



September 11, 2017

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-1678-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs**

Dear Ms. Verma:

340B Health respectfully submits these comments in response to the Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register on July 20, 2017, setting payment rates under the outpatient prospective payment system (OPPS) for calendar year (CY) 2018.<sup>1</sup> 340B Health represents more than 1,300 public and private nonprofit hospitals that participate in the federal 340B drug pricing program. The Proposed Rule would reduce OPPS payments for separately payable drugs when purchased under the 340B program and provided by hospitals that participate in that program.<sup>2</sup> 340B Health urges the Centers for Medicare and Medicaid Services (CMS) to withdraw the proposal to reduce Part B drug payments to 340B hospitals and provides the following comments, which are explained in more detail below.

- 1. CMS's proposal would harm hospitals' ability to treat low-income patients without reducing patient costs or Medicare spending**
- 2. CMS's proposal would violate the 340B statute**
- 3. CMS's proposal would violate the Medicare statute**
- 4. CMS's proposal relies on a faulty premise that fails to recognize that 340B hospitals serve patients with more expensive medical needs**
- 5. CMS's proposed modifier for non-340B drugs billed under the OPPS would pose operational and financial challenges for 340B hospitals**

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<sup>1</sup> Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558 (July 20, 2017) (CMS-1678-P).

<sup>2</sup> The proposed rule would reduce payments for separately payable, non-pass-through drugs. In the interest of brevity, this comment letter refers to the drugs impacted by the proposal simply as "separately payable," by which we mean only separately payable, non-pass-through drugs.

## **I. Background on the 340B Program**

Congress enacted the 340B program in 1992 to provide resources to hospitals serving high volumes of low-income patients to enable those hospitals to provide more comprehensive services and treat more patients.<sup>3</sup> The program requires drug manufacturers to sell certain outpatient drugs at discounts to health care providers that serve low-income and other disadvantaged populations. These safety-net providers, referred to as “covered entities” in the 340B statute, use their 340B drug savings to serve more patients and provide more services at no cost to the government. The law conditions coverage of a pharmaceutical manufacturer’s drugs under Medicaid and Medicare Part B on the company’s participation in the 340B program. Most drug manufacturers that do business in the U.S. participate in the 340B program. The program is administered by the Health Resources and Services Administration (HRSA), a subcomponent of the U.S. Department of Health and Human Services (HHS).

The definition of “covered entity” includes many providers that serve the nation’s poorest or most vulnerable people. Six categories of hospitals may qualify as covered entities: disproportionate share (DSH) hospitals, children’s hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals.<sup>4</sup> Of these, DSH hospitals, rural referral centers, and sole community hospitals are paid under the OPSS and would be harmed by CMS’s proposal to reduce payments for separately payable drugs. Children’s hospitals and cancer hospitals are paid the higher of their reasonable costs or the OPSS rate, and accordingly, some children’s and cancer hospitals may be harmed by the proposal.

## **II. CMS’s Proposal Would Harm Hospitals’ Ability to Treat Low-Income Patients Without Reducing Patient Costs or Medicare Spending**

By law, the 340B program helps hospitals that treat a high percentage of Medicaid and low-income Medicare patients.<sup>5</sup> CMS’s proposal would contravene 340B’s purpose by significantly reducing the savings that hospitals currently receive through the program and, in turn, severely hamper their ability to care for low-income patients. Moreover, the proposal would harm patient care without reducing patient costs or Medicare spending.

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<sup>3</sup> Congress enacted the 340B program in November 1992. 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. The program is named for section 340B of the Public Health Service Act (“PHSA”). See H. Rpt. No. 102-384, Part II, Pg. 12, 102<sup>nd</sup> Congress, Second Session.

<sup>4</sup> Disproportionate share hospitals are defined under the Medicare program as hospitals that serve a disproportionate percentage of low-income patients. 42 U.S.C. § 1395ww(d)(5)(A). Hospitals in each of the six 340B categories must meet at least one of three conditions: (1) be owned or operated by a state or local government; (2) be a public or private non-profit corporation that is formally granted governmental powers by a state or local government; or (3) be a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. 42 U.S.C. § 256b(a)(4)(L). DSH hospitals must have a DSH percentage greater than 11.75 percent. *Id.* § 256b(a)(4)(L)(ii). There are also eleven categories of non-hospital covered entities, many of which tend to be small providers that focus on under-served patient populations. They include FQHCs; FQHC “look-alikes”; state-operated AIDS drug assistance programs; the Ryan White Comprehensive AIDS Resources Emergency Act clinics and programs; tuberculosis, black lung, family planning, and sexually transmitted disease clinics; hemophilia treatment centers; Title X public housing primary care clinics; homeless clinics; Urban Indian clinics; and Native Hawaiian health centers.

<sup>5</sup> 42 U.S.C. § 256b(a)(4)(L)(ii)-(O).

**a. 340B hospitals treat high levels of low-income patients, and CMS's proposal would harm their ability to treat these patients**

Multiple reports and national data demonstrate that the 340B program is used by hospitals that provide a high level of care to low-income patients. 340B DSH hospitals treat 64 percent more Medicaid and low-income Medicare patients than non-340B hospitals.<sup>6</sup> Although 340B DSH hospitals account for only 36 percent of all Medicare acute care hospitals, they provide nearly 60 percent of all uncompensated care.<sup>7</sup> 340B DSH hospitals are also significantly more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, including trauma centers, HIV/AIDS services, and immunizations.<sup>8</sup> Compared to non-340B providers, 340B DSH hospitals treat many more Medicare Part B beneficiaries who are low-income cancer patients, dually eligible for Medicaid, disabled, have end stage renal disease, or are racial or ethnic minorities.<sup>9</sup> Despite the benefit they receive from 340B, 340B DSH hospitals have outpatient Medicare margins that are 22 percent and 21 percent less than those of non-340B DSH hospitals and other non-340B hospitals, respectively.<sup>10</sup>

340B Health conducted a survey of 340B hospitals to evaluate the impact the proposal would have on their ability to treat their low-income patients. Hospitals unanimously reported that they are concerned about the proposed payment reduction, with 97 percent reporting that they are very concerned. The impact on hospitals would be substantial, with the median hospital reporting an estimated loss between \$1 million and \$2 million. Over two-thirds of respondents reported that the proposed rule would result in a loss of one-fifth or more of their 340B savings that pertain to outpatient areas.

