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CMS Includes Several Changes in OPPS Proposed Rule

On August 4, 2020, the *Centers for Medicare & Medicaid Services* (CMS) released the latest in a series of recently-published proposed rules, the *Outpatient Prospective Payment System* (OPPS) and *Ambulatory Surgical Center* (ASC) proposed rule for fiscal year (FY) 2021. This proposed rule builds upon executive orders such as "*Protecting and Improving Medicare for Our Nation's Seniors*," signed by President Trump in October 2019[1] and Trump Administration initiatives such as "*Patients Over Paperwork*."[2] In a press release, CMS highlighted the proposed rule's focus on increasing competition among providers to give patients more choice, lowering out-of-pocket surgery costs, increasing provider flexibility, and allowing patients to make more informed decisions about their care.[3] This year, achieving these ends may mean major changes to the current system, as evidenced by CMS proposals such as the elimination of the *inpatient only* (IPO) list, cutting payments for 340B pharmaceuticals, reducing taxpayer spending, and changing physician-owned hospital rules.[4]

Payment Rate Updates

For 2021, CMS proposes increasing OPPS payment rates by 2.6% for hospital outpatient departments (HOPDs) that meet the requisite quality criteria – this rate increase is calculated as the estimated inpatient market basket increase of 3.0% minus the *multifactor productivity* (MFP) adjustment of 0.4%.[5] For HOPDs that fail to meet quality requirements, CMS proposes implementing a 2% reduction in payments through the application of a 0.9805 factor (termed a "*reporting ratio*") to all payments and copayments.[6] CMS estimates that it will provide approximately $83.9 billion in total payment to OPPS providers in 2021, a $7.5 billion increase from 2020.[7]

ASC rates will also increase 2.6%, by way of the same calculation described above for OPPS rates, for a total of approximately $5.45 billion, a $160 million increase from 2020.[8]

Elimination of the Inpatient Only (IPO) List

CMS proposes two measures to increase patient choice and to potentially pass on savings to patients through lower out-of-pocket expenses. First, CMS would phase out the IPO list and the 1,740 services currently included in it.[9] The IPO list was first established in 2000 and is a list of treatments and procedures that are only allowed to be performed in an inpatient setting, to maintain quality and control over more complex procedures.[10] The proposed elimination of the IPO list is an acknowledgement by CMS of: (1) the many stakeholders that have long requested that a physician to be able to use their clinical judgement to determine where procedures should be performed; and, (2) medical and technological advances that now allow for many more procedures to be performed safely in an outpatient setting.[11] According to the proposed rule, the IPO list would be gradually phased out through 2024, beginning with the removal of musculoskeletal services in 2021 (e.g., arthroplasties, osteotomies, replacements, revisions/reconstructions, fusions).[12] Removed procedures would be subject to the "*two-midnight rule*" for inpatient admission eligibility,[13] but would be exempt from medical review activities for two years.[14]

Addition to ASC Covered Procedures List

In addition to eliminating the IPO list, CMS proposes designating 12 codes as *permanently* office-based under the ASC *Covered Procedures List* (CPL), five of which were *temporarily* office-based in 2020 and seven of which would be newly designated as office-based.[15] Further, CMS proposes to continue 11 codes that were *temporarily* office-based in 2020 through 2021.[16] Two codes that were designated as *temporarily* office-based in 2020 are proposed to not be renewed as office-based in 2021.[17] Additionally, CMS proposes two options for expanding the ASC-CPL in future years: (1) modifying criteria for addition and allowing stakeholders to nominate procedures to be added to the CPL; or, (2) keeping general standard criteria while eliminating five general exclusion criteria.[18] CMS hopes that either of these options will allow the ASC-CPL to increase services offered and lower costs for patients.[19]

340B Program Cuts

CMS proposes further cutting reimbursement for drugs acquired under the 340B drug discount program. 340B allows hospitals that meet certain qualifications (e.g., specialized clinics, sole community hospitals, federally qualified health centers, and critical access hospitals[20]) to buy select outpatient drugs at or below cost.[21] The program was created to extend scarce resources, but has been criticized by officials from the *Department of*

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Health and Human Services (HHS) for the large profit margin it has created between what hospitals pay for those drugs and their reimbursement from Medicare.[22]

Just weeks before CMS published the OPPS proposed rule, the U.S. Court of Appeals for the District of Columbia settled a case against CMS and HHS, holding that the agencies were within their bounds to make 28.5% cuts in the 340B program in previous years' OPPS rules.[23] Seemingly heartened by the ruling, CMS now proposes cutting the program once again from an *average selling price* (ASP) of -22.5% to an ASP of -28.7%, resulting in lower reimbursements for 340B hospitals.[24] This percentage was calculated from a subtotal ASP of -34.7% plus a 6% add-on for overhead costs to reach an ASP of -28.7%, a number that is based partially on the results of Hospital Acquisition Cost Surveys.[25] As in previous years, CMS suggests that rural *Sole Community Hospitals* (SCHs), *prospective payment system*-exempt (PPS-exempt) cancer hospitals, and children's hospitals would all be exempt from this payment policy in 2021 and beyond.[26]

