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CY 2021 Medicare Hospital OPPS & ASC Payment System Proposed Rule

Summary of Key Provisions

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On August 4, the Centers for Medicare and Medicaid Services (CMS) released the proposed rule impacting reimbursement for outpatient services in 2021. The proposed changes are intended to increase patient choice by expanding Medicare payments to more services in different sites of service, which will allow patients more flexibility in making decisions with regard to health services. The Proposed Rule is open for comments until October 5, 2020, with the Final Rule expected to be published around December 1, 2020.

Executive Summary

CMS is required to annually review and update payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS), including services rendered in hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs). These changes consider relative payment rates, wage adjustments, new technology, new services, and other factors that impact how services are delivered and the associated costs. The five most significant changes contained in the proposed rule are as follows:

1. **Continued Emphasis on Site Neutrality in Payments** – The proposed rule continues the Trump administration's stance on Medicare payment reform by working to ensure Medicare pays the same rate for the same service regardless of where it is provided.

2. **Elimination of Inpatient Only List** – CMS is proposing to remove all restrictions on services currently classified as "inpatient only" over a three-year period, beginning in 2021. This change could continue the migration of volume out of the hospital inpatient setting and into lower cost (or lower reimbursed) ambulatory surgical care centers.

3. **Payment Rates for 340B Drugs** – After several years and several different court rulings, it appears the path has been cleared for a significant payment reduction in the reimbursement of 340B drugs. CMS is proposing setting payment rates for 340B drugs at the average sales price (ASP) minus 28.7%.

4. **OPPS and ASC Payment Rates** – CMS is proposing an 2.6% increase for both OPPS and ASC payment rates.

5. **Relaxation of Physician-Owned Hospital Rules** – The rule prohibiting the expansion of physician-owned hospitals has remained largely unchanged since it went into effect in 2010. CMS is proposing to remove certain provisions of this rule for hospitals classified as high-Medicaid facilities. Among other things, the proposed changes would remove the cap on additional operating rooms, procedure rooms, and beds that can be approved in an exception for expansion.

More details regarding the OPPS/ASC Proposed Rule are discussed below.

Site Neutrality

The *Executive Order on Protecting and Improving Medicare for Our Nation's Seniors*, issued by President Trump in October 2019, required the Secretary of Health and Human Services (HHS) to "ensure that Medicare payments and policies encourage competition and a diversity of sites for patients to access care."[i] In response, the Proposed Rule includes several changes that would impact where certain services may be provided.

Elimination of Inpatient Only List

CMS has proposed to eliminate the Inpatient Only (IPO) list over a three-year transition period. This would begin with the removal of 266 musculoskeletal-related services in 2021, with additional services to be removed in subsequent years. The list of services proposed for removal in 2021 is detailed in Table 31 of the Proposed Rule.

In addition, CMS proposed to continue the two-year exemption for medical review activities related to services removed from the IPO list, which was finalized in the CY 2020 OPPS/ASC final rule. This

means that for two years, claims for the newly-removed services that are provided during an inpatient stay will not be denied for noncompliance with the 2-midnight rule. This exemption period is intended to allow providers to become acclimated to the recently removed procedures and update their systems accordingly.

ASC Covered Procedures List

The Proposed Rule seeks to expand the number of procedures that can be performed in an ASC and receive Medicare reimbursement. The following eleven procedures have been proposed to be added to the ASC Covered Procedures List (CPL) in 2021, as detailed in Table 40 of the Proposed Rule:

- 0266T – Implantation or replacement of carotid sinus baroreflex activation device (total system);
- 0268T – Implantation or replacement of carotid sinus baroreflex activation device (pulse generator only);
- 0404T – Transcervical uterine fibroid(s) ablation with ultrasound guidance;
- 21365 – Open treatment of complicated fracture(s) of malar area, including zygomatic arch and malar tripod, with internal fixation and multiple surgical approaches;
- 27130 – Total hip arthroplasty;
- 27412 – ACI (autologous chrondrocyte implantation), knee;
- 57282 – Vaginal colpopexy, extra-peritoneal approach;
- 57283 – Vaginal colpopexy, intra-peritoneal approach;
- 57425 – Laparoscopic colpopexy;
- C9764 – Endovascular revascularization, with intravascular lithotripsy; and
- C9766 – Endovascular Revascularization, with intravascular lithotripsy and atherectomy.

