

# Holland & Knight

## **CMS Releases 2021 OPSS and ASC Proposed Rule**

The Centers for Medicare & Medicaid Services (CMS) on August 4, 2020, published the Calendar Year (CY) 2021 Hospital Outpatient Prospective Payment System (OPSS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule.

Among notable changes, CMS proposes to pay Average Sales Price (ASP) minus 28.7% for 340B drugs; change the expansion exception process for a subset of physician-owned hospitals, expand the prior authorization process to include two new categories of services reimbursed under the OPSS; and eliminating the “Inpatient Only list.”

**Comments on the proposed rules are due by October 5, 2020.** Due to the public health emergency (PHE), CMS plans to implement the rule 30-days after it is finalized instead of the standard 60-day period. The Final Rule will likely be released in early December, providing little time for hospitals to adapt to changes made by the Final Rule before they take effect on January 1, 2021.

Review the [Proposed Rule](#), the [Fact Sheet](#), and the [Press Release](#).

Below is a summary of the highlights of the Proposed Rule.

## **Proposed HOPD and ASC Payment Updates**

CMS proposes an increase of 2.6 percent for OPSS payment rates in CY 2021, which it estimates will result in a total of approximately \$83.9 billion in payments to OPSS. CMS will continue the statutory 2.0 percentage point reduction for hospitals failing to meet the hospital outpatient quality reporting requirements.

CMS proposes an increase of 2.6 percent for ASC payment rates in CY 2021, which is consistent with CMS’ policy for CYs 2019 through 2023 to update the ASC payment system using the hospital market basket update. CMS estimates this will result in a total of approximately \$5.45 billion in payments to ASC providers.

## **Cancer Hospital Payment Adjustment**

CMS proposes to continue to provide additional payments to cancer hospitals, so a cancer hospital’s payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average payment-to-PCR for the other OPSS hospitals using the most recently submitted or settled cost report data.

The *21st Century Cures Act* requires that this weighted average PCR be reduced by 1.0 percentage point, the data and the required 1.0 percentage point reduction requires a proposed target PCR of 0.89 be used to determine the CY 2021 cancer hospital payment adjustment to be paid at cost report settlement.

## **Elimination of the Inpatient Only List**

The Inpatient Only (IPO) List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for postoperative recovery time, or the underlying physical

condition of the patient. CMS concluded that the list is not necessary to identify services that require inpatient care because of changes in medical practice, including new technologies and innovations.

Beginning with 2021, CMS proposes to eliminate the IPO list over three calendar years, starting with the removal of 300 musculoskeletal-related services in 2021. They are asking for comments on whether three years is an appropriate timeframe for the elimination; any other services that are candidates for removal in CY 2021; and the sequence of removal over the three years. CMS also proposes to continue the 2-year exemption from site-of-service claims denials and recovery audit contractor referrals for services removed from the IPO. Given the significant surge in the number of newly removed services due to the proposed elimination of the IPO, CMS requests comments on whether the 2-year exemption is still adequate.

### **Payment for 340B Drugs and Biologics**

CMS adopted a policy to pay average sales price (ASP) -22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus PBDs paid under the PFS. In last year's rule, CMS acknowledged the ongoing litigation relating to the lower payment amount, including a district court ruling that the agency exceeded statutory authority in adjusting the payment rate for 340B drugs.

CMS conducted a survey to gather data on hospital acquisition costs for 340B drugs following the court ruling that found that CMS acted beyond its statutory authority but also acknowledged that CMS might base the payment amount of average acquisition cost when survey data are available.

In early August 2020, the DC Circuit Court of Appeals reversed the lower district court's ruling and held that CMS in fact, reasonably interpreted the Medicare statute as authorizing the rate reductions under a "general adjustment authority" with the purpose "to reimburse hospitals for their acquisition costs accurately."

Based on the results of this survey of hospital acquisition costs for 340B drugs, CMS is now proposing the pay for 340B drugs for CY 2021 and subsequent years at ASP minus 34.7 percent, plus an add-on of 6 percent of the ASP. This results in a net payment rate of ASP minus 28.7 percent for 340B drugs. For biosimilars, CMS is proposing to set net reimbursement at ASP minus 28.7 percent of the biosimilar's ASP, not minus 28.7 percent of the reference product's ASP.

Similar to the previous policy, rural sole community hospitals, PPS-exempt cancer hospitals, and children's hospitals are exempt from this lower 340B reimbursement. Wholesale Acquisition Cost (WAC) will be used for products without an ASP available.

### **Hospital Star Ratings**

CMS proposes a methodology to calculate the Overall Hospital Quality Star Rating utilizing data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website. CMS also proposes to update and simplify how the ratings are calculated, reduce the total number of measure groups, and stratify the readmission measure group based on the proportion of dual-eligible patients.

