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To: Strategic Health Care Clients

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Re: Additional Details Concerning CMS' Proposed Outpatient Payment System and Physician Fee Schedule Rules

As follow-up to our memos that provided initial - or immediate - read of the proposed 2021 Outpatient Prospective Payment System and Physician Fee Schedule rules, here we provided more granular data concerning proposed regulatory changes. Again, the OPPS proposed rule here, and the PFS proposed rule here. As previously noted, comments on the proposed rules are due no later than 5 pm EST, October 5th.

Proposed Outpatient Payment System Rule

In-Patient Only (IPO) List

Likely the most prominent proposed rule change is CMS' discussion of the agency's intention to eliminate the IPO, or the "Inpatient Only" list of 1,740 services that currently can only be performed and reimbursed as an inpatient service. The AHA's immediate reaction was to state it was "concerned" with the proposed IPO list change and would "evaluate the provision carefully."

On background, CMS typically discusses the IPO list in its annual OPPS rule making. As early as 2001, the agency recognized in its OPPS rule making given advances in technology and surgical technique IPO list procedures could eventually be performed safely in the outpatient setting. Most recently, CMS, for example, removed TKA in 2018 from the IPO list and THA in 2020 in response to previous rule making comments that, for example, regulations should not supersede the physician's knowledge and assessment of a patient's condition, that the physician can appropriately determine whether a procedure can be safely performed in a hospital outpatient setting, and excluding procedures from the outpatient setting could have an adverse effect on advances in surgical care. CMS has also received previous comments noting alternatively, without the IPO list, patient safety and quality could be put at risk or decline.

In the proposed 2021 OPPO rule, CMS states, "while we agree with commenters in previous rule makings that the IPO list was necessary," the agency has "reconsidered the various stakeholders comments requesting that we eliminate the IPO list." "We have concluded," the agency states, "that we no longer believe there is a need for the IPO list in order to identify services that require inpatient care. Instead, we agree with past commenters that the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required." CMS restates advances in medicine, for example, laparoscopy, improved perioperative anesthesia and expedited

rehabilitation protocols, that have today blurred "the difference between the need for inpatient care and the sufficiency of outpatient care." (The proposed at least suggests, clinicians will still have the discretion to perform what was an IPO listed service in the inpatient setting.) CMS states further "we now believe that quality of care is unlikely to be negatively affected by the elimination of the IPO list."

Procedurally, CMS proposes to eliminate the IPO list over a three-year period, i.e., between 2021 and 2023, or entirely eliminate the IPO list by January 1, 2024. CMS proposes to eliminate in 2021 the 266 musculoskeletal services on the IPO list. Table 31 in the proposed rule lists the 266 musculoskeletal-related services and CPT codes. Concerning reimbursement for the 1,740 IPO listed services under the OPPS, CMS states only, "they will be newly priced under the OPPS." Concerning related revenue effects, the proposed contains no related economic analysis.

CMS is seeking a range of comments regarding this proposed regulatory reform. Among others, should the IPO list be eliminated and if so under what time period? Should CMS restructure or create new APCs (Ambulatory Payment Classification) to allow for OPPS payment for services that are removed from the IPO list and what effect will eliminating the list have on care quality?

340B-Acquired Drugs

Again, CMS is proposing to pay ASP minus 28.7% for 340B drugs. As clients are aware, on July 31, 2020, the US Court of Appeals for the District of Columbia Circuit held that CMS does have authority under the Social Security Act to reduce Medicare payment rates for 340B-eligible drugs reimbursed under the OPPS. For 2021 CMS is proposing to further revise payments by using 2018 and 2019 drug acquisition cost data from the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs to establish payment for CY 2021 and beyond. As a result, CMS is proposing to pay for 340B purchased drugs at ASP minus 34.7% with an add-on of 6% for a new proposed rate change of ASP minus 28.7%. It should be noted, providers will be unable to calculate themselves CMS payment formulation because 340B survey data is not publicly available. The proposed does note that CMS may delay the agency's proposed 2021 policy, i.e., CMS solicits comments to continue the current policy of ASP minus 22.5%.

