September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-1695-P: Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Changes for 2019

Dear Administrator Verma:

340B Health respectfully submits these comments in response to the 340B payment policy proposals included in the Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register on July 31, 2018, setting payment rates under the outpatient prospective payment system (OPPS) for calendar year (CY) 2019.[1] 340B Health represents more than 1,300 public and nonprofit hospitals that participate in the federal 340B drug pricing program. Our membership spans a broad spectrum of hospitals including academic medical centers, community hospitals, children's hospitals and rural facilities. Congress enacted the 340B program to provide resources to hospitals serving high volumes of low-income and rural patients to enable those safety-net hospitals to provide more comprehensive services and treat more patients.[2]

The Proposed Rule would continue the nearly 30 percent payment reduction to certain 340B hospitals that was finalized by the Centers for Medicare and Medicaid Services (CMS) as part of the final rule setting OPPS payment rates for CY 2018. The Proposed Rule would also extend the payment reduction to 340B drugs provided in non-excepted off-campus hospital outpatient departments (HOPDs). **340B Health strongly opposes CMS's proposed continuation of the payment cuts in 2019 and its proposal to extend the payment cuts to non-excepted HOPDs.**

Since the 340B payment reduction took effect on January 1, hospitals have reported that the reduced payments affect their ability to treat low-income patients. The findings of a recent survey of 340B Health members indicate that the 340B payment policy has harmed hospitals' ability to treat patients and that 340B hospitals have significant concerns regarding CMS's proposals to continue and extend the payment cuts. Hospitals reported the following:

- **The payment reduction has limited hospitals' ability to provide services to low-income patients in a number of ways. The most common responses were reducing clinical and other patient services (72 percent) and reducing staff (61 percent). Other impacts on patient care include:**
    - **Reduced uncompensated care levels**
    - **Fewer free/discounted drugs for patients**
    - **Fewer discounts on patient copayments**
    - **One or more clinics closed**
    - **One or more outpatient pharmacies closed**

- **100 percent of hospitals reported that they are concerned by the proposal to continue the payment reduction, with 95 percent of hospitals reporting that they are very concerned**

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[1] See Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 37046 (July 31, 2018) (CMS-1695-P).
[2] Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106, Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b; see also H Rpt. No. 102-384, Part II, Pg. 12, 102nd Congress, Second Session.

- **94 percent of hospitals reported that they are concerned by the proposal to extend the payment reduction to non-excepted HOPDs, with 79 percent of hospitals reporting that they are very concerned**

340B Health opposes CMS's 340B payment proposals for the following reasons, which we explain in more detail below.

1. Reducing payment to 340B hospitals harms hospitals' ability to treat low-income patients and proposals to continue and expand the cuts would worsen the impact

2. CMS's payment reduction does not reduce patient costs, Medicare spending, or address skyrocketing drug prices

3. CMS's payment reduction violates the 340B statute

4. CMS's payment reduction violates the Medicare statute

5. CMS's payment reduction relies on a faulty premise that fails to recognize that 340B hospitals serve patients with more expensive medical needs

I. CMS's 340B payment reduction harms hospitals' ability to treat low-income patients, and proposals to continue and expand the cuts would worsen the impact

a. 340B hospitals treat high volumes of low-income patients, and CMS's 340B payment reduction harms hospitals' ability to treat these populations

340B hospitals have a documented record of providing high levels of care to low-income individuals, and hospitals report that CMS's payment reduction to 340B hospitals affects their ability to treat low-income patients. CMS's proposal to continue and expand the cuts would further harm care for low-income patients.

Although 340B disproportionate share (DSH) hospitals represent 38 percent of hospitals, they provide 60 percent of all uncompensated care.[3] 340B DSH hospitals provide the vast majority of services received by Medicaid and low-income Medicare patients and are much more likely than non-340B hospitals to provide critical health care services that are vital to low-income patients, but are often unreimbursed, including HIV/AIDS services, trauma care, and outpatient alcohol/drug abuse services.[4] 340B DSH hospitals treat significantly more Medicare Part B beneficiaries who are low-income cancer patients, and are more likely than non-340B hospitals to treat beneficiaries who are dually eligible for Medicaid, disabled, have end stage renal disease, or are racial or ethnic minorities.[5]

