Executive Summary

1. Certain hospitals are eligible for and participate in the 340B Drug Pricing Program, which is administered by HRSA and allows entities to purchase outpatient drugs at a discount – approximately 34%, on average\(^1\).

2. Beginning in CY 2018\(^2\), CMS has reduced payment to hospitals for separately payable drugs purchased under the 340B Program by 28.5% to lower beneficiary copay and improve Medicare program’s efficiency and equity.
   - Estimated $1.6B in reduced drug payments were reallocated to increase OPPS payment rates by 3.2% to all hospitals for non-drug items and services.

Key Findings from the analysis estimating the impact of reverting back to the CY 2017 OPPS payment policy:

- Beneficiary cost-sharing for separately payable drugs at 340B OPPS hospitals would increase by $472.8 million.
- 82% of all OPPS hospitals would see net total payment decreases:
  - 89% of rural hospitals and 80% of urban hospitals
  - 49% of 340B hospitals

HRSA: Health Resources and Services Administration; CMS: Centers for Medicare & Medicaid Services; OPPS: Outpatient Prospective Payment System;

1. MedPAC’s Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3
2. CMS. "Calendar Year 2018 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule." November 2017
Background on OPPS Payment Adjustment
HRSA and CMS Operate Different Programs, with Different Purposes

1. HRSA operates the 340B Program which allows certain qualifying hospitals and other entity types to purchase outpatient drugs from manufacturers at a discount
   - As reported in MedPAC’s March 2016 Report to Congress, OIG estimated the average 340B discount to be approximately 34%¹
   - According to HRSA, 340B discounts range from 25% to 50% of the cost of the drugs²

2. CMS uses the outpatient prospective payment system (OPPS) to reimburse for Medicare-covered outpatient hospital services and pay separately for certain drugs that are administered during an outpatient hospital visit.

3. OPPS payment change to the Medicare reimbursement rate for drugs purchased under the 340B Program does not impact the discount amount that hospitals receive from manufacturers.

HRSA: Health Resources and Services Administration; CMS: Centers for Medicare & Medicaid Services; MedPAC: Medicare Payment Advisory Commission; OIG: Office of Inspector General
1. MedPAC’s Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3,
2. GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, January 2020
The OPPS Rule Reduces Cost-Sharing and Medicare Payments for Part B Drugs Purchased Under 340B

- The CY 2018 OPPS final rule and subsequent annual rules, including the finalized CY 2021 rule, adjust Part B payments to all separately payable, non-pass-through Part B drugs (excluding vaccines) purchased through the 340B Program.

- CMS cited patient copayments, increased number of 340B covered entities, and rise of Part B drug prices as reasons for the payment change.

### Payment Change

<table>
<thead>
<tr>
<th>Previous</th>
<th>ASP + 6%*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current OPPS Rule</td>
<td>ASP – 22.5%*</td>
</tr>
</tbody>
</table>

28.5 Percentage Point Reduction

### Reporting Requirements

CMS established modifiers for facilities to report any separately payable drugs acquired under 340B

Initially, CMS estimated the OPPS payments for separately payable drugs, including beneficiary cost-sharing, would decrease by $1.6 billion, with a corresponding increase in payments for non-drug services by 3.19% for all hospitals.

OPPS: Outpatient Prospective Payment System; ASP: Average Sales Price; CMS: Centers for Medicare & Medicaid Services

*Avalere analysis reflects the impact of budget sequestration of 2013, which reduced the Part B drug add-on payment from ASP + 6% to ASP + 4.3% and for 340B-purchased drugs from ASP - 22.5% to ASP - 23.7%.

Of note, sequestration has been temporarily lifted due to the public health emergency.

Source: Centers for Medicare & Medicaid Services, "Calendar Year 2018 Outpatient Prospective Payment System and Ambulatory Surgical Center final rule," November 2017
Illustration of Medicare’s OPPS Payment for Separately Payable Drugs and Impact on Beneficiary Copayments

- Current OPPS payment policy involves different reimbursement rates for separately payable drugs based on whether the hospital purchases the drug under the 340B Program.

- Hospitals that participate in the 340B Program can purchase outpatient drugs at a discount – approximately 34%, on average, but the discount range varies among facilities and drugs¹.