Physician-Owned Hospitals

Again, CMS proposes to remove unnecessary regulatory restrictions regarding expansion. Despite Stark law, physicians could, until significant restrictions were imposed under the 2010 ACA, make self-referrals to hospitals they owned. Under the proposed 2021 rule, CMS would remove expansion limits for "high Medicaid facilities" under the agency's Patients over Paperwork Initiative. Specifically, Medicaid hospitals would be able to request an exception to the prohibition of expansion at any time thereby eliminating the restriction that exceptions can only be submitted every two years. If CMS approves a hospital's expansion request, the hospital could exceed 200% of its number of beds, operating rooms and procedure rooms. Requests for expansion could include facilities that are not located on the hospital's main campus. A hospital qualifies as a "high Medicaid" facility when a hospital: is not the only hospital in a county; has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than any other hospital located in the county in which it is located for the three most recent 12-month periods; does not discriminate against beneficiaries of federal health care programs; and, does not permit hospital practicing physicians to do so. CMS solicits comments on whether it should maintain the opportunity for community input on any requests for exceptions to expansion process submitted by "high Medicaid facilities".

Prior Authorization

Under the proposed, CMS intends to expand the prior authorization to include two new categories of reimbursed services. For CY 2020, CMS finalized a proposal to establish a process by which hospitals are required to submit a prior authorization request for a provisional affirmation of coverage before a

covered outpatient service claim is submitted for reimbursement. The policy applied to five categories of services: blepharoplasty; botulinum toxin injections; panniculectomy; rhinoplasty; and, vein ablation. For CY 2021, CMS proposes to include two new categories of services: cervical fusion with disc removal; and, implanted spinal neurostimulators. Services in these two categories would be subject to prior authorization for dates of service on, or after, July 1, 2021.

ASC Covered Procedures List

CMS is proposing a new method for identifying services to be added to the ASC covered procedures list (CPL). Like the IPO list, CMS reviews the ASC CPL annually to determine what if any services should be added or removed. Because of the access issues caused by the ongoing COVID-19 pandemic, CMS is interested in creating new delivery access points – particularly since many ASCs have been closed. As a result, CMS proposes to add 11 procedures to the ASC CPL, including total hip arthroplasty. (A list of related codes appears in Table 40 a FR page 48963.) Specifically, CMS seeks comments on two alternative processes for identifying new ASC CPL procedures.

Alternative 1 – Nomination Process. Stakeholders, that include including medical societies, would nominate procedures for consideration to be added to the ASC CPL. Any procedures recommended to CMS would be reviewed as part of the annual rulemaking cycle, with CMS summarizing the recommendations and the justification for inclusion or exclusion on the list. Comments would be submitted as part of the annual rulemaking cycle, with final decisions published in each year's final rule. CMS would also modify a subset of the criteria used to evaluate the inclusion of a service on the ASC CPL. Under this proposal, the nomination process would begin in CY 2021 for CY 2022.

Alternative 2 – Revision of Exclusion Criteria. CMS would use the existing process for annually reviewing services for consideration but CMS would eliminate the following five of the current eight general exclusion criteria for adding surgical procedures to the ASC CPL: generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are generally emergent or life-threatening in nature; and, commonly require systemic thrombolytic therapy.

CMS has excluded as ASC CPL procedures if the procedure requires inpatient care, i.e., is on the IPO list. With the proposed elimination of the IPO list over a three-year period, CMS proposes to exclude procedures designated as requiring inpatient care as of December 31, 2020. Under proposed alternative 2, CMS could implement the change for CY 2021. Under this approach, CMS identified 270 procedures that could be added to the ASC CPL.

Proposed Physician Fee Schedule Rule

Direct Supervision via Telehealth and Incident-to-Billing

CMS will allow supervising physicians, who previously had to be in the building and immediately able to assist in a clinical procedure, to supervise via real-time, interactive, audio-visual telemedicine. This will be limited to 2021. CMS is asking for comments on whether additional "guardrails" are needed to make the change permanent. Specifically interested in patient safety/clinical appropriateness; concerns around utilization and fraud, waste and abuse and how those concerns might be addressed.