Despite the financial benefit that 340B DSH hospitals receive from participating in the 340B program, 340B DSH hospitals are more financially vulnerable than non-340B hospitals, and CMS's 340B payment policy further reduces the already limited financial resources available to 340B hospitals. The Government Accountability Office (GAO) recently found that the median 340B DSH hospital has a 31 percent lower total facility margin than non-340B DSH hospitals, and 340B DSH hospitals are more reliant on Medicaid patients as a share of their total patient revenues compared to non-340B hospitals.[6] In addition, 340B DSH hospitals'

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[3] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients (March 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf
[4] *Id.*
[5] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services to Low-Income Patients (March 12, 2018), https://www.340bhealth.org/files/LowIncomeOncology.pdf; Dobson DaVanzo, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices (November 15, 2016), https://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf
[6] Government Accountability Office, Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program (June 2018), https://www.gao.gov/assets/700/692587.pdf

outpatient Medicare margins are 22 percent and 21 percent less than those of non-340B DSH hospitals and other non-340B hospitals, respectively.[7]

Hospitals have reported that the loss in payment since January 1, 2018 limits their ability to serve their low-income populations. In a recent 340B Health survey, hospitals' most common responses were that the cuts were reducing clinical and other patient services (72 percent) and reducing staff (61 percent). Hospital respondents also reported having to reduce uncompensated care, pharmacy and non-pharmacy services, the number of free/discounted drugs, and discounts on patient copayments. Other examples included closing clinics and outpatient pharmacies. One-hundred percent of hospitals reported that they are concerned by CMS's proposal to continue the payment cuts, with 95 percent reporting that they are very concerned. Ninety-four percent of hospitals reported that they are concerned by the proposal to extend the payment cuts to non-excepted HOPDs, with 79 percent reporting that they are very concerned.

St. Mary-Corwin Hospital in Pueblo, Colorado, reported that the 340B payment reduction has resulted in a nearly $1,000,000 loss and contributed to the hospital having to drastically reduce patient care services, including closing its surgical unit and reducing its intensive care unit. The hospital, which was operating on already narrow financial margins prior to the 340B payment reduction, has also had to significantly reduce staff, eliminating 300 jobs to remain financially viable after the payment cuts.

Reduced reimbursement, coupled with increasing costs for Part B drugs, have prevented Clifton Springs Hospital in Clifton, New York from filling pharmacy staff positions that would assist patients with medication reconciliation.

Creating yet another obstacle for 340B hospitals and their ability to treat patients, CMS's payment reduction has prompted other payers to reduce payment to 340B hospitals and require hospitals to bill for 340B-acquired drugs using the "JG" and/or "TB" modifiers. Nearly half of hospital respondents to 340B Health's survey reported that other payers, such as Medicare Advantage plans, have imposed or proposed to implement payment cuts similar to CMS's payment reduction, with the median hospital indicating a loss of an additional 11-to-20 percent of 340B savings as a result. Hospitals facing these further payment reductions will face additional challenges meeting the needs of their low-income patients.

b. CMS data confirms that CMS's 340B payment reduction harms hospitals that treat high volumes of low-income patients

CMS's own data confirms that the 340B payment reduction reduces overall reimbursement to hospitals treating high volumes of low-income patients. In its rule finalizing OPPS payment rates for CY 2018, CMS estimated that hospitals with higher DSH patient percentages, which reflect higher levels of care to Medicaid and low-income Medicare patients, are most impacted by the 340B payment reduction.[8] More specifically, CMS estimated that the 340B payment reduction combined with the payment increase to all hospitals paid under the OPPS for non-drug items and services would result in a 3.2 percent payment increase for hospitals that do not qualify for 340B due to having a DSH patient percentage of 0, whereas hospitals with a DSH patient percentage of 35 percent or greater, a category which includes a majority of 340B DSH hospitals, were estimated to see a 2.2 percent decrease in payment.[9] Thus, the 340B payment reduction actually increases payments to hospitals that see *fewer* Medicaid patients. CMS also estimated that non-profit and government hospitals, which include many 340B hospitals, would realize overall payment decreases.[10] These statistics run counter to the fundamental purpose of the 340B program, which is to support providers that meet 340B's rigorous standards of providing significant care to Medicaid and low-income Medicare populations.