It was noted that CMS's position regarding which procedures can be safely performed in an ASC setting has changed as some of their concerns regarding trained staff, equipment, and other factors have been addressed over time. Notably, the Proposed Rule also points to the COVID-19 pandemic highlighting the need to provide more healthcare access points, and the benefit of providing more flexibility for physicians and patients to choose ASCs as the site of care.

In addition to proposing that these eleven procedures be added to the ASC CPL in 2021, the Proposed Rule also proposes two alternatives for changing how procedures are added to the ASC CPL in the future. The first option involves a nomination process in 2021 for procedures to be added in 2022. Under this approach, CMS would provide suggested parameters that external parties, such as specialty societies, would use to nominate procedures that can meet regulatory standards and be safely performed in an ASC. CMS would then review the nominations and make its proposals during the annual rulemaking process.

The second option would involve CMS revising criteria for covered ASC surgical procedures under 42 CFR 416.166, keeping the general standards but eliminating five of the general exclusions. The Proposed Rule indicates that these changes would result in around 270 services added to the ASC CPL. CMS is seeking public comment regarding both of the proposed approaches.

340B-Acquired Drugs

The Proposed Rule includes changes to the payment methodology for certain covered outpatient drugs purchased at discounted prices, as allowed in Section 340B of the Public Health Service Act.[ii] Historically, reimbursement for these drugs was paid based on Average Sales Price (ASP) plus 6%. CMS changed the payment methodology in 2018 to ASP minus 22.5%. However, a U.S. District Judge later ruled that the HHS exceeded its authority in reducing the 340B reimbursement, and the cuts were vacated. A similar ruling was made relating to 2019 340B cuts. However, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia upheld the decision by HHS to implement the payment reductions[iii], paving the way for the changes reflected in the 2021 Proposed Rule.

CMS proposed a net payment rate of ASP minus 28.7% for 340B drugs acquired in 2021 and subsequent years. This rate was based on a rate of ASP minus 34.7%, with a 6% add-on for overhead and handling costs. The Proposed Rule states that these adjustments were determined based on the results of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs.

The Proposed Rule also makes an alternative proposal of continuing to pay ASP minus 22.5%, consistent with current Medicare policy.

Further, rural sole community hospitals, PPS-exempt cancer hospitals, and children's hospitals are proposed to be exempt from either of these 340B payment proposals and would continue to be paid ASP plus 6%.

OPPS Payment Rates

The Proposed Rule includes an Outpatient Department (OPD) fee schedule increase factor of 2.6%, which reflects a market basket increase of 3% for inpatient services less the multifactor productivity adjustment of 0.4% required by the Affordable Care Act. CMS estimates that this will result in an increase of about $7.5 billion in total payments to OPPS providers for CY 2021 as compared to 2020.

Further, it is proposed that CMS will continue to implement a 2% reduction in payments for facilities that fail to meet hospital outpatient reporting requirements.

Partial Hospitalization Program Update

CMS proposes to maintain the current unified rate structure for the Partial Hospitalization Program (PHP), with a single PHP Ambulatory Payment Classification (APC) for each provider type for days with three or more services per day. The PHP is an outpatient program consisting of a group of intensive mental health services furnished in either a hospital outpatient department or Community Mental Health Centers. It is proposed that the per diem rate for these services for 2021 would be calculated based on updated cost data, with a cost floor based on the CY 2019 final geometric mean per diem cost for each provider type.

Device Pass-Through Payment Applications

Five device pass-through payment applications are addressed in the Proposed Rule. Two of these received preliminary approval through the quarterly review process:

- CUSTOM*FLEX®* ARTIFICIAL*IRIS*; and
- EXALT™ Model D Single-Use Duodenoscope.

CMS is seeking comments on all five applications and will make a final determination in the 2021 OPPS/ASC final rule.

Cancer Hospital Payment Adjustment

The Proposed Rule includes a proposal to continue providing additional payments to cancer hospitals such that the adjusted payment-to-cost ratio is equal to the payment-to-cost ratio of other OPPS hospitals, reduced by 1 percentage point as required by the 21st Century Cures Act. Accordingly, the payment adjustments will be calculated as the amount needed to result in a payment-to-cost ratio of 0.89.

ASC Payment Rates

In prior final rules, CMS adopted a policy for 2019 through 2023 to update the ASC payment system using the hospital market basket update. For 2021, the payment rate is proposed to increase by 2.6%, which reflects a hospital market basket increase of 3% less a multifactor productivity adjustment required by the Affordable Care Act of 0.4%. CMS estimates that this increase will result in an increase in total payments to ASCs in 2021 by approximately $160 million over 2020 amounts.