Telehealth Visits in Nursing Facility Settings

CMS is seeking comment on continuing to allow telehealth visits instead of in person at the point of admission and periodically for SNF patients, specifically, CMS would like comments on whether the in-person visit requirement is necessary, or whether two-way, audio/video

telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary. Additionally, CMS is looking at changing frequency limitations to one visit every three days , rather than 30 days.

Payment for Audio-Only E/M services

CMS is not proposing to continue post these services PHE and is seeking comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and subsequently with a higher value.

Payment for Office/Outpatient Evaluation and Management (E/M) and Analogous Visits

CMS is proposing to revalue the following code sets that include, rely upon or are analogous to office/outpatient E/M visits commensurate with the increases in values we finalized for office/outpatient E/M visits for 2021:

- End-Stage Renal Disease (ESRD) Monthly Capitation Payment (MCP) Services - proposing to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code.
- Transitional Care Management (TCM) Services (CPT Codes 99495 AND 99496) - because both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M visit), CMS is proposing to increase the work RVUs associated with the TCM codes commensurate with the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients.
- Maternity Services - proposing to increase the work RVUs, physician time, and PE inputs in the form of clinical staff time associated with the maternity packages by accepting the revaluation recommendation from the AMA RUC.
- Cognitive Impairment Assessment and Care Planning - proposing to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483.
- Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits (HCPCS codes G0438, G0439, G0402) - proposing to revise the work, physician time, and direct PE inputs for these codes as shown.
- Emergency Department Visits (CPT codes 99283-99285) - proposing values consistent with the principle that the levels 1-3 ED visits should remain the same as the levels 1-3 new patient office visits but the levels 4-5 ED visits should have a higher value than the corresponding office visits, due to the complexity of the patients requiring that level of emergency care.
- Therapy Evaluations - proposing to adjust the work RVUs for evaluation services and psychiatric diagnostic evaluation services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits.
- Psychiatric Diagnostic Evaluations and Psychotherapy Services - proposing to increase the work RVU for CPT code 90834 from 2.00 to 2.25 based on the marginal increase in work value for CPT code 99214 from CY 2020 to CY 2021. Similarly, for CPT code 90832, which describes 30 minutes of psychotherapy, we are proposing to increase its work RVU based on the increase to CPT code 99213, which is most commonly billed with the 30 minutes of

psychotherapy add-on, CPT code 90833. For CPT code 90837, which describes 60 minutes of psychotherapy, we propose to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838, which is the office/outpatient E/M visit code most frequently billed with the 60 minutes of psychotherapy add-on.

Episode Bundle for Counseling and Treatment of Opioid Use Disorders/OUDs

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Part B benefit for OUD treatment services, including medications for medication-assisted treatment (MAT) furnished by opioid treatment programs (OTP). CMS is proposing to: add two add-on codes for nasal naloxone, reimbursed at average sales price (ASP) + 0, and another add-on code for auto-injector naloxone, using lowest price available (lower of ASP + 0, wholesale acquisition cost (WAC), or national average drug acquisition cost, to be used for a bundled episode of care for treatment of opioid use disorders; use WAC + 0 for the drug component when ASP is not available; allow enrollment submission on institutional claims; and, require a face-to-face medical exam or biopsychosocial assessment to bill the periodic assessment add-on code and allow periodic assessments to be furnished via two-way interactive audio-video communication technology.

MIPS

Among other changes, CMS proposes to lower the previously finalized performance threshold of 60 points to 50 points for 2021; proposes to increase the cost component from 15% to 20% and reduce the quality component from 45% to 40%; proposing 206 total quality measures by removing 14 and making substantive changes to 12; and, proposing to use performance period, not historical benchmarks, to score quality measures for 2021. In addition, CMS is proposing to end the APM scoring standard and to establish a new MIPS APM Performance Pathway.