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[7] Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf. The GAO found that 340B DSH hospitals, non-340B DSH hospitals, and other non-340B hospitals have outpatient Medicare margins of -10.0%, -8.2%, and -8.3%, respectively. In order to express the differences between these figures as percentages, we performed the following math: Non-340B DSH vs. 340B DSH = (-8.2 – (-10))/8,2 = 22.%
Other Non-340B Hospitals vs. 340B DSH = (-8.3 – (-10))/8.3 = 21%.

[8] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52356, 52628 (November 13, 2017).

[9] *Id.*

[10] *Id*.

c. Researchers have noted that CMS's 340B payment reduction will likely negatively impact 340B hospitals and their ability to serve their low-income patients

Researchers and analysts have also recognized the negative impact of CMS's payment reduction on 340B hospitals' ability to care for low-income patients. S&P Global Ratings noted the significance of the 340B program as a "critical resource for many hospitals that serve the most vulnerable patients" and cautioned that CMS's payment reduction to 340B hospitals "will likely weaken 340B hospitals' operating performance at a time of already tightening margins."[11] Moody's Investors Services describes CMS's payment reduction as a challenge for 340B hospitals that are already grappling with narrow operating margins.[12] Researchers with the Pew Charitable Trusts have noted that 340B hospitals provide greater levels of uncompensated care than non-340B hospitals and that reductions in 340B savings, such as from the Medicare payment cuts, would likely affect the ability of 340B hospitals to provide uncompensated care and would reduce 340B hospital margins, which are already lower than non-340B hospital margins.[13]

d. Congress has expressed bipartisan concern that CMS's 340B payment reduction will harm low-income patients

Congress has also expressed concern to CMS about the payment reduction's impact on 340B providers' ability to serve their patients. In 2017, more than half of the House of Representatives—228 Members—wrote to Administrator Verma urging CMS to abandon its proposal to reduce payments to 340B hospitals out of concern that the 340B payment reduction "will directly limit the ability of hospitals to offer necessary services to vulnerable patients and their communities, especially low-income individuals and rural communities."[14] Fifty-seven Senators wrote to CMS Administrator Verma and the then-Acting Secretary of the U.S. Department of Health and Human Services (HHS), noting that hospitals in their states had raised significant concerns that CMS's proposal to reduce OPPS payments to 340B hospitals would strain already scarce resources. The Senators urged CMS to "ensure that reimbursement for 340B providers enables them to continue serving the most vulnerable."[15] Based on the results of the 340B Health survey and CMS's own data, the Medicare Part B payment reduction falls far short of the Senators' goals.

e. CMS's 340B payment reduction has created additional operational costs for 340B hospitals that reduce resources even more and further harm their ability to treat their low-income patients

On top of the payment reduction, 340B hospitals must also expend resources to comply with CMS's modifier requirements for billing 340B drugs under the OPPS, reducing the level of resources they have available to treat their low-income patients. For example, a hospital in North Carolina reported that it has spent significant amounts of money to determine compliant processes for billing 340B drugs under the OPPS using the modifiers. Intermountain Healthcare, a health system in Utah, estimated that to date, staff has expended nearly 150 hours implementing the modifier requirements and ensuring compliance. Another health system reported expending approximately 250 hours on implementation and compliance. Hospitals are also reporting having to expend resources to review Medicare Advantage contracts to determine whether they include reimbursement decreases and/or modifier requirements for 340B drugs. These additional operational costs for 340B hospitals strain their already scarce resources and further limit their ability to treat low-income patients.

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[11] S&P Global Ratings, Cuts to the 340B Drug Pricing Program May Render U.S. Hospitals Serving Vulnerable Patient Groups Vulnerable Themselves, (May 29, 2018), https://www.politico.com/f/?id=00000163-b12d-d9d9-a767-f9bffb540002

[12] *See* Healthcare Finance, Moody's: CMS Proposed Changes to Medicare's Outpatient Prospective Payment System Could Hurt Hospitals, (August 13, 2018),https://www.healthcarefinancenews.com/news/moodys-cms-proposed-changes-medicares-outpatient-prospective-payment-system-could-hurt; *see also* Becker's Hospital CFO Report, Moody's: Margin Contraction Puts Nonprofit Hospitals on Unsustainable Path, (August 29, 2018), https://www.beckershospitalreview.com/finance/moody-s-margin-contraction-puts-nonprofit-hospitals-on-unsustainable-path.html

[13] *See* The Journal of American Medical Association, Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenues, (August 2018), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2681652.