Hospitals consistently reported that the loss in reimbursement would harm their ability to treat their low-income patients, with hospitals unanimously reporting that the loss in payment would affect their ability to serve their low-income and rural patients in at least one way. In particular, 86 percent of hospitals said that the proposed rule would affect their ability to provide clinical services, such as by having to close clinics or limit infusion services. A number of hospitals reported that the proposed cuts would especially affect their ability to provide infusion and oncology services to their low-income patients. One hospital noted, "The 340B program is essential for our chemo infusion services and medications for the Clinics. Without this program, hundreds will go with limited or no treatment options." Another reported that the proposed cuts may require them to close their infusion service. And another stated, "These reductions would essentially cause our oncology services to stop. The 340B program is paramount for allowing our institution to provide outpatient oncology infusion

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<sup>6</sup> Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016), [http://www.340bhealth.org/files/Update\\_Report\\_FINAL\\_11.15.16.pdf](http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017), <http://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 (Nov. 15, 2016), [http://www.340bhealth.org/files/Demographics\\_Report\\_FINAL\\_11.15.2016.pdf](http://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf).

<sup>10</sup> Government Accountability Office (GAO), Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals 20 (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 =  $(-8.3 - (-10))/8.3 = 21\%$

therapy for all patients. Additionally, the outpatient infusion center would not be able to continue caring for other disease states, such as autoimmune disorders.”

Seventy-four percent of hospitals reported an impact on their ability to provide pharmacy services, including staffing, offering discounted drugs, and operating programs such as medication therapy management. For example, one hospital reported that it “would lose the ability to provide free/reduced drug cost to under-insured patients at the time of discharge, thus patients could be sent home without the needed medications to help keep them out of the hospital. Also, pharmacy services would most likely be reduced. These services are those that focus on optimizing care within, and at the point of transition to home from the hospital. Continued care beyond discharge would also be compromised, thus, potentially resulting in higher rates of readmissions.”

More than two-thirds of respondents reported the proposed rule would affect their ability to provide uncompensated care, which would directly impact access to care for low-income and rural individuals. Nearly half of hospitals indicated that the proposal would impact quality of care and patient outcomes.

United Hospital Center, in Bridgeport, West Virginia, reported, “Reducing reimbursement of our Medicare patients would impact our ability to provide costly medications through our outpatient services to patients without or with inadequate insurance. We would be forced to reduce our services that provide care to this underserved population.”

One hospital stated, “Our system would likely eliminate or significantly cut back on the extra programs and services it offers, such as providing drugs to our community ambulance service providers, providing an anticoagulation clinic that deeply discounts Coumadin, providing a respiratory clinic that covers the out-of-pocket medication expenses for 227 patients, providing \$2.4 million in community benefit services, and \$1.3 million in charity care.”

University of Illinois Hospital and Health Sciences System in Chicago, Illinois, reported, “The proposed reduced reimbursement for separately billed Medicare Part B drugs will require us to seriously reassess our investment in programs [ ] which provide access to patients who would not otherwise be able to access the healthcare. The savings we experience from participation in the 340B program allow us to address the social and economic barriers our patients face every day and include: non-emergency medical transportation, housing support for homeless patients and medication assistance.”

Hospitals are particularly concerned that the impact of the proposed reimbursement changes on their ability to treat patients could be amplified if Medicare Advantage (MA) plans follow the lead of Medicare Part B and reduce drug reimbursement to 340B hospitals. In response to 340B Health’s survey, 81 percent of hospitals noted the impact of the proposed payment cuts would be much worse if they were adopted by MA plans, in addition to Medicare Part B. MA plans commonly use Medicare rates to set hospital reimbursement amounts.<sup>11</sup> Moreover, in some parts of the country, MA plans cover a significant share of Medicare beneficiaries, with 31 percent of beneficiaries across the country covered by MA plans, on average, in 2016, and more than 40 percent of beneficiaries covered by MA plans in at least five states.<sup>12</sup>

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<sup>11</sup> MedPAC, March 2017 Report to the Congress: Medicare Payment Policy, page 52 (March 2017).

<sup>12</sup> Kaiser Family Foundation, Medicare Advantage (May 11, 2016), <http://www.kff.org/medicare/fact-sheet/medicare-advantage/>.

**b. CMS underestimates the impact the proposal would have on hospitals' ability to treat patients and ignores government warnings about the impact of 340B cuts on hospitals**

CMS appears to have concluded that its proposal would not strip hospitals of all of their 340B savings.<sup>13</sup> However, the agency underestimates the proposal's financial impact on 340B hospitals and how it would affect their ability to treat patients.

**i. The proposal would take away nearly the entire 340B discount for many drugs**

The proposal would take away almost the entire 340B discount for many 340B drugs. Most of the drugs affected by the proposal are brand name drugs. The standard 340B ceiling price for a brand name drug is the average manufacturer price (AMP) minus 23.1%, although the price can be lower if the drug's best price is lower or if the manufacturer increases the price of the drug more quickly than the rate of inflation.<sup>14</sup> If a brand name drug's 340B ceiling price is based on the standard formula, then the proposal would strip the hospital of nearly all its 340B savings. AMP has been found to be close to ASP.<sup>15</sup> Therefore, the proposed reimbursement rate of ASP - 22.5% is nearly identical to AMP - 23.1%, leaving the hospital with virtually no 340B savings.

CMS mistakenly assumes that 340B hospitals purchase most 340B drugs at sub-ceiling prices negotiated by HRSA's Prime Vendor Program (PVP), which are lower than 340B ceiling prices.<sup>16</sup> However, hospitals that we spoke with estimate that less than 10 percent of the drugs affected by the proposal are available at a sub-ceiling price.

Taking away nearly all of hospitals' 340B savings on Part B drugs would ignore the warnings of several government watchdog agencies. The Medicare Payment and Advisory Commission (MedPAC) noted the importance of allowing hospitals to "retain a share of the funds they receive through the 340B program [to give] them an incentive to continue to participate in the program."<sup>17</sup> The HHS Office of the Inspector General (OIG) stated that paying an add-on amount above the ceiling price would incentivize hospitals to participate in 340B<sup>18</sup> and recognized that Medicare payment rates should exceed 340B drug acquisition costs.<sup>19</sup> Under CMS's proposed policy, a 340B hospital would not receive an add-on payment above the 340B acquisition cost and could choose to withdraw from the program as a result. If a hospital were to withdraw from 340B, patients would lose access to services funded by 340B savings, and neither Medicare, beneficiaries, nor other providers would benefit from the reduced payment cuts. The Medicare Advisory Panel on Hospital Outpatient Payment, which advises CMS on setting payment rates under the OPPIs, also weighed in on CMS's proposal. The panel

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<sup>13</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33633 (July 20, 2017).

<sup>14</sup> 42 U.S.C. § 256b(a)(1)-(2).