<table>
<thead>
<tr>
<th>340B Hospital Drug Purchase Price</th>
<th>Medicare Payment to 340B Hospitals for Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASP  $1,000.00</td>
<td>$155.00</td>
</tr>
<tr>
<td>340B Discount Price  $660.00</td>
<td>$607.60</td>
</tr>
<tr>
<td>Non-340B Discount Price</td>
<td>$831.04</td>
</tr>
</tbody>
</table>

340B Drug = ASP - 22.5%  Non-340B Drug = ASP + 6%

---

Reversing 340B payment policy would increase beneficiary cost-sharing by 37% for 340B drugs.

ASP: Average Sales Price

Note: Example is illustrative only. 340B discount price reflects 34% of the ASP. The ASP-based payment is split to reflect the beneficiary paying 20% and Medicare paying 80% of drug cost. Medicare payment is adjusted to represent a 2% reduction due to the sequester (currently suspended due to public health emergency). Beneficiary coinsurance is not impacted by the sequester. The amounts shown only reflect payments for a drug and do not account for premiums or other payments.

1. MedPAC’s Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3
Net Impact of the OPPS Policy Reversal
Overall Analytic Approach

To better understand the overall impact associated with a reversal of the current OPPS payment policy, Avalere modeled changes to Part B drug and services spending.

**In this analysis, Avalere:**


- Projected 2021 Part B payments for drugs and services under the current policy, using CMS’ total payment estimates from the CY 2021 OPPS rule impact file*.

- Simulated payment changes for drugs and services under the policy reversal and return to the ASP + 6.0% methodology for 340B drugs**.

- Estimated net impact on total OPPS payments.

- Stratified data and results to demonstrate impact on specific subsets of hospitals.

Note: See Appendix for full description of methodology.

* CY2021 OPPS Final Rule Impact File

**The budget sequestration of 2013 reduced the Part B add-on payment to 4.3%; the sequester also further reduced the 340B drug payment rate from -22.5% to -23.7%. Of note, Avalere did not model the temporarily suspension of the sequestration due to the public health emergency.**
Nearly 90% of Rural OPPS Hospitals Would See Decrease in Net Payments Under OPPS Payment Policy Reversal

Approximately 82% of all OPPS hospitals would see a reduction in net payments as a result of a 340B drug payment policy reversal

1 All rural sole community and essential access hospitals would see a reduction in net OPPS payments as a result of reversing the policy.

83% of rural OPPS hospitals in the analysis are not subject to 340B drug payment cut and they have benefited from the OPPS redistribution effects resulting from the increase in base payment rates for non-drug items and services.

### Impact of the OPPS Payment Change on All Hospitals, Stratified by Rural vs. Urban

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Total Hospitals</th>
<th>Number of Hospitals Estimated to See Decrease in Net Payment</th>
<th>Percentage of Hospitals Estimated to See Decrease in Net Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural</td>
<td>725</td>
<td>644</td>
<td>88.8%</td>
</tr>
<tr>
<td>Sole community and essential access</td>
<td>427</td>
<td>427</td>
<td>100.0%</td>
</tr>
<tr>
<td>Urban</td>
<td>2,729</td>
<td>2,184</td>
<td>80.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,454</strong></td>
<td><strong>2,828</strong></td>
<td><strong>81.9%</strong></td>
</tr>
</tbody>
</table>
Under a Policy Reversal, Half of 340B Hospitals Would See a Net Payment Decrease in Total OPPS Payments

77% of rural OPPS 340B hospitals would see a net decrease in total OPPS payments

<p>| Impact of the OPPS Payment Change on 340B Hospitals*, Stratified by Rural vs. Urban |
|--------------------------------|------------------------|-------------------------|------------------------|</p>
<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Total Hospitals</th>
<th>Number of Hospitals Estimated to See Decrease in Net Payment</th>
<th>Percentage of Hospitals Estimated to See Decrease in Net Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural</td>
<td>356</td>
<td>275</td>
<td>77.2%</td>
</tr>
<tr>
<td>Urban</td>
<td>876</td>
<td>334</td>
<td>38.1%</td>
</tr>
<tr>
<td>Total</td>
<td>1,232</td>
<td>609</td>
<td>49.4%</td>
</tr>
</tbody>
</table>

- While OPPS 340B hospitals would see an increase in drug payments under a policy reversal, for 49.4% of those hospitals the corresponding budget neutrality payment reduction for all non-drug items and services outweighs the drug payment increase.
- Across all OPPS 340B hospitals in the country, the aggregate beneficiary cost-sharing amount for separately payable drugs is estimated to increase by $472.8 million under a policy reversal.