[14] United States Congress Letter to Administrator Verma, September 27, 2017, https://mikethompson.house.gov/sites/mikethompson.house.gov/files/340B%20Letter%20FINAL%20Signed.pdf

[15] United States Senate Letter to Acting Secretary Wright and Administrator Verma, October 6, 2017, https://www.340bhealth.org/files/2017.10.06_FY18_OPPS_Proposed_Rule_on_340B_FINAL_SIGNATURES.pdf

II. CMS's 340B payment reduction does not reduce patient costs, Medicare spending, or skyrocketing drug prices

CMS's payment reduction to 340B hospitals does not reduce patient costs because the payment reduction is implemented in a budget neutral manner, offsetting any reduction in Medicare spending for 340B drugs by increasing payments for non-drug services. Beneficiary coinsurance amounts are a percentage of the Medicare payment for a service. Therefore, the payment policy has increased beneficiary coinsurance obligations for non-drug services, and beneficiaries do not see overall reductions in out-of-pocket costs as a result of the 340B payment reduction. Similarly, the payment cuts cannot reduce overall Medicare spending, as CMS is implementing the cuts in a way that reduces spending in one category but increases spending in another.

The 340B payment reduction also does not address the underlying cause of high drug costs, which are the high list prices for drugs set by manufacturers. Drug manufacturers set prices for pharmaceuticals based on what the market will bear.[16] Moreover, 340B discounts account for less than 2 percent of manufacturer revenues[17] and thus cannot plausibly account for the double and triple-digit price increases of many critical drugs.[18] Reducing payments to 340B hospitals does not impact drug manufacturers or how they set their list prices.

Though 340B Health supports CMS's goal of reducing drug costs for Medicare and beneficiaries, reducing payments to 340B hospitals does not achieve this goal. A majority of the House of Representatives agrees. Late last year, 228 members of the House wrote to CMS saying that CMS's assertion that reducing payment to 340B hospitals would address high drug costs for Medicare beneficiaries was "flawed" and that CMS's payment reduction "would not benefit many Medicare beneficiaries, including dually eligible Medicare beneficiaries."[19] The Members of Congress urged CMS to abandon the proposal to reduce 340B payments and to "redirect its efforts towards actions to address the cost of drugs via other policies that would not harm" hospitals or patients.[20]

The 340B payment policy only makes it more difficult for safety net providers to treat low-income patients, which could make it more difficult for patients to access needed services at 340B hospitals. We encourage CMS to withdraw the proposals to continue and extend the payment reduction and restore Part B payment levels to the pre-2018 levels mandated by law.

III. CMS's 340B Payment Reduction Violates the 340B Statute

The payment reduction that went into place on January 1, 2018, and the current proposal to expand those reductions to 340B drugs provided in non-excepted off-campus HOPDs violate the 340B statute. These reductions contravene the Congressional intent to expressly define the types of hospitals that may benefit from 340B discounts and instead transfer a portion of the 340B benefit to providers that are expressly excluded from the program. The 340B benefit is a result of access to discounted prices as well as the ability to continue being reimbursed by payers at standard rates, thereby generating a financial benefit. Congress chose to provide the 340B benefit to statutorily-defined "covered entities."[21] Among the specified covered entities are several types of hospitals that serve high volumes of Medicaid and low-income Medicare patients or are located in remote, rural areas. The 340B payment reduction reduces access to the 340B benefit for these hospitals and redistributes the dollars to all hospitals paid under the OPPS, which include hospitals that do not meet these eligibility criteria.