<sup>15</sup> See Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Overview of the 340B Drug Pricing Program 27 (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>. MedPAC's analysis, which CMS relied on in the proposal (82 Fed. Reg. 33634), used ASP as a proxy for AMP, explaining that "ASP is slightly lower than AMP because ASP includes all discounts and rebates, while AMP does not include prompt-pay discounts. The Office of Inspector General found that in 2011, the difference between ASP and AMP was 3 percent at the median, with ASP generally lower than AMP."

<sup>16</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33632 (July 20, 2017).

<sup>17</sup> MedPAC, June 2015 Report to Congress: Medicare and the Health Care Delivery System, page 78 (June 2015).

<sup>18</sup> OIG, OEI-12-14-00030, Part B Payments for 340B-Purchased Drugs, page 11 (Nov. 2015).

<sup>19</sup> OIG, Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System, OEI-03-09-00420 (Oct. 22, 2010). OIG examined how much Medicare Part B pays 340B hospitals for separately payable drugs and found that payment amounts exceeded acquisition costs for 340B hospitals, but this was "an expected result given the purpose of the 340B Program."

recommended that CMS not move forward with reducing payment to 340B hospitals and instead collect data from public comments and other sources on the impact that reduced payments would have on 340B hospitals.

**ii. CMS did not account for costs hospitals incur participating in 340B**

In addition to underestimating how much of a hospital's savings the proposal would take away, CMS failed to account for various costs that hospitals incur participating in the 340B program. For example, hospitals incur substantial compliance costs, such as the cost of implementing software and hiring additional staff to ensure 340B compliance. 340B program compliance costs many hospitals hundreds of thousands of dollars annually. Split-billing software, which hospitals use to manage their 340B inventory, may have an annual fee of \$120,000 or more. Personnel dedicated to 340B compliance can have salaries ranging from \$50,000 to \$300,000 or more depending upon the size and scope of the organization's 340B program. In response to 340B Health's survey, the median hospital reported that the cost of implementing and maintaining systems for compliance with the 340B program was between \$200,000 and \$300,000.

DSH hospitals and free-standing children's and cancer hospitals also incur costs to be in 340B due to the 340B statute's group purchasing organization (GPO) prohibition.<sup>20</sup> HRSA policy effectively requires these hospitals to make their initial purchase of any drug at a non-340B, non-GPO price, typically wholesale acquisition cost (WAC).<sup>21</sup> WAC prices are usually significantly higher than 340B ceiling prices. The GPO prohibition also requires hospitals to use WAC drugs for 340B-ineligible outpatients, as well as Medicaid patients (including dually eligible beneficiaries) if a hospital has decided not to use 340B drugs for Medicaid beneficiaries (i.e., "carve out"). In response to 340B Health's survey, over one-third of the hospitals subject to the GPO prohibition reported that Medicare Part B reimbursement for non-retail drugs purchased at WAC is a significant share of their total Part B drug reimbursement. Even if a hospital is not subject to the GPO prohibition, the hospital still must buy drugs for 340B-ineligible outpatients and carved-out Medicaid patients at non-340B prices that are likely higher than 340B prices.

340B hospitals can also incur costs when they bill Medicare for non-340B drugs and the reimbursement rates do not cover the costs of those drugs. CMS incorrectly assumes that all drugs billed to Medicare Part B by 340B hospitals are purchased at 340B prices.<sup>22</sup> However, hospitals report that many of the drugs they bill to Medicare are not 340B drugs. Medicare payments may not fully compensate hospitals for the acquisition costs of these drugs, particularly for drugs purchased at WAC prices, adding to the costs that 340B hospitals can incur. In response to 340B Health's survey, nearly 40 percent of hospitals reported having trouble accessing 340B pricing for separately paid Part B drugs. In addition, 30 percent of respondents that are subject to the 340B program's orphan drug exclusion indicated that reimbursement for orphan drugs was a significant share of their total Part B drug reimbursement. Because manufacturers are not required to sell orphan drugs to these hospitals at 340B prices,<sup>23</sup> this also means not all drugs billed by 340B hospitals to Part B are 340B drugs. When current Medicare reimbursement rates fail to compensate hospitals for the acquisition costs of these drugs, the hospitals incur a loss. CMS failed to account for these costs.

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<sup>20</sup> 42 U.S.C. § 256b(a)(4)(L)(iii)-(M).

<sup>21</sup> Health Resources and Services Administration, 340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation 3 (Feb. 7, 2013), <https://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.

<sup>22</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33711 (July 20, 2017).

<sup>23</sup> 42 U.S.C. § 256b(3).

**c. CMS's proposal would harm patient care without reducing costs for hospital patients, Medicare beneficiaries, or the Medicare program**

The proposed rule states that reducing payment to 340B hospitals is intended, in part, to reduce copays for Medicare beneficiaries.<sup>24</sup> Shortly after CMS issued the proposed rule, HHS issued a press statement, wherein HHS Secretary Tom Price stated that CMS's proposal would reduce drug costs to seniors by \$180 million per year.<sup>25</sup> However, CMS proposes to implement the payment reduction in a budget neutral manner, ensuring that any reduction in spending for 340B drugs would be offset by increased spending and copayments for other services.<sup>26</sup> The proposal is especially likely to increase costs for uninsured patients, since 340B hospitals provide a disproportionate amount of care to that population. Hospitals report to 340B Health that the proposed payment reduction would affect their ability to continue providing discounts to low-income patients, with more than two-thirds of respondents to 340B Health's survey reporting that the proposed rule would affect their ability to provide uncompensated care.

While CMS proposes to implement this proposal in a budget neutral manner within OPPS, it also suggests that it may decide to redistribute the funds saved through the proposal in other ways.<sup>27</sup> Any type of redistribution to non-340B hospitals would pass drug company discounts on to providers that do not have a confirmed record of providing services to low-income populations. This is true even if the funds were redistributed to hospitals that serve the uninsured, as such hospitals may not be serving a high share of Medicaid and low-income Medicare populations, key targets for the 340B program. Research shows that 340B DSH hospitals with uncompensated care (charity care and bad debt) levels below the median level of uncompensated care across all hospitals nevertheless treat more Medicaid and low-income Medicare patients than non-340B hospitals with uncompensated care levels above the median level.<sup>28</sup> Also, it is undisputed that Medicaid chronically underpays providers.

Not only would the proposal not reduce beneficiary copays, it is likely to reduce the assistance that low-income beneficiaries and other low-income patients currently receive. In response to a 340B Health survey, nearly three-quarters of the respondents indicated that they provide some form of beneficiary copay assistance for their low-income Medicare patients. However, reducing Part B drug payments to 340B hospitals will make it more difficult for hospitals to meet the needs of these patients.

In addition, CMS's proposal does nothing to address the root cause of skyrocketing Part B drug costs – the prices set by manufacturers. Between 2013 and 2015, average annual inpatient drug spending in community

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<sup>24</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33634 (July 20, 2017).

