



June 2015

# MEDICARE PART B DRUGS

## Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals

Accessible Version

# GAO Highlights

Highlights of [GAO-15-442](#), a report to congressional requesters

## Why GAO Did This Study

Approximately 40 percent of all U.S. hospitals participate in the 340B Drug Pricing Program, and the majority of 340B discounted drugs are sold to hospitals. Medicare reimburses hospitals for Part B drugs under a statutory formula regardless of the prices hospitals paid for the drugs. Stakeholders have questioned the increase in hospital participation in the 340B program, and the implications for Medicare and its beneficiaries, especially regarding cancer care; and whether certain of the program's hospital eligibility criteria target hospitals appropriately.

GAO was asked to review hospitals' participation in the 340B and Medicare programs. This report (1) compares 340B hospitals with non-340B hospitals in terms of financial and other characteristics and (2) compares spending for Medicare Part B drugs at 340B hospitals, for all drugs and for oncology drugs, with spending at non-340B hospitals. To examine hospital participation using the most recent data available, GAO analyzed 2008 and 2012 data from HRSA and CMS to compare characteristics and Medicare Part B drug spending for 340B hospitals and non-340B hospitals.

## What GAO Recommends

Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals.

View [GAO-15-442](#). For more information, contact James Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

June 2015

## MEDICARE PART B DRUGS

### Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals

## What GAO Found

Certain providers, including hospitals that serve a disproportionate number of low-income patients, have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program, which is administered by the Health Resources and Services Administration (HRSA) within the Department of Health & Human Services (HHS). In 2012, these hospitals—referred to as 340B disproportionate share hospitals (DSH) because they are eligible for the program based on their serving a disproportionate share of low-income patients and other specified criteria—were generally larger and more likely to be teaching hospitals compared with non-340B hospitals. They also tended to provide more uncompensated and charity care than non-340B hospitals; however, there were notable numbers of 340B hospitals that provided low amounts of these types of care. For example, 12 percent of 340B DSH hospitals were among the hospitals that reported providing the lowest amounts of charity care across all hospitals in GAO's analysis. Overall financial margins for 340B DSH hospitals tended to be lower compared with non-340B hospitals, which could be attributable, in part, to the tendency for 340B DSH hospitals to provide more uncompensated and charity care.

GAO found that in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was \$144, compared to approximately \$60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, uses a statutorily defined formula to pay hospitals for drugs at set rates regardless of hospitals' costs for acquiring the drugs. Therefore, there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries. HRSA and CMS have limited ability to counter this incentive because the 340B statute does not restrict covered entities from using drugs purchased at the 340B discounted price for Medicare Part B beneficiaries and the Medicare statute does not limit CMS reimbursement for such drugs.

In commenting on a draft of this report HHS noted some concerns with GAO's conclusions and suggested that further analysis may be needed to examine patient outcomes and differences in health status. GAO believes its methods appropriately support its conclusions as further discussed in the report.

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## Abbreviations

CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
GME	graduate medical education
HHS	Department of Health & Human Services
HRSA	Health Resources and Services Administration
IME	indirect medical education
IPPS	inpatient prospective payment system
MDH	Medicare-dependent hospital
OPPS	outpatient prospective payment system
PPS	prospective payment system

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June 5, 2015

## Congressional Requesters

The 340B Drug Pricing Program requires drug manufacturers to sell most outpatient drugs at deeply discounted prices to certain providers and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid.<sup>1</sup> Entity eligibility for the program is defined in statute and includes certain hospitals that serve a disproportionate number of low-income patients.<sup>2</sup> Participating hospitals, referred to as 340B hospitals, benefit from lower outpatient drug prices and may also benefit from the revenue generated when they are reimbursed by Medicare and other payers at rates that exceed the discounted prices the hospitals pay for outpatient drugs.<sup>3</sup> The 340B statute does not specify how covered entities should use the savings or any resulting revenue associated with the discounts.<sup>4</sup>

Currently, approximately 40 percent of all U.S. hospitals participate in the program, and the majority of 340B discounted drugs are sold to hospitals.<sup>5</sup> Some members of Congress and certain stakeholders, such as drug manufacturers, have raised questions about the increasing number of hospitals that participate in the 340B Program. They question

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<sup>1</sup>Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

<sup>2</sup>Eligibility is also extended to clinics and other entities that participate in certain qualifying federal programs.

<sup>3</sup>Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. In general, Medicare Part A covers inpatient hospital services and Medicare Part B covers outpatient hospital services, as well as physician services and certain other services. Under Medicare Part B, Medicare reimburses all hospitals for outpatient drugs at set rates regardless of whether the drugs were obtained at a 340B discounted price. The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS).

<sup>4</sup>According to the Department of Health & Human Services (HHS), the intent of the 340B Program is to enable covered entities to stretch scarce Federal resources to reach more eligible patients and provide more comprehensive services.

<sup>5</sup>In 2011 we reported that nearly a third of all U.S. hospitals participated in the 340B Program. See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, [GAO-11-836](#) (Washington, D.C.: Sept. 23, 2011).

whether certain of the program's hospital eligibility criteria appropriately target hospitals for participation. They contend that participating hospitals do not necessarily use the program and program revenues to help vulnerable patients, such as low-income uninsured patients, and that the program gives hospitals incentives to maximize the revenue that they earn through it. In contrast, they contend that nonhospital entities that are eligible for the 340B Program on the basis of their participation in qualifying federal programs must operate within the rules of those programs, so there is some assurance that those entities will use the program, including any revenue generated through it, to help the vulnerable patients they serve. Other stakeholders, such as organizations representing 340B hospitals, emphasize that participating hospitals are safety net providers that serve more low-income, uninsured, and underinsured patients than other hospitals. Such stakeholders contend that the program is intended to allow hospitals to use the revenue they generate through the 340B Program to help them cover their operating costs and make up any financial losses, as well as to implement programs to benefit vulnerable patients.