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[16] *See* The Journal of American Medical Association, The High Cost of Prescription Drugs in the United States, (August 2016), https://www.ncbi.nlm.nih.gov/pubmed/27552619

[17] Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers (July 2017), https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf; Coukell AJ, Dickson S. Reforming the 340B Drug Pricing Program Tradeoffs Between Hospital and Manufacturer Revenues. JAMA Intern Med. Published online May 21, 2018. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2681652

[18] *See e.g.,* HHS Office of the Inspector General, Increases in Reimbursement for Brand-Name Drugs in Part D 5, (June 4, 2018), https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf (finding that the unit costs for Medicare Part D brand-name drugs rose nearly six times faster than inflation from 2011 to 2015).

[19] United States Congress Letter to Administrator Verma, September 27, 2017, https://mikethompson.house.gov/sites/mikethompson.house.gov/files/340B%20Letter%20FINAL%20Signed.pdf

[20] *Id.*

[21] 42 U.S.C. § 256b(a)(4).

CMS's own data demonstrated this point when the agency estimated that hospitals with lower DSH patient percentages, reflecting lower levels of care to low-income patients, will see overall payment increases after the 340B payment reduction and redistribution, whereas hospitals with higher DSH patient percentages will see overall payment decreases.[22] CMS also estimated that non-profit and government hospitals, which are the types of hospitals that can qualify for the 340B program, would realize overall payment decreases because of the payment reduction. Providing a portion of the 340B benefit to hospitals that do not qualify for the 340B program is inconsistent with the 340B statute.

Further, Congress did not address the intersection of Medicare and the 340B program in the 340B statute. Congress would have addressed the interplay between these two programs in the law if it intended for Medicare to reduce payment to 340B hospitals. When Congress has intended there to be a nexus between the 340B program and other federal health care programs, it has been indisputable. For example, federal law addresses the intersection of the 340B program and the Medicaid program both in the 340B statute[23]and in the Medicaid statute.[24] To date, Congress has not affirmatively addressed an interplay between the 340B program and Medicare. If Congress intended to provide Medicare with the authority to reduce payment to 340B hospitals, it would have done so expressly through the 340B statute or elsewhere in federal law.

IV. CMS's Proposal to Extend the 340B Payment Reduction to Non-Excepted HOPDs is Inconsistent with the Medicare Statute and CMS's Policy

CMS proposes to extend the 340B payment reduction to 340B drugs administered in non-excepted off-campus HOPDs. Currently, the 340B payment reduction does not apply to 340B drugs administered in non-excepted HOPDs, because services provided in these locations are not paid under the OPPS and the payment reduction only applies under the OPPS.[25] Applying the 340B payment reduction to non-excepted HOPDs would be inconsistent with the Medicare statute and CMS policy.

The site neutrality provisions included in Section 603 of the Bipartisan Budget Act of 2015 amended the Medicare statute to exclude items and services furnished by new off-campus HOPDs from payment under the OPPS.[26] Section 603 requires Medicare to pay for items and services furnished by non-excepted HOPDs under the "applicable payment system" under Medicare Part B.[27] CMS has defined the applicable payment system as the Medicare physician fee schedule (MPFS).[28] The MPFS pays physicians for separately payable drugs at ASP + 6 percent.[29] Therefore, CMS must pay for 340B drugs administered in non-excepted HOPDs at ASP + 6 percent. CMS's proposal to pay for 340B drugs administered in non-excepted HOPDs at ASP – 22.5 percent is inconsistent with this statutory obligation and CMS's application of Section 603.

CMS recognized this point in prior rulemaking. In its implementation of Section 603, CMS applied a relativity adjuster to reduce the payment that would otherwise be made under the OPPS for services provided in non-excepted HOPDs to be in line with MPFS payment rates.[30] At the same time, CMS noted it was not applying a relativity adjuster to separately paid drugs, because those drugs are paid the same rate whether under the OPPS or the MPFS.[31] CMS stated it would reimburse hospitals for separately payable drugs administered in non-excepted HOPDs at ASP + 6 percent, "consistent with payment rules in the physician office setting."[32] CMS's