<sup>25</sup> Department of Health and Human Services (HHS) Press Release, HHS Secretary Price: Trump Administration is Taking Action on Drug Prices (July 13, 2017), <https://www.hhs.gov/about/news/2017/07/13/hhs-secretary-price-trump-administration-taking-action-drug-prices.html>. Although it is unclear from the press release, it appears that HHS came up with the \$180 million estimate by applying the standard Medicare beneficiary copayment percentage of 20% to CMS's total savings estimate of \$900 million.

<sup>26</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33711-33712 (July 20, 2017).

<sup>27</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33712 (proposed July 20, 2016).

<sup>28</sup> Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals, Nov. 15, 2016, available at [http://www.340bhealth.org/files/Update\\_Report\\_FINAL\\_11.15.16.pdf](http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf).

hospitals increased by 23.4%, with spending increasing by 38.7% on a per admission basis.<sup>29</sup> Manufacturers have increased the costs of drugs that seniors commonly rely on. For example, AbbVie Inc. raised the price of its arthritis drug Humira by more than 126% since 2011.<sup>30</sup> The price of Johnson & Johnson's arthritis drug Remicade went up almost 63% during the same time period.<sup>31</sup> New data confirm that increases in drug prices are a major factor contributing to increases in Medicare expenditures for separately payable Part B drugs.<sup>32</sup>

CMS cites to an HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) issue brief, acknowledging that higher drug prices and price increases have led to higher Part B drug spending, and also claims that growth in the 340B program has led to increased Medicare spending.<sup>33</sup> However, there is no reference to 340B in the ASPE document, and this citation does not provide evidence that 340B increases Medicare spending. Moreover, a recent report confirms that the 340B program cannot plausibly cause manufacturers to increase drug prices. In 2015, the total amount of discounts that providers received through the 340B program was \$6.1 billion, which represents just 1.3% of total net U.S. drug spending in 2015.<sup>34</sup> Additionally, manufacturers' obligations under the 340B program remain nominal and pale in comparison to manufacturer expenditures on other general industry costs such as advertising and patent expiries.<sup>35</sup>

### III. CMS's Proposal Would Violate the 340B Statute

CMS's proposal would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts. CMS's proposal would hijack Congress's carefully crafted statutory scheme by seizing 340B discounts from hospitals and transferring the funds to providers that Congress *excluded* from the 340B program. This would violate section 340B of the Public Health Service Act.

Discounts under the 340B program are only available to "covered entities."<sup>36</sup> Congress defined fifteen types of covered entities.<sup>37</sup> Congress thus intended the benefits of the program to accrue to these, and only these, providers. Among the specified covered entities are several types of hospitals, including certain "subsection (d)" hospitals defined under the Medicare statutes at 42 U.S.C. § 1395ww(d). Congress's reference to these Medicare definitions demonstrates that it considered the Medicare program when it adopted the 340B program and decided not to grant discounts to all Medicare hospitals. Rather, Congress made a deliberate decision to limit the benefits of the 340B program only to Medicare hospitals that serve large numbers of poor or other underprivileged patients.

When Congress has intended federal health care programs to intrude upon the 340B program, it has been crystal clear. Indeed, Congress has addressed the relationship between 340B and Medicaid several times. Federal law entitles state Medicaid agencies to receive a rebate from drug manufacturers on drugs provided to

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<sup>29</sup> American Hospital Association Final Report, Trends in Hospital Inpatient Drug Costs: Issues and Challenges (Oct. 11, 2016), <http://www.aha.org/content/16/aha-fah-rx-report.pdf>.

<sup>30</sup> Caroline Hunter, Reuters, Makes took big prices increases on widely used drug (Apr. 4, 2016), <http://www.reuters.com/article/us-usa-healthcare-drugpricing-idUSKCN0X10TH>.

<sup>31</sup> *Id.*

<sup>32</sup> MedPAC, A Data Book: Health Care Spending and the Medicare Program, (June 2017), at [http://medpac.gov/docs/default-source/data-book/jun17\\_databooksec10\\_sec.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/data-book/jun17_databooksec10_sec.pdf?sfvrsn=0)

<sup>33</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33633 (July 20, 2017).

<sup>34</sup> Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers 4 (July 2017), [http://www.340bhealth.org/files/340B\\_Financial\\_Impact\\_7\\_17.pdf](http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf).

<sup>35</sup> *Id.* at 25.

<sup>36</sup> 42 U.S.C. § 256b(a)(1).

<sup>37</sup> *Id.* § 256b(a)(4).

Medicaid recipients.<sup>38</sup> Originally, only Medicaid fee-for-service drugs were eligible for rebates, and when Congress enacted the 340B program, it directed the Secretary of HHS to develop a mechanism to protect manufacturers from giving both a Medicaid rebate and a 340B discount on the same drug, often referred to as a “duplicate discount.”<sup>39</sup> In 2010, Congress expanded the rebate program to Medicaid managed care.<sup>40</sup> When Congress expanded the rebates to managed care drugs, it expressly exempted drugs purchased by 340B program covered entities.<sup>41</sup>

In contrast, Congress has been wholly silent on the relationship between 340B and Medicare Part B, which indicates Congress’s intent that Medicare should not encroach upon the 340B program by redistributing discounts to non-340B providers. The 340B statute and Medicare have coexisted since 1992 when Congress enacted 340B. Congress has had ample opportunity in the past 25 years to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, and it has not done so. Indeed, in 2003, Congress enacted 42 U.S.C. § 1395(t)(14), which governs OPPS payments for drugs, and Congress could have addressed the treatment of 340B at that time, but it did not.<sup>42</sup> In 2010, Congress enacted the Affordable Care Act, which amended both the 340B and the Medicare statutes, but Congress did not empower CMS to redistribute 340B savings to non-340B hospitals or to Part B generally.<sup>43</sup> Congress’s silence demonstrates that it does not intend the Medicare program to intrude upon the operation of the 340B program.<sup>44</sup>

CMS’s proposed cut to 340B hospitals is also contrary to Congress’s intent for the 340B program to enable safety-net providers to “reach more patients” and furnish “more comprehensive services.”<sup>45</sup> CMS’s proposal would undermine this purpose by preventing the operation of the 340B statute. Although manufacturers would still have to give 340B discounts, 340B hospitals would receive no benefit from those discounts. The statutory purpose of 340B—to permit covered entities to “reach more patients” and furnish “more comprehensive services”—would be fatally undermined because CMS would commandeer the 340B savings and use it for other purposes, distributing it to non-340B hospitals through a budget neutrality adjustment to OPPS payments. The 340B program’s purpose of aiding safety-net hospitals cannot be achieved if 340B providers have to pass their savings to the Medicare program for the benefit of non-340B hospitals.

