

Key Takeaways from the CY 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule

Comments due October 5, 2020

On August 4, 2020, the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule.¹ The CMS fact sheet for the Proposed Rule can be found [here](#). Key takeaways from the Proposed Rule are summarized below. Please see the end of this document for a glossary of key terms. *Note that due to the delayed release of the Proposed Rule, the Final Rule will be effective 30 days from publication, instead of the usual 60 days.*²

Esketamine

- CMS proposes to continue to assign HCPCS code G2082 to New Technology APC 1508 and HCPCS code G2083 to New Technology APC 1511.**³ CMS established G2082 and G2083 effective January 1, 2020 to facilitate beneficiary access to treatment for treatment-resistant depression using esketamine.⁴ The agency proposes to continue to assign these codes to New Technology APCs 1508 and 1511, respectively, for CY 2021 because no OPPS claims have been reported for either code.⁵ CMS pays for services under New Technology APCs, which are defined solely by cost, until sufficient claims data have been submitted to allow CMS to assign the service to a clinical APC.⁶

Code	Long Descriptor	CY 2020 APC	Proposed CY 2021 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of <u>up to 56 mg</u> of esketamine nasal self-administration, includes 2 hours post-administration observation.	1508	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of <u>greater than 56 mg</u> of esketamine nasal self-administration, includes 2 hours post-administration observation.	1511	1511

- **No change in policy.**

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340B Proposals

- **CMS proposes to reduce payments for 340B drugs and biologics from average sales price (ASP) – 22.5% to ASP – 28.7%.⁷** Based on the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs, CMS is proposing to pay for drugs and biologics purchased under the 340B Drug Pricing Program ASP – 34.7%, plus an add-on of 6% of the product’s ASP, for a net payment rate of ASP – 28.7%. When acquired under 340B, WAC priced drugs and biologics would be paid at WAC – 28.7%.⁸
 - **Current policy:** CMS pays for 340B separately payable drugs and biologics at ASP – 22.5%—the rate established in the CY 2018 OPPS Final Rule.
 - **2021 proposal:** CMS proposes to pay for 340B separately payable drugs and biologics at a net rate of ASP – 28.7%.
 - **Why it matters:** CMS is proposing to further reduce reimbursement for drugs and biologics acquired under the 340B program to more closely align the Medicare payment rate to hospital acquisition costs.⁹
- **Follow-on biosimilars would continue to be eligible for pass-through status, meaning they would be eligible for payment at ASP + 6% rather than ASP – 28.7% when purchased under the 340B program (subject to sequestration).¹⁰** CMS announced in the CY 2018 Final Rule that all biosimilar biological products would be eligible for pass-through status, not just the first biosimilar to market for a given reference product.¹¹
 - **No change in policy.**
- **CMS proposes to continue to base reimbursement for non-pass-through biosimilars purchased under the 340B program entirely on the ASP of the biosimilar.¹²** CMS proposes to pay non-pass-through biosimilar products acquired under the 340B program at the ASP of the biosimilar – 28.7% of the biosimilar’s ASP, instead of the ASP of the biosimilar – 28.7% of the reference product’s ASP. Although using ASP – 28.7% instead of ASP – 22.5% for 340B drugs and biologics is a new proposal, using the biosimilar’s ASP rather than the reference product’s ASP in calculating reimbursement for 340B biosimilars is the continuation of a policy established in the CY 2019 OPPS Final Rule.¹³
 - **No change in policy.**

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Price Transparency

- **CMS does not propose to delay implementation of hospital price transparency requirements.** Last year, CMS finalized a policy requiring hospitals to report their standard charges—including both gross charges and payer-specific negotiated charges—for all items and services online in a machine-readable file, effective January 1, 2021.¹⁴ Additionally, CMS will require hospitals to post online payer-specific negotiated charges for certain “shoppable” services (i.e., non-urgent health care services that consumers can schedule in advance).¹⁵ CMS has not proposed to delay this policy. Hospitals that fail to comply with these requirements could be fined up to \$300 per day.¹⁶
 - **No change in policy.**

Other Payment Proposals

- **The Proposed Rule would maintain payment for non-340B outpatient drugs at ASP + 6%.¹⁷** Payment for separately payable drugs and biologicals remains stable at ASP + 6%. This payment rate is generally subject to sequestration, resulting in payment of ASP + 4.3%. The application of sequestration is temporarily suspended through December 31, 2020 due to COVID-19.¹⁸
 - **No change in policy.**
- **CMS proposes to continue to pay WAC + 3% for new, non-340B drugs for which ASP data are not yet available.** In the CY 2019 Final Rule, CMS reduced payments from WAC + 6% to WAC + 3% for non-340B drugs during the first quarter of sales when ASP is unavailable. CMS proposes to maintain this payment reduction in CY 2021.¹⁹
 - **No change in policy.**
- **The Proposed Rule would increase payment rates by 2.6% in CY 2021 for hospitals paid under OPSS.** This increase reflects a hospital market basket increase of 3.0%, minus a 0.4 percentage point adjustment for multi-factor productivity.²⁰
 - Note that hospitals that do not meet the reporting requirements under the Medicare Hospital Outpatient Quality Reporting program would incur a 2% reduction to their annual OPSS update factor.²¹
- **The packaging threshold would be maintained at its current rate of \$130 for CY 2021.²²** If finalized, drugs and biologicals with a per-day cost of less than or equal to \$130 would be packaged with the service or procedure with which they are associated.²³
 - **No change in policy.**

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Commenting on the Proposed Rule

Interested stakeholders can submit comments electronically by visiting [regulations.gov](https://www.regulations.gov). Alternatively, comments can be submitted by mail to the following addresses:

Regular Mail

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-1850

Express or Overnight Mail

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Commenters must refer to file code CMS-1736-P when commenting on the Proposed Rule. The deadline for submitting comments is 5:00 p.m. ET on October 5, 2020.