[22] 82 Fed. Reg. at 52628.
[23] 42 U.S.C. § 256b(a)(5)(A).
[24] 42 U.S.C. § 1396r-8(a)(5); 42 U.S.C. § 1396r-8(j)(B).
[25] 83 Fed. Reg. at 37145.
[26] Pub. L. No. 114-74 § 603, Bipartisan Budget Act of 2015; 42 U.S. Code § 1395l(t)(1)(B)(v). Note that new off-campus HOPDs that are no longer paid under the OPPS are generally referred to as "non-excepted HOPDs."
[27] 42 U.S. Code § 1395l(t)(21)(C) (noting that the "applicable payment system" is not under subsection (t), Prospective Payment System For Hospital Outpatient Department Services).
[28] Final Rule, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79562, 79699-79719 (Nov. 14, 2016).
[29] 42 U.S. Code § 1395u(o).
[30] 81 Fed. Reg. at 79723.
[31] *Id.*
[32] *Id*. at 79725.

proposal to extend the 340B payment reduction to 340B drugs in non-excepted HOPDs is therefore inconsistent with CMS's prior rulemaking.

In addition, CMS does not cite legal authority that would allow CMS to pay under the MPFS for 340B drugs administered in non-excepted HOPDs at a rate other than ASP + 6 percent. For the authority to reduce payment to 340B hospitals under the OPPS, CMS cites a provision in the Medicare statute that addresses Medicare payment under the OPPS.[33] We continue to believe that this provision does not give CMS the authority to pay for 340B drugs at ASP – 22.5 percent. Nevertheless, even if this provision authorizes CMS's payment reduction under the OPPS, it only applies under the OPPS and does not support CMS's proposal to adjust payment under the MPFS. For the reasons outlined above, CMS lacks the authority to extend the 340B payment reduction to 340B drugs administered in non-excepted HOPDs, and its proposal to do so is inconsistent with the Medicare statute and CMS policy.

CMS's proposal is also inconsistent with Congressional intent. Congress intended for Section 603 to equalize payment between hospital and non-hospital settings. CMS agreed in prior rulemaking, noting that for its payment policy to be in accordance with the Congressional intent behind Section 603, CMS policy "should ultimately equalize payment rates between nonexcepted off-campus PBDs and physician offices to the greatest extent possible…."[34] Yet, CMS is proposing to pay hospitals for 340B drugs administered in non-excepted HOPDs at a rate that is lower than what physicians receive for the same drugs, inconsistent with Congress's intentions.

V. CMS's 340B Payment Reduction Relies on a Faulty Premise That Fails to Recognize That 340B DSH Hospitals Serve Patients with More Expensive Medical Needs

340B Health is concerned that, in support of policies reducing payment to 340B hospitals, CMS continues to rely on the faulty premise put forth in a 2015 GAO report that 340B DSH hospitals may be using more drugs or more expensive drugs than necessary.[35] In its discussion of its proposal to continue and extend the 340B payment cuts in 2019, CMS references the 2018 OPPS final rule, which finalized the 340B payment reduction for 2018. The 2018 OPPS final rule referenced the GAO report as a basis for reducing reimbursement to 340B hospitals. CMS stated that the payment reduction will address unnecessary drug utilization in 340B hospitals and cited to the 2015 GAO report, which found that per beneficiary Part B drug spending was more than twice as high at 340B DSH hospitals than at non-340B hospitals.[36] As we expressed in our comments in response to CMS's proposal to set payment rates under the OPPS for CY 2018, 340B Health has significant concerns regarding the GAO report and we urge CMS not to rely on the report's conclusions in support of policies that reduce payment to 340B hospitals for the reasons outlined below.

A 2017 report by Dobson DaVanzo and Associates demonstrates that 340B DSH hospitals incur higher spending than non-340B hospitals because their patients are more expensive to treat – not because of inappropriate drug use, as stated by the GAO.[37] Dobson DaVanzo found that 340B DSH hospitals share facility characteristics that are associated with higher drug spending and that compared to non-340B hospitals, 340B DSH hospitals treat more Medicare beneficiaries who are dually eligible for Medicaid, disabled, have end stage renal disease, or are a racial or ethnic minority. These beneficiaries are often in poorer health than other patients and more expensive to treat.[38]

Additional research shows that patient characteristics like these should be taken into account when evaluating drug spending patterns in Medicare.[39] Although GAO attempted to evaluate whether spending differences were