HRSA views discriminatory reimbursement as a threat to the 340B program. HRSA has expressed concerns that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings. HRSA explains that “if covered entities were not able to access resources freed up by the drug discounts when they... bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.”<sup>46</sup>

According to HRSA, the 340B program was established to provide additional financial resources to covered entities without increasing the federal budget. The difference between a 340B drug’s lower acquisition cost and

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<sup>38</sup> *Id.* § 1396r-8.

<sup>39</sup> 42 U.S.C. § 256b(a)(5)(A)(ii).

<sup>40</sup> Patient Protection and Affordable Care Act, Pub. L. 111-148, § 2501(c) (2010).

<sup>41</sup> 42 U.S.C. § 1396r-8(j)(1).

<sup>42</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 621, 117 Stat. 2066, 2307 (2003).

<sup>43</sup> See, e.g., Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, §§ 2501, 2902, 3402, 7101- 03, 124 Stat. 119, 309, 333, 488, 821-28 (2010).

<sup>44</sup> See *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2337-39 (2014).

<sup>45</sup> H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

<sup>46</sup> HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005), <https://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm>.

standard reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. Covered entities use these savings to treat more vulnerable patient populations or to improve services for those populations.

Thus, the plain language of the 340B statute and Congress's intent that the 340B program benefit covered entities forbids CMS from reducing Medicare payments to 340B hospitals for pass-through drugs. HHS, including CMS, must give effect to the purpose of the 340B statute to provide savings to 340B hospitals for the hospitals' use. A reduction to Part B OPPS payments for the stated purpose of taking 340B savings for the Medicare program would impermissibly contravene the purpose of the 340B statute and would be contrary to law.

#### **IV. CMS's Proposal Would Violate the Medicare Statute**

##### **a. CMS does not have the authority to vary payment to 340B hospitals**

The Medicare statute also forbids CMS from setting different prices for the same drug (i.e., based on the 340B status of the provider). The OPPS is established at 42 U.S.C. § 1395l(t). Subparagraph (14) addresses payment for certain "specified covered outpatient drugs" that are furnished as part of covered outpatient department services and separately payable. Payment for such drugs must be equal to one of the following:

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w-3a of this title, or section 1395w-3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.<sup>47</sup>

CMS calculates the payment rate for separately payable drugs by using the methodology in subparagraph (II) because CMS does not have average acquisition cost data. Thus, CMS determines reimbursement for pass-through drugs by using the methodology at 42 U.S.C. § 1395w-3a(b) by adding 6 percent to the ASP for the drug. In the proposed rule, CMS specifically cites to subparagraph (II) for its authority to reduce payment to 340B hospitals.<sup>48</sup>

Only subparagraph (I) permits CMS to vary payment "by hospital group." Subparagraph (II) does not contain the language of subparagraph (I) permitting CMS to vary payment "by hospital group." By including "by hospital group" in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices "by hospital group" if hospital acquisition data is not available. Thus, the subparagraph (II)

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<sup>47</sup> 42 U.S.C. § 1395l(t)(14)(A)(iii).

<sup>48</sup> 82 Fed. Reg. at 33634.

methodology must apply to “the drug,” and CMS may not vary payment for the same drug based upon the type of hospital.<sup>49</sup>

**b. CMS must issue a regulation to implement any payment reduction to 340B hospitals**

CMS has announced its proposed payment reduction solely in preamble commentary and has not proposed a regulation to implement the change. Even if the proposed payment reduction is lawful, CMS cannot implement it without issuing a regulation. The Medicare statute requires CMS to issue regulations when altering the substantive standards for payment: “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . . .”<sup>50</sup> CMS’s proposal falls squarely within this requirement because it would change the substantive legal standard governing payments to 340B hospitals for separately payable drugs. Accordingly, CMS may not impose the change without issuing a regulation.

**c. Redistributing the savings from the proposal to “Part B generally” would violate the Medicare statute**

Twice in the proposed rule, CMS requests comments on redistributing the savings from its reduced reimbursement for separately payable 340B drugs under the OPSS to “Part B generally” rather than simply increasing the OPSS conversion factor (which would spread the savings across payment for all OPSS services).<sup>51</sup> CMS seems to suggest that it may redistribute the savings to services that are covered under Part B outside OPSS, such as payments to physicians or to ambulatory surgery centers. CMS is prohibited by the Medicare statute from redistributing the savings from the reduced reimbursement for separately payable 340B drugs to Part B services not covered under OPSS.

When OPSS was enacted, CMS was required to estimate what it would have paid hospitals under the pre-OPSS system in 1999 and what Medicare beneficiaries would have paid in copayments in 1999.<sup>52</sup> It was also required to establish relative weights for hospital outpatient services, known as Ambulatory Payment Classifications or APCs.<sup>53</sup> It was then required to establish a conversion factor, which is the base rate to which the APCs are applied.<sup>54</sup> The amount of the conversion factor was required to be such that CMS’s estimate of the *total* amount of payments under OPSS would equal the total amount that it would have paid under the pre-OPSS in 1999.<sup>55</sup> The conversion factor is updated each year based on the hospital market basket index, with some adjustments.<sup>56</sup> CMS is also required to look at the APC weights and other adjustments each year to determine whether they need updating, but any updates have to be budget neutral.<sup>57</sup>

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<sup>49</sup> GAO came to a similar conclusion, acknowledging that CMS does not have the statutory authority to limit Part B reimbursement for 340B drugs. GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, page 30 (June 2015), <https://www.gao.gov/assets/680/670676.pdf>.

<sup>50</sup> 42 U.S.C. § 1395hh(a)(2); see also *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017) (“[T]he Medicare Act requires notice-and-comment rulemaking for any (1) ‘rule, requirement, or other statement of policy’ that (2) ‘establishes or changes’ (3) a ‘substantive legal standard’ that (4) governs ‘payment for services.’”).

<sup>51</sup> 82 Fed. Reg. 33,558, 33,634, 33,712 (July 20, 2017).

<sup>52</sup> 42 U.S.C. 1395l(t)(3)(A); 42 C.F.R. § 419.30.

<sup>53</sup> 42 U.S.C. 1395l(t)(2); 42 C.F.R. § 419.31.

<sup>54</sup> 42 U.S.C. §§ 1395l(t)(3)(C), 1395l(t)(3)(D); 1395l(t)(4); 42 C.F.R. § 419.32(c).

<sup>55</sup> 42 U.S.C. § 1395l(t)(3)(C)(i)(I); 42 C.F.R. § 419.32(a).

<sup>56</sup> 42 U.S.C. § 1395l(t)(3)(C)(ii), (iv); 42 C.F.R. § 419.32(b).