* Rural sole community hospitals and essential access hospitals have been excluded from the 340B drug payment rate reduction under OPPS and continue to be reimbursed at ASP + 6%.
Policy Reversal Could Impact Hospitals’ Ability to Serve Low-Income Patients

Uncompensated care rates are comparable at 340B and non-340B hospitals

Uncompensated Care Rate /

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Total Hospitals*</th>
<th>Weighted Average of Uncompensated Care as % of Total Operating Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>All 340B Hospitals**</td>
<td>1,231</td>
<td>4.2%</td>
</tr>
<tr>
<td>Non-340B Hospitals, Acute Care only***</td>
<td>1,757</td>
<td>4.4%</td>
</tr>
</tbody>
</table>

OPPS: Outpatient Prospective Payment System;
* Hospitals with data available for calculation of the uncompensated care metric.
** Enrolled in the 340B program as of February 2021.
*** 451 non-acute care hospitals i.e., psychiatric, rehabilitation and long-term care are not captured since they largely do not report uncompensated care costs.
Source: Avalere analysis of FY 2018 Medicare cost report data.
82% of All OPPS Hospitals Would See a Reduction in Net Total OPPS Payments

Percentage of all OPPS hospitals with decrease in net total OPPS payments in each state

Share of Hospitals with Decreased Net Total OPPS Payments

- <50%
- 50-59%
- 60-69%
- 70-79%
- 80-89%
- 90-99%
- 100%

Note: Hospitals in MD are not paid under OPPS methodology and excluded from the analysis.
89% of Rural OPPS Hospitals Would See a Reduction in Net Total OPPS Payments; 100% in 21 States

Percentage of rural OPPS hospitals with decrease in net total OPPS payments in each state

Share of Hospitals with Decreased Net Total OPPS Payments

- 0%
- 60-69%
- 70-79%
- 80-89%
- 90-99%
- 100%

Note: Hospitals in MD are not paid under OPPS methodology and excluded from the analysis. Also, there were no rural hospitals identified in DC, DE, NJ, RI, and PR, therefore the share of hospitals with decrease in payments is 0%.
Appendix
Methodology

**Part B Drug Selection:** Avalere analyzed 2019 Medicare Standard Analytical File that includes 100% of fee-for-service claims from hospital outpatient departments, the most recent data available.

- Avalere captured all drugs included in the quarterly 2019-2020 ASP Drug Pricing Files¹
- Vaccines/Numerical codes: Avalere excluded vaccines per OPPS rule

**Part B Drug Spending:** Avalere identified total Medicare reimbursement for Part B drugs (government and beneficiary portion), separating between non-340B and 340B volume as indicated on claims by non-pass-through status indicator “K” and modifiers “JG” and “TB” for the latter. Avalere projected 2019 claims-based drug reimbursement using the ~4% average change in OPPS payment rates for separately payable drugs based on Addendum B data from 2019, 2020 and 2021 rules.

**Hospital Selection:** Analysis captures 3,454 hospitals paid under OPPS and included in the final rule’s Impact File.² To prevent overstating the impact of a policy reversal, the analysis excludes 104 hospitals that did not participate in 340B in 2019 but are participating in the program as of February 2021 and meet criteria for the reduced drug payments in 2021.

Of note, the final rule’s Impact File does not include 340B-eligible children’s and free-standing cancer hospitals that receive proportional adjustments to their OPPS payment rates. Similarly, critical access hospitals and hospitals located in Maryland are eligible for 340B prices but not paid under OPPS.

**340B Participation:** Avalere assessed current (as of February 2021) hospital 340B participation using the 340B Office of Pharmacy Affairs information System.

**Total OPPS Net Payment Impact:** Avalere used the CMS-estimated hospital-level total OPPS payments for CY2021 as a baseline² to model the impact of the policy reversal that captures both the 340B drug payment increase back to ASP+6% for impacted hospitals and the reduction in annual base rate updates implemented back in 2018 for budget neutrality. For a subset of 227 hospitals that were subject to the reduced payment rate in 2019 but are no longer 340B as of February 2021, Avalere modeled their baseline 2021 drug payments to reflect ASP+6%.

¹ ASP Drug Pricing Files
² CY2021 OPPS Final Rule Impact File