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Glossary

Key Term	Definition
HCPCS	The Healthcare Common Procedure Coding System (HCPCS) is a set of health care procedure codes used by health care providers to describe the specific items and services provided. ²⁴
APC	The ambulatory payment classification (APC) is the OPSS unit of payment in most cases. CMS assigns individual services (HCPCS codes) to APCs based on similar clinical characteristics and similar costs. The APC payment rate and calculated copayment apply to each service within the APC. ²⁵
340B	The 340B drug discount program allows certain health care providers to pay less for covered outpatient drugs. Under 340B, certain safety net health care providers can obtain discounted prices on covered outpatient drugs from drug manufacturers. Drug manufacturers are required to provide discounts on covered outpatient drugs as a condition of their drugs being covered by Medicaid. ²⁶
ASP	Average Sales Price (ASP) reflects the weighted average of sales prices to all purchasers, excluding nominal sales to certain entities and sales exempt from the calculation of Medicaid best price. ASP is calculated from sales data using a CMS formula and includes most discounts and rebates. ²⁷
WAC	Wholesale Acquisition Cost (WAC) is the manufacturer's published "list price" for a drug to wholesalers or direct purchasers. WAC is reported in wholesale price guides or other publications of drug pricing data. It does not include discounts or rebates. ²⁸
Biosimilar	A biosimilar (also known as a follow-on biologic) is a biological product that is highly similar to another biological product already licensed by FDA (known as the reference product). ²⁹
Sequestration	Sequestration is an automatic reduction in federal spending (generally by a uniform percentage) across all non-exempted federal programs. ³⁰

¹ CMS, 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; and Physician-Owned Hospitals, Proposed Rule, 85 Fed. Reg. 48,772 (Aug. 12, 2020) *available at* <https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf> [hereinafter "OPPS Proposed Rule"].

² *Id.* at 49,043.

³ *Id.* at 48,837.

⁴ *Id.*

⁵ *Id.*

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⁶ CMS, Process and Information Required for a New Technology Ambulatory Payment Classification (APC) Assignment Under the Hospital Outpatient Prospective Payment System (OPPS) at 4, *available at* <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/newtechapc.pdf>.

⁷ OPPS Proposed Rule at 48,889.

⁸ *Id.* at 48,889–90.

⁹ *Id.* at 48,885–86.

¹⁰ *Id.* at 48,882.

¹¹ CMS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59,216, 59,351 (Dec. 14, 2017), *available at* <https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf>.

¹² OPPS Proposed Rule at 48,881–82.

¹³ *Id.* at 48,881.

¹⁴ CMS, Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524, 65,560 (Nov. 27, 2019), *available at* <https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf>.

¹⁵ *Id.* at 65,575–76.

¹⁶ *Id.* at 65,590.

¹⁷ OPPS Proposed Rule at 48,880.

¹⁸ Coronavirus Aid, Relief, and Economic Security (CARES) Act, § 3709, <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf>.

¹⁹ OPPS Proposed Rule at 48,880.

²⁰ *Id.* at 49,045.

²¹ *Id.* at 48,801.

²² *Id.* at 48,877.

²³ *See id.*

²⁴ CMS, HCPCS – General Information, HCPCS Background Information, <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html> (last accessed Aug. 12, 2020).

²⁵ CMS, Medicare Learning Network: Hospital Outpatient Prospective Payment System at 5 (Mar. 2020), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HospitalOutpaysysfctsh.pdf> (last accessed Aug. 12, 2020).

²⁶ Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Overview of the 340B Drug Pricing Program at vii (May 2015), <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0> (last accessed Aug. 10, 2020); 42 U.S.C. §§ 256b, 1396r-8.

²⁷ 42 U.S.C. § 1395w-3a(b)(4)(A), (b)(6), (c)(1)–(3); *see also* MedPAC, Part B Drugs Payment Systems at 2 (Oct. 2017), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0 (last accessed Aug. 10, 2020).

²⁸ 42 U.S.C. § 1395w-3a(c)(6)(B).

²⁹ Food and Drug Administration, Biosimilar and Interchangeable Products (Oct. 2017), <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products> (last accessed Aug. 10, 2020).

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³⁰ Congressional Research Service, Medicare and Budget Sequestration at 1 (Feb. 16, 2018), https://www.everycrsreport.com/files/20180216_R45106_fd97ee14ac3cccb6634abb9616e6f899f9d816a4.pdf (last accessed Aug. 10, 2020).

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