<sup>57</sup> 42 U.S.C. § 1395l(t)(9); 42 C.F.R. § 419.32(d) and 419.50.

In short, CMS is required to pay an amount under OPSS that is equal to the amount that it would have paid under the pre-OPSS system (based on 1999 data and updated by the market basket). CMS's proposal to redistribute the savings from the reimbursement for separately payable Part B drugs under OPSS to other categories of Part B services violates the Medicare statute because it would reduce aggregate payments below 1999 levels (as adjusted for inflation). CMS cannot redistribute savings from OPSS to other payment systems under Part B.

**d. CMS must go through notice and comment rulemaking before adopting a rule to redistribute the savings from the proposal through a means other than adjusting the conversion factor**

CMS cannot implement its proposals without issuing another proposed rule that clearly lays out the alternatives and financial impact on interested parties. CMS has not quantified the impact of its various proposals for implementing the reduction in payments to 340B hospitals. For this reason, any final rule would not be a "logical outgrowth" of the proposed rule.

CMS states that its proposal to reduce reimbursement for 340B drugs is budget neutral. Specifically, CMS states, "the reduced payments for separately payable drugs purchased through the 340B drug pricing program would increase payment rates (and by extension, beneficiary coinsurance liabilities) for other items and services paid under the OPSS by an offsetting aggregate amount."<sup>58</sup> However, CMS requests comments on whether the savings should instead be distributed by a method that would not distribute across all OPSS items and services. As discussed above, CMS requested comments on whether the savings for its reduced reimbursement for separately payable Part B drugs should be distributed to items and services covered under Part B outside OPSS. In addition, CMS requests comments on whether it should apply part or all of the saving generated by the payment reduction to increase payment for specific services under OPSS or whether the savings should be targeted to hospitals that treat a large share of indigent patients, particularly patients who are uninsured. CMS also seeks comments on whether the redistribution of savings would result in unnecessary increases in the volume of covered services paid under the OPSS that should be adjusted.<sup>59</sup>

CMS may not finalize these proposals because they would not be a "logical outgrowth" of the proposed rule, which does not specify the alternatives or quantify the impacts. The Medicare statute states that:

If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.<sup>60</sup>

In addition, the Administrative Procedure Act prohibits an agency from promulgating a rule that differs from a proposed rule unless the final rule is a "logical outgrowth" of the proposed rule.<sup>61</sup>

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<sup>58</sup> 82 Fed. Reg. at 33,711-12.

<sup>59</sup> 82 Fed. Reg. at 33,558, 33,634, 33,712.

<sup>60</sup> 42 U.S.C. § 1395hh(a)(4).

<sup>61</sup> See, e.g., *Allina Health Services v. Sebelius*, 746 F.3d 1102, 1107 (D.C. Cir. 2014); *Ass'n of Private Sector Colleges and Universities v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012).

The proposals for redistributing the savings could have very significant financial impacts on certain categories of hospitals. Clearly, it would have a significant negative financial impact on 340B hospitals. Also, one of CMS's proposals is to increase payment for certain services under OPPS. CMS does not state what services it is considering for this special treatment or what the impact would be on hospitals that provide varying amounts of those services. Similarly, CMS does not provide a formula or any details on the alternative to redistribute the savings to hospitals that serve a large number of indigent patients. CMS cannot adopt these alternative payment options without issuing a second proposed rule that discusses the financial impact of its options and puts interested parties on clear notice of the alternatives.

In *Allina Health Services v. Sebelius*, the Secretary proposed a rule that would have very little financial impact on hospitals and instead adopted a rule that had a substantial financial impact on hospitals. While the adopted rule was only one of two alternatives available, the D.C. Circuit held that CMS should have estimated and published the financial impact of the regulation *before* it adopted it.<sup>62</sup> The court's *Allina* decision forecloses CMS's proposal to redistribute 340B funds until it specifies the financial impact of its proposals.

#### **V. CMS's Proposed Payment Cut Relies on a Faulty Premise That Fails to Recognize That 340B DSH Hospitals Serve Patients With More Expensive Medical Needs**

CMS's proposal is based on the faulty premise put forward in a 2015 Government Accountability Office (GAO) report that 340B DSH hospitals may be using more drugs or more expensive drugs than necessary.<sup>63</sup> However, research demonstrates that 340B DSH hospitals incur higher drug spending not because of inappropriate drug use, but because their patients are more expensive to treat. Moreover, GAO did not find that 340B hospitals use drugs inappropriately, and there are other explanations for why Part B drug spending may be higher in 340B hospitals.

##### **a. 340B DSH hospitals incur higher Part B drug spending because they treat sicker patients**

A 2017 report by Dobson DaVanzo and Associates demonstrates that 340B DSH hospitals incur higher drug spending than non-340B hospitals not because of inappropriate drug use, but because their patients are more expensive to treat.<sup>64</sup> CMS should not reduce payment rates to 340B hospitals on the basis of the preliminary work done by GAO when other research suggests 340B DSH hospitals incur higher drug spending due to their sicker patients and other safety net hospital characteristics.

Dobson DaVanzo found that 340B DSH hospitals share facility characteristics that are associated with higher drug spending, and the types of patients they serve are generally more expensive to treat.<sup>65</sup> For example, compared to non-340B hospitals, 340B DSH hospitals treat more Medicare beneficiaries who are dually eligible for Medicaid, disabled, have ESRD, or are a racial or ethnic minority.<sup>66</sup> These beneficiaries are often in poorer

<sup>62</sup> *Allina*, 746 F.3d 1102, at 1108.

<sup>63</sup> GAO-15-442, 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>.

<sup>64</sup> Dobson, AI, Murray, Kennan, and DaVanzo, Joan, Financial Challenges Faced by 340B Disproportionate Share Hospitals In Treating Low-Income Patients (Aug. 4, 2017), [http://www.340bhealth.org/files/Financial\\_Challenges\\_Final\\_Report\\_08.04.17.pdf](http://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf).