Quality Reporting Programs

No measure additions or removals are being proposed for either the Hospital Outpatient Quality Reporting or ASC Quality Reporting Programs. There are proposals to update and refine certain requirements for measurement and reporting.

Hospital Quality Star Rating

CMS is proposing changes to update and simplify how Overall Hospital Quality Sar Ratings are calculated. The proposed changes include the following:

- Reducing the number of measure groups to five:
  - Mortality;
  - Safety of Care;
  - Readmissions;
  - Patient Experience; and
  - Timely and Effective Care;
- Using a simplified method to calculate measure group scores;
- Stratifying the Readmission measure group based on the proportion of dual-eligible patients;
- Changing the reporting threshold to require hospitals to report on at least three measures for three measure groups (but must include Mortality or Safety of Care).

The changes are intended to both simplify the methodology as well as improve predictability and comparability of the Overall Star Ratings. Additionally, it is proposed that critical access hospitals and VA hospitals be included in the Overall Star Ratings.

Comprehensive APCs

The Proposed Rule includes the creation of two new comprehensive Ambulatory Payment Classifications (APCs) in 2021:

- C-APC 5378 – Level 8 Urology and related Services; and
- C-APC 5465 – Level 5 Neurostimulator and Related Services.

The addition of these two classifications would increase the total number of C-APCs to 69.

Supervision Changes

It is proposed that the minimum level of supervision required for non-surgical extended duration therapeutic services be changed to general supervision for the entire service. Previously, the initiation portion of the service was required to have direct supervision.

Further, it is proposed that direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services include the virtual presence of a physician through audio/video technology in real-time, if deemed appropriate in the judgment of the supervising physician.

Prior Authorization

The Proposed Rule includes the addition of two HOPD service categories that would require prior authorization for dates of service on or after July 1, 2021:

- Cervical fusion with disc removal; and
- Implanted spinal neurostimulators.

These services were identified for inclusion based largely on the volume of claims for these procedures increasing at a drastically higher rate than the average overall annual increase for outpatient services. CMS believes that prior authorization is an appropriate control method to prevent unnecessary increases in volume for these services, while still allowing the procedures when deemed medically necessary.

Physician-Owned Hospitals

CMS proposes relaxation of certain restrictions on expansion for physician-owned hospitals. These hospitals must meet the “whole hospital exception” or the “rural provider exception” to be compliant with physician self-referral regulations (more commonly known as the “Stark Law”). To meet these exceptions, such hospitals have generally been limited to the number of operating rooms, procedure rooms, and beds for which they were licensed on March 23, 2010, unless granted an exemption by CMS.

CMS proposes to remove certain provisions in the expansion exception process applicable to physician-owned hospitals that qualify as "high Medicaid facilities." A hospital is considered to be a "high Medicaid facility" if it is the not the sole hospital in a county, has annual Medicaid admissions for each of the most recent three years greater than the percentage for other hospitals in the same county, and does not discriminate or allow its physicians to discriminate against beneficiaries of Federal health care programs. For hospitals meeting these criteria, CMS is proposing to:

- Remove the cap on additional operating rooms, procedure rooms, and beds that can be approved in an exception;
- Remove the requirement that expansions occur only on the hospital's main campus; and
- Allow the hospital to apply for an exception more than once every two years.

Conclusion

CMS is accepting public comments on the Proposed Rule until October 4, 2020. While the final rules are usually issued 60 days before the effective date, the Proposed Rule waives the 60-day requirement in light of the current COVID-19 public health emergency. Due to prioritizing efforts related to the pandemic, CMS indicates that it may need an additional 30 days to complete the CY 2021 OPPS and ASC Payment System final rule. CMS expects to provide the final rule 30 days in advance of the January 1, 2021 effective date.

[i] United States, Executive Office of the President [Donald Trump]. Executive Order 13890: Protecting and Improving Medicare for Our Nation's Seniors. 3 Oct. 2019. 84 FR 53573, pp. 53573-53576, www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/.
[ii] 42 CFR Part 10 – 340 B Drug Pricing Program
[iii] Richard P. Church, Andrew D. Ruskin, Leah D/Aurora Richardson, Victoria K. Hamscho. *The National Law Review*, Vol. X, Num. 245, 1 Sep. 2020, www.natlawreview.com/article/340b-update-appeals-court-upholds-340b-payment-reduction-under-opps-cms-proposes.