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[33] 42 U.S. Code § 1395l(t)(14)(A)(iii)(II).
[34] 81 Fed. Reg. at 79728.
[35] GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating 340B Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf
[36] 82 Fed. Reg. at 52624.
[37] Dobson DaVanzo, Financial Challenges Faced by 340B Disproportionate Share Hospitals in Treating Low-Income Patients, (August 4, 2017), https://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf
[38] Kaiser Family Foundation, Medicaid's Role for Dual Eligible Beneficiaries, (August, 2013), https://kaiserfamilyfoundation.files.wordpress.com/2013/08/7846-04-medicaids-role-for-dual-eligible-beneficiaries.pdf
[39] The American Journal of Managed Care, Differences in Spending on Provider-Administered Chemotherapy by Site of Care in Medicare, (July 19, 2018), https://www.ajmc.com/journals/issue/2018/2018-vol24-n7/differences-in-spending-on-provideradministered-chemotherapy-by-site-of-care-in-medicare

due to patient health status using the CMS-Hierarchical Condition Categories (HCC) model, this model is not appropriate for making that determination with respect solely to drug spending and has been criticized for not accurately capturing cancer patients' health status and for under-predicting expenditures.[40]

Second, the GAO's finding related to use of drugs by 340B hospitals was not dispositive and there are other reasons why spending may be higher in 340B hospitals that do not suggest inappropriate prescribing behavior. In fact, HHS noted that the GAO study was a "useful initial analysis" but characterized the report's finding as "not supported by the study methodology."[41] HHS further commented that drug spending may be higher in 340B DSH hospitals because "a higher volume of physician-administered drugs could lead to better clinical outcomes."[42] Indeed, the vast majority of the National Cancer Institute (NCI)-designated comprehensive cancer centers in the country are associated with 340B hospitals,[43] and a patient's receipt of care in an NCI-designated comprehensive cancer center has been correlated with a 37 percent decrease in the likelihood that the patient will die within 30 days of admission.[44]

340B Health reiterates that CMS should not base the payment reduction to 340B hospitals on the GAO's report when other researchers have concluded that 340B DSH hospitals incur higher drug spending because their patients are sicker and more costly to treat.

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340B Health respectfully requests that CMS withdraw its proposal to continue the 340B payment cuts in 2019 and its proposal to extend the payment cuts to non-excepted HOPDs, and instead restore the payment policy in place prior to January 1, 2018. Reducing payment to 340B hospitals harms hospitals' ability to treat low-income patients without reducing patient costs, Medicare spending, or drug prices, and proposals to continue and expand the cuts would worsen the impact. Moreover, CMS's payment reduction violates both the 340B and Medicare statutes. Thank you for the opportunity to comment on the Proposed Rule.

Sincerely,

Maureen Testoni
Interim President and CEO

Amanda Nagrotsky
Legal Counsel

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[40] *See* MedPAC, June 2014 Report to Congress, Improving Risk Adjustment in the Medicare program, http://medpac.gov/docs/default-source/reports/jun14_ch02.pdf?sfvrsn=0 (noting that the CMS-HCC model substantially over-predicts the cost of the least costly beneficiaries and under-predicts the cost of the most costly beneficiaries); *see also* Letter from Healthcare Quality & Payment Reform to Administrator Tavenner, (CMS) (August 26, 2014), http://www.chqpr.org/downloads/CHQPRComments_CMS-1612-P_PhysicianPaymentPoliciesfor2015.pdf (noting that the CMS HCC risk adjustment model does not account for the patient's stage of cancer which significantly impacts the oncologist's treatment method and explaining that as a result, "what appears to be higher-than average risk-adjusted spending for a provider may actually be caused by having sicker patients who are not accurately classified in the risk adjustment system.").

[41] GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating 340B Hospitals (June 2015), https://www.gao.gov/assets/680/670676.pdf.

[42] *Id.* at 38.

[43] NCI-Designated Cancer Centers, https://www.cancer.gov/research/nci-role/cancer-centers; OPA Covered Entity Database, https://opanet.hrsa.gov/340B/Views/CoveredEntity/CESearch.

[44] Friese CR, Silber JH, and Aiken LH, National Cancer Institute Cancer Center Designation and 30-day Mortality for Hospitalized, Immunocompromised Cancer Patients, Cancer investigation 28(7):751-757 (2010).