<sup>65</sup> *Id.*

<sup>66</sup> Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net

health than other patients and are more expensive to treat.<sup>67</sup> Similarly, many 340B hospitals may be more likely to specialize in cancer care compared to non-340B hospitals, considering that 78 percent of the 69 NCI-designated cancer care centers in the country are affiliated with 340B DSH hospitals,<sup>68</sup> and cancer is incredibly expensive to treat. 340B DSH hospitals also treat more low-income cancer patients than non-340B providers,<sup>69</sup> and low-income cancer patients are more expensive to treat.<sup>70</sup>

As such, it would be expected that Medicare drug spending per drug user would be higher in 340B DSH hospitals compared to non-340B hospitals. Dobson DaVanzo's analysis found that nearly 60 percent of 340B DSH hospitals in the analysis shared patient and facility characteristics that cause higher spending.<sup>71</sup> The researchers removed these hospitals from the analysis to ensure that the more expensive nature of these hospitals' patients and facilities did not skew the results. The spending difference between the remaining 340B DSH hospitals and non-340B hospitals was substantially reduced.<sup>72</sup> This demonstrates that spending differences between 340B and non-340B hospitals are largely due to the more expensive nature of the patients that 340B hospitals treat.<sup>73</sup>

**b. GAO's finding was not dispositive, and there are other explanations for spending differences between 340B and non-340B hospitals**

GAO made clear that its research related to use of drugs by 340B hospitals was not dispositive, stating only that higher spending in 340B hospitals "may" be in response to 340B financial incentives.<sup>74</sup> There are other

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Hospitals, Nov. 15, 2016, available at [http://www.340bhealth.org/files/Update\\_Report\\_FINAL\\_11.15.16.pdf](http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf); Dobson DaVanzo & Associates, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices, Nov. 15, 2016, [http://www.340bhealth.org/files/Demographics\\_Report\\_FINAL\\_11.15.2016.pdf](http://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf).

<sup>67</sup> Kaiser Family Foundation, Medicaid's Role for Dual Eligible Beneficiaries, Aug. 2013, <https://kaiserfamilyfoundation.files.wordpress.com/2013/08/7846-04-medicoids-role-for-dual-eligible-beneficiaries.pdf>; Michael Ulrich, Challenges For People With Disabilities Within The Health Care Safety Net, Health Affairs Blog (Nov. 18, 2014), <http://healthaffairs.org/blog/2014/11/18/challenges-for-people-with-disabilities-within-the-health-care-safety-net/>; Juliette Cubanski and Patricia Neuman, Medicare Doesn't Work As Well For Younger, Disabled Beneficiaries As It Does For Older Enrollees, Health Affairs 29:9, 1725–1733 (Sept. 2010), <http://content.healthaffairs.org/content/29/9/1725.full.pdf>; Medicare Payment Advisory Commission (MedPAC), A Data Book: Health Care Spending and the Medicare Program. (June 2016), <http://medpac.gov/docs/default-source/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>; Kaiser Family Foundation, Profile of Medicare Beneficiaries by Race and Ethnicity: A Chartpack, March 9, 2016, <http://kff.org/medicare/report/profile-of-medicare-beneficiaries-by-race-and-ethnicity-a-chartpack/>; Amresh Hanchate, Andrea C. Kronman, Yinong Young-Xu, Arlene S. Ash, and Ezekiel Emanuel, Racial and Ethnic Differences in End-Of-Life Costs: Why Do Minorities Cost More Than Whites?, Arch Intern Med., 169(5): 493–501, (March 9, 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3621787/>.

<sup>68</sup> NCI-Designated Cancer Centers, <https://www.cancer.gov/research/nci-role/cancer-centers>; OPA Covered Entity Database, <https://opanel.hrsa.gov/340B/Views/CoveredEntity/CESearch>.

<sup>69</sup> Dobson DaVanzo & Associates, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Providers (May 2017), <http://www.340bhealth.org/files/LowIncomeOncology.pdf>.

<sup>70</sup> Runhua Shi, Hannah Taylor, Jerry McLarty, Lihong Liu, Glenn Mills and Gary Burton, Effects of payer status on breast cancer survival: a retrospective study, BMC Cancer 2015 15:211 (April 2015); Gary V. Walker, Stephen R. Grant, B. Ashleigh Guadagnolo, Karen E. Hoffman, Benjamin D. Smith, Matthew Koshy, Pamela K. Allen, and Usama Mahmood, Disparities in Stage at Diagnosis, Treatment, and Survival in Nonelderly Adult Patients With Cancer According to Insurance Status, J Clin Oncol 32:3118-3125 (Oct. 2014); Blumen H, Fitch K, Polkus V. Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Type of Service. *American Health & Drug Benefits*. 2016;9(1):23-32.

<sup>71</sup> Dobson, Al, Murray, Kennan, and DaVanzo, Joan, Financial Challenges Faced by 340B Disproportionate Share Hospitals In Treating Low-Income Patients (Aug. 4, 2017), [http://www.340bhealth.org/files/Financial\\_Challenges\\_Final\\_Report\\_08.04.17.pdf](http://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, page 29 (June 2015), <https://www.gao.gov/assets/680/670676.pdf>.

reasons why spending may be higher in 340B hospitals that do not suggest inappropriate behavior on the part of 340B hospitals. In fact, HHS noted that the study was a “useful initial analysis,” but characterized the report’s finding as “not supported by the study methodology.”<sup>75</sup> HHS said that drug spending may be higher in 340B DSH hospitals because “a higher volume of physician-administered drugs could lead to better clinical outcomes.”<sup>76</sup> Indeed, 85 percent of the 48 National Cancer Institute (NCI)-designated comprehensive cancer centers in the country are associated with 340B hospitals,<sup>77</sup> 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.<sup>78</sup> HHS also suggested that the spending differences may be explained by differences between 340B and non-340B patients, noting that “further analysis of the differences in spending [based on health status] seems warranted.”<sup>79</sup>

GAO used the CMS-Hierarchical Condition Categories (HCC) model to evaluate whether spending differences are due to patient health status and concluded that the differences do not appear to be due to differences in health status. However, this model is not appropriate for evaluating whether differences in health status explain drug spending differences. For example, GAO examined spending differences specifically for oncology drugs and found higher 340B spending. However, the model is not used to predict spending on Part B drugs or on oncology drugs. Rather, it is used to predict the overall cost of treating a Medicare patient.<sup>80</sup> In addition, the CMS-HCC model understates the severity of the health status of 340B DSH hospital patients.<sup>81</sup> In particular, it has been criticized for not accurately capturing cancer patients’ health status and for under-predicting expenditures for high-cost beneficiaries, and it does not evaluate the severity and complexity of cancer patients.<sup>82</sup> The fact that 340B hospitals may be more likely to provide highly specialized cancer services could, therefore, skew the findings and result in higher 340B spending levels.

If 340B DSH hospitals were using more drugs or more expensive drugs than necessary to maximize a financial incentive, as suggested by GAO, one would expect that the 340B hospitals would have healthier financial margins as a result. However, GAO found that 340B DSH hospitals have lower financial margins than non-340B hospitals, even with the benefit they obtain from 340B.<sup>83</sup> This suggests that there are other explanations

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<sup>75</sup> *Id.* at 38.

<sup>76</sup> *Id.*

<sup>77</sup> NCI-Designated Cancer Centers, <https://www.cancer.gov/research/nci-role/cancer-centers>; OPA Covered Entity Database, <https://opanel.hrsa.gov/340B/Views/CoveredEntity/CESearch>.

