2022 OPPS FINAL RULE OVERVIEW: CMS FINALIZES POLICIES ON 340B, HOSPITAL PRICE TRANSPARENCY, AND INPATIENT ONLY LIST

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On 2 November 2021, the Centers for Medicare & Medicaid Services (CMS) released the 2022 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgery Center (ASC) Payment System final rule (OPPS Final Rule),[1] in which the agency finalized several of the policies it proposed in the 2022 OPPS/ASC Payment System proposed rule (OPPS Proposed Rule).[2] In summary, in the OPPS Final Rule, CMS finalized its proposals to:

- Substantially increase financial penalties for noncompliance under the hospital price transparency rules;
- Continue the payment rate of Average Sale Price (ASP) minus 22.5% for separately payable drugs or biologicals acquired through the Section 340B of the Public Health Service Act (340B Program); and
- Halt the elimination of the Inpatient Only (IPO) list, and remove the regulatory references to the elimination of the list.

These policies will take effect 1 January 2022.

HOSPITAL PRICE TRANSPARENCY

As we had discussed in a prior client alert addressing the price transparency provisions in the OPPS Proposed Rule, CMS had proposed to significantly increase financial penalties on hospitals for noncompliance with CMS's price transparency rules (collectively, the Hospital Price Transparency Rule or the Rule). Currently, penalties for noncompliance may not exceed US$300 per day. In finalizing its price transparency policies as proposed, CMS increases the dollar amount of a Civil Monetary Penalty (CMP) it may impose on a hospital for noncompliance. Beginning 1 January 2022, the new penalties are as follows (all amounts are per hospital):

- Maximum penalty for full year of noncompliance: US$2,007,500
- Minimum penalty for full year of noncompliance: US$109,500
- Daily penalty – hospitals with bed counts greater than 30: US$10 per bed
- Maximum daily penalty – hospitals with bed counts greater than 30: US$5,500
- Maximum daily penalty – hospitals with bed counts less than 30: US$300[3]

In addition to increasing the CMP for noncompliance, CMS also finalized its proposal to update the Rule's prohibition of certain activities that the agency views as barriers to accessing the machine-readable file. As such,

CMS will now specifically require that the machine-readable file be accessible to automated searches and direct downloads.[4]

340B PROGRAM INFUSED DRUGS REIMBURSEMENT CUT

The 340B Program allows participating hospitals and other providers to purchase certain covered outpatient drugs from manufacturers at discounted prices. In the Calendar Year (CY) 2018 OPPS final rule, CMS reduced payments to hospitals for separately payable drugs or biologicals acquired through the 340B Program from ASP plus 6% to ASP minus 22.5%.

In the OPPS Final Rule, CMS finalized its proposal without modification to continue the payment rate of ASP minus 22.5% for separately payable drugs or biologicals acquired through the 340B Program.[5] Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals will continue to be excepted from this payment policy.[6]

Relatedly, and as discussed in a prior client alert, the Supreme Court announced in July 2021 that it accepted the American Hospital Association's petition for certiorari in American Hospital Association v. Becerra. At issue is CMS's nearly 30% cut to payments for specified covered outpatient drugs under the OPPS for certain hospitals participating in the 340B Program, which provider groups have been challenging in court since 2017. Provider groups have been urging CMS to reverse the payment reductions as part of the CY 2022 OPPS rulemaking process. CMS's decision to continue the 340B payment cuts leaves open the possibility that the key issue—whether CMS exceeded its authority to adjust the payment rates under the existing statutory framework—will ultimately be decided by the Supreme Court.

INPATIENT ONLY LIST

The IPO list was established in rulemaking as part of the initial implementation of the OPPS; the list identifies services for which Medicare will make payment only when such services are furnished in the inpatient hospital setting.[7] In CY 2021 OPPS final rule,[8] CMS finalized its proposal to eliminate the IPO list over a three-year period.[9] As part of the first phase of the elimination of the IPO list, CMS removed 298 codes from the list beginning in CY 2021.[10]

Following its decision to eliminate the IPO list, CMS indicated it received a significant number of stakeholder comments strongly opposing that decision.[11] In the OPPS Final Rule, CMS has finalized its proposal with some minor modifications (a) to halt the elimination of the IPO list; (b) to codify in regulation the agency's five longstanding subregulatory criteria for determining whether a service or procedure should be removed from the IPO list; and (c) to add back to the IPO list 293 of the 298 services that were removed in CY 2021.[12] As a result of this change, CMS has amended the implementing regulations to remove the reference to the elimination, through a three-year transition, of the list of services and procedures designated as requiring inpatient care.[13]

K&L Gates' Health Care practice routinely assists health systems, hospitals, and other providers and suppliers with legal advice and strategic considerations, including providing advice on reimbursement matters and preparing clients' public comments on proposed and final rulemakings. Contact the authors of this article or another K&L Gates lawyer for assistance with the Hospital Price Transparency Rule or to receive updates on Medicare reimbursement.

FOOTNOTES

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model, (display copy) [hereinafter OPPS Final Rule].

[2] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals, 86 Fed. Reg. 42018 (4 Aug., 2021) [hereinafter OPPS Proposed Rule].

[3] OPPS Final Rule (display copy), at 1240–41.

[4] *Id*. at 1232.

[5] *Id*. at 520.

[6] *Id*. at 513–14.

[7] OPPS Proposed Rule, 86 Fed. Reg. 42018, 42115 (4 Aug., 2021).

[8] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19), 85 Fed. Reg. 85866 (29 Dec., 2020).

[9] *Id*.at 86093.

[10] *Id*.at 86094.

[11] OPPS Proposed Rule, 86 Fed. Reg. at 42156.

[12] OPPS Final Rule (display copy), at 636–37.

[13] *Id*. at 666.

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