Quality Reporting Changes

In order to emphasize quality care and improve measurements, the CMS suggests several changes to quality reporting for HOPDs and ASCs in 2021.[27] In its light revisions to both quality programs, CMS updates and refines language regarding reporting requirements and limiting compliance burden.[28] No measures were removed or added in the proposed rule.[29]

Hospital quality star ratings, by contrast, received numerous methodology updates, including simplifying calculations and reducing the number of measure groups.[30] Under the proposed rule, hospitals will have to report on at least three measures in three different groups, with one group being either *Mortality* or *Safety of Care*, in order to receive an overall star rating.[31] CMS hopes that these changes will reduce provider burden, allow ratings to be more predictable, and increase comparability between ratings.[32]

Prior Authorization

CMS will also expand its prior authorization requirement for HOPDs (whereby providers must submit an application to CMS explaining the medically necessary nature of the treatment before providing treatments to patients and submitting a claim for payment) to two new treatments (cervical fusion with disc removal and implanted spinal neurostimulators) in order to encourage the provision of only medically necessary care.[33] An October 2019 review from the *Journal of the American Medical Association* (JAMA) found that between $12.8 and $28.6 billion could be saved annually from eliminating overtreatment and low-value care.[34] CMS believes that prior authorization is an effective method for discouraging these two practices.[35]

Flexibilities for Physician-Owned Hospitals

Physician-owned hospitals may see more flexibility in 2021. The *Patient Protection and Affordable Care Act* (ACA) placed a moratorium on physician-owned hospitals, wherein those already in existence could not expand the number of operating rooms, procedure rooms, or beds in their facilities.[36] CMS proposes that physician-owned hospitals that are classified as "*high Medicaid facilities*," i.e., hospitals that serve more Medicaid beneficiaries than other hospitals in the area,[37] be allowed to apply for an expansion exception once every two years; no longer have a cap on the number of beds that can be approved in that exception; and, no longer be allowed to only expand those facilities located on the hospital's main campus.[38]

Stakeholder Reactions

Stakeholders expressed both praise of and concern for the changes in the 2021 OPPS proposed rule. *Ambulatory Surgery Center Association* (ASCA) CEO, Bill Prentice, acknowledged greater ASC use with future Medicare savings of billions of dollars, but said he "*remain[s] concerned that… [this proposal] does not take the needed step of addressing [the negative impact of weight scaling on ASC rates]*."[39] *American Hospital Association* (AHA) Executive Vice President, Tom Nickels, strongly criticized the proposed rule in general as a threat to hospital viability.[40] As regards the 340B program changes, he stated that the cuts "*decimate the intent of the 340B program*" and "*exacerbate the strain… on hospitals serving vulnerable communities*."[41] Nickels cited the COVID-19 crisis in asserting that the proposed rule "*will result in the continued loss of resources for 340B hospitals*."[42] 340B Health, which represents over 1,400 hospitals, similarly stated that it was "*disappointed*" in this "*damaging payment policy… that hurts safety-net hospitals and their patients*."[43] Bruce Siegel, President and CEO of America's Essential Hospitals, similarly noted that the hospitals targeted by these cuts are the same ones "*straining under the heavy costs of responding to COVID-19*."[44] The cuts, he says, undermine "*program savings for hospitals that operate with little or no margin*" and will jeopardize "*access to care in underserved communities*."[45]

Nickels stated that the AHA also strongly opposes loosening restrictions on physician-owned hospitals, citing research that shows higher costs through physician self-referral.[46] He also expresses worry about the "*cherry-picking*" of profitable patients in these facilities, which could jeopardize the community's "*access to full-service care*."[47] The elimination of the IPO list was also a source of concern for the AHA, which asserted that many complex surgical procedures need the "*care and coordinated services provided in the inpatient setting*."[48]

Conclusion

The potential impact of the 2021 OPPS proposed rule has yet to be determined. CMS Administrator Seema Verma characterized the potential changes as an opening of options for patients so that they can make the best decisions possible along with physician guidance to help surgeries cost less for patients without lowering the quality of treatment.[49] However, as noted above, other

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stakeholders expressed strong concerns about the cuts to 340B and the elimination of the IPO list. Many believe that these changes would undermine protections put in place for at-risk hospitals that have been further hurt by the COVID-19 pandemic, and may lessen quality of care while increasing the burden of administration for hospitals.

The final rule is set to be released before the end of 2020, with comments due by October 5, 2020.[50]

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