### **Hospital Quality Reporting Programs**

For the Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) programs, CMS does not propose any measure additions or removals for either program. CMS does propose to revise and codify previously finalized administrative procedures, clarify requirements, and expand the review and corrections process to further align and reduce the burden for the two programs.

### **Prior Authorization**

Last year, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. The change applied to five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

This year, the agency proposed to expanded prior authorization requirements for two additional services: cervical fusion with disc removal and implanted spinal neurostimulators to curb unnecessary utilization. Services in these two categories would be subject to prior authorization for dates of service on or after July 1, 2021. CMS estimates annual Medicare savings of \$31,844,388.

It is likely this policy will expand in future rulemakings.

### **Site-Neutral Payment Policy for Clinic Visits**

As finalized in CY2019 OPPS/ASC final rule, CMS completed the implementation of the two-year phase-in of applying the Medicare Physician Fee Schedule (MPFS) rate for the clinic visit service (G0463 – Hospital outpatient clinic visit for assessment and management of a patient) when provided at an off-campus PBD and reimbursed under OPPS. This clinic visit is the most common service billed under OPPS and typically occurs in the physician's office. CMS instituted the proposal based on its authority to restrict unnecessary increases in the volume of covered services.

In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to implement the change. However, on July 17, 2020, the US Court of Appeals for the District of Columbia Circuit ruled in favor of CMS, holding that the agency's regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. In light of this recent court ruling, CMS will continue the site-neutral policy in 2021. CMS has not released information on how or if it will address reprocessing 2019 claims that were previously reprocessed at the higher OPPS rate.

### **Physician Owned-Hospitals (POHs)**

Generally, physician-owned hospitals may not increase the number of operating rooms, procedure rooms, and beds beyond those that were licensed on March 23, 2010 (the *Affordable Care Act* enactment date). In the original statutory language, an exception process to this prohibition was included for POHs that qualify as an "applicable hospital." Later, an additional exception was created for POHs that qualified as a "high Medicaid facility." The requirements and statutory direction for these two exceptions were different but CMS implemented a single process to address both.

In this rule, CMS proposes to remove certain expansion limits for “high Medicaid facilities” as part of its Patients over Paperwork Initiative. CMS proposes the following flexibilities applicable only to qualifying Medicaid facilities:

- Hospitals can request an exception to the prohibition of expansion at any time, provided that the facility has not submitted another exception request that is pending a CMS decision. This proposal would eliminate the restriction that exceptions can only be submitted every two years for Medicaid hospitals.
- If CMS approves a hospital’s request for expansion, the hospital can exceed 200% of its baseline number of beds, operating rooms and procedure rooms.
- Requests for expansion may include facilities that are not located on the hospital’s main campus.
- A bed counts toward a hospital’s baseline number if the bed is considered licensed for purposes of state licensure.

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 the hospital is located for the three most recent 12-month periods; and
- does not discriminate against beneficiaries of federal health care programs, and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

CMS solicits comments on whether it should maintain the opportunity for community input on any requests for exceptions to the expansion process submitted by “high Medicaid facilities”.

#### **Pass-Through Time Extension Due to COVID-19**

CMS is requesting comments on whether pass-through status should be extended for an additional time period due to the effects of COVID-19 on the use of those items with pass-through status. CMS is also proposing to clarify that a new medical device is part of the Food and Drug Administration’s (FDA’s) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation does not need to meet the substantial clinical improvement criterion.

#### **Comprehensive Ambulatory Payment Classifications (APCs)**

CMS proposes to create two new comprehensive APCs, including C-APC 5378 (Level 8 Urology and Related Services) and C-APC 5465 (Level 5 Neurostimulator and Related Procedures).

#### **2-Midnight Rule**

CMS proposes to continue a 2-year exemption from Beneficiary and Family-Centered Care Quality Improvement Organizations referrals to RACs and RAC reviews for “patient status” (that is, site-of-service) for procedures that are removed from the inpatient-only list under the OPSS beginning on

January 1, 2021. The agency seeks comments on whether the 2-year exemption period continues to be appropriate, or if a longer or shorter period may be more warranted.

**Clinical Laboratory Date of Service (DOS) Policy**

CMS proposes excluding cancer-related protein-based Multianalyte Assays With Algorithmic Analysis (MAAAs), which are not generally performed in the hospital outpatient setting, from the HOPPS packaging policy, instead adding them to laboratory date-of-service (DOS) provisions. If finalized, this would mean that Medicare would pay for cancer-related protein-based MAAAs under the Clinical Laboratory Fee Schedule (CLFS) instead of the HOPPS, and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements.