Procurement Organization Conditions for Certification** – Organ procurement organizations (OPOs) are responsible for securing the maximum number of transplantable organs and are subject to the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). Currently, CMS enforces Conditions for Coverage (CfCs) for OPOs to receive payments from Medicare. OPO's must 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. See p. 660.

  CMS proposes 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. CMS also proses to revise the time period for this outcome measure by using 12 of the 24 months of data following the effective date of the final rule. See p. 662.

- **Request for Information: Potential Changes to the Organ Procurement Organization and Transplant Center Regulations** – CMS is considering a comprehensive proposal to update the CfCs for OPOs and potentially the Conditions of Participation (CoPs) for transplant centers and, beginning on p. 663 requests public input on what revisions may be appropriate. The agency is specifically seeking information on questions that can be found on page 664 of the proposed rule. Additionally, CMS is seeking 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 (p. 665).

- **Update to the Per Diem Rate for Partial Hospitalization Programs (PHP)** – CMS proposes 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 proposes to 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. 373.

- **Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy** – CMS solicits 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. 680, CMS describes three potential changes to the existing DOS exception and requests comment.

- **Proposed Changes to Requirements for Grandfathered Children's Hospitals-Within-Hospitals** – Beginning on p. 706, CMS proposes to revise the regulations to allow grandfathered children's hospitals-within-hospitals (HwHs) to increase the number of beds without resulting in the loss of grandfathered status. Existing regulations define an HwH as "a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital." The regulation provides for the grandfathering

of HwHs that were in existence on or before September 30, 1995, "so long as the HwH continues to operate under the same terms and conditions, including the number of beds."

CMS states that it has sought to examine areas in which the rules for co-located entities are no longer necessary, and has determined that "there is no Medicare payment policy rationale for prohibiting grandfathered children's HwHs from increasing their number of beds," particularly given the low number of Medicare claims submitted by such entities. The agency seeks comments on any unintended consequences.