<sup>78</sup> 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).

<sup>79</sup> GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, page 38 (June 2015), <https://www.gao.gov/assets/680/670676.pdf>.

<sup>80</sup> See MedPAC, June 2014 Report to Congress, Improving Risk Adjustment in the Medicare program, available at [http://medpac.gov/docs/default-source/reports/jun14\\_ch02.pdf?sfvrsn=0](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).

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*; Letter from Healthcare Quality & Payment Reform to Administrator Tavenner, (CMS) (Aug. 26, 2014) available at [http://www.chqpr.org/downloads/CHQPRComments\\_CMS-1612-P\\_PhysicianPaymentPoliciesfor2015.pdf](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.”).

<sup>83</sup> GAO-15-442, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, pages 16-20 (June 2015), <https://www.gao.gov/assets/680/670676.pdf>. The median total facility margin for 340B DSH hospitals was 33% less than it was for non-340B DSH hospitals and 47% less than it was for other non-340B hospitals. Lower overall margins may be due to 340B hospitals providing more charity care and uncompensated care. The GAO found that 340B DSH hospitals tend to have higher total Medicare margins, likely due to receiving higher payments than other hospitals for uncompensated care, medical education, and outlier case adjustments. Nevertheless, the GAO found that 340B DSH hospitals have lower outpatient Medicare margins, despite the benefit they receive from 340B.

for higher spending in 340B hospitals, other than inappropriate drug use. Given Dobson DaVanzo's research, the non-dispositive nature of GAO's findings, and HHS's concerns, it would not be appropriate for CMS to act on the basis of the GAO's report.

## **VI. The Proposed Modifier for Non-340B Separately Payable Drugs and Possible Acquisition Cost Billing Would Pose Operational and Financial Challenges for 340B Hospitals**

In addition to lowering reimbursement for 340B drugs, CMS proposes to require hospitals to submit a modifier for non-340B separately payable drugs billed to Medicare Part B, stating that the "lack of information within [Medicare OPPS] claims data has limited researchers' and [the agency's] ability to precisely analyze differences in acquisition cost of 340B and non-340B-acquired drugs."<sup>84</sup> It is unclear how the modifier would help CMS or researchers analyze differences between the acquisition cost of 340B and non-340B drugs. 340B hospitals do not currently share their 340B acquisition costs for separately payable Part B drugs with CMS, and the proposal would not require 340B hospitals to do so.

Although it is unclear from the proposal, we assume that 340B hospitals would be able to submit the modifier to identify claims for which 340B drugs were not used in order to be reimbursed at ASP + 6%. If our assumption is correct, then CMS does not plan to reimburse 340B hospitals at ASP – 22.5% for their use of non-340B outpatient drugs. However, we are concerned about the challenges and costs of implementing the requirement. Many hospitals use a virtual inventory system for their 340B drugs. Since a hospital with a virtual inventory has a single physical stock of drugs, the hospital does not know if the particular pill or dose given to a patient was purchased at a 340B or non-340B price. In addition, the hospital does not know whether it will replenish the drug using its non-340B account or a 340B account until after it retrospectively determines that the patient was 340B-eligible or 340B-ineligible. It would be costly for a hospital to hold claims for a period of time and wait to bill Medicare in order to retrospectively identify eligibility and apply the modifier to non-340B claims.

Hospitals have reported to us that adding the modifier would need to be done manually and would require the purchase, implementation, and testing of additional software; or upgrading or revising existing software to add components, which also must be purchased, implemented, and tested. One hospital questioned whether it would be beneficial to continue participating in the 340B program due to the labor and cost of applying the modifier. Another hospital said it already has the software and set-up to apply the modifier, but that it still would take six months to build, implement, and test for the modifier and that building and testing would cost \$50,000 and \$112,000, respectively. A hospital reported that CMS's JW modifier for discarded drugs created a significant labor and compliance burden and is concerned that the new modifier would be worse.

In response to 340B Health's survey, a large, urban academic medical center reported, "The compliance requirement of adding a modifier to indicate drugs were not purchased at 340B for claims is not feasible and administratively burdensome. Our current system does not have the capability to flag claims, and we would not be able to meet the January 1, 2018 implementation deadline. As such, increased compliance would require additional administrative and personnel costs which are not accounted for in the proposed reduction in reimbursement."

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Outpatient Medicare margins for 340B DSH hospitals were 22% less than non-340B DSH hospitals and 21% less than other non-340B hospitals.

<sup>84</sup> Centers for Medicare and Medicaid Services, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558, 33633 (July 20, 2017).

Another hospital noted that it “does not have current capability to add additional modifier for billing purposes” and estimated “it would take at least 6-12 months to obtain resources and do the interface work that would be required.”

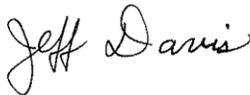
CMS said it intends to provide more information about the modifier in the OPPS final rule and/or subregulatory guidance, “including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B program.”<sup>85</sup> In this statement, it appears that CMS may be saying that covered entities do not receive 340B discounts on dually eligible beneficiaries. Generally, covered entities can use 340B drugs for Medicaid patients, including dually eligible beneficiaries, as long they comply with federal and state rules intended to protect pharmaceutical manufacturers from having to pay both a 340B discount and a Medicare rebate on the same drug (i.e., a “duplicate discount”).<sup>86</sup>

CMS said it is “seeking public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim.” 340B Health is concerned about the challenges and costs of implementing acquisition cost billing. Hospital chargemasters are not designed to bill drugs to one payer at a different rate than other payers. Hospitals have told us that acquisition cost billing would require investment in expensive software upgrades, obtaining a second chargemaster, or devising burdensome manual workarounds. In response to 340B Health’s survey, 94 percent of hospitals indicated that the reporting of the actual acquisition cost on a separate line of the Part B claim form would be problematic, with nearly 79 percent saying that such a requirement would be very problematic. As such, CMS should continue to reimburse 340B hospitals at the same rate as non-340B hospitals and not require different billing requirements for 340B hospitals.

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CMS should withdraw its proposal to cut OPPS payments to 340B hospitals for separately payable drugs. CMS’s proposal would harm 340B hospitals’ ability to treat low-income patients without reducing patient costs or Medicare spending. Moreover, the proposal would violate both the 340B and Medicare statutes. For these reasons, CMS should continue to reimburse 340B hospitals for separately payable drugs at ASP + 6 percent, the same rate paid to non-340B hospitals. Thank you for the opportunity to comment on the Proposed Rule.

Sincerely,



Jeff Davis  
Legislative and Policy Counsel

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<sup>85</sup> *Id.* at 33635.

<sup>86</sup> 42 U.S.C. § 256b(a)(5)(A); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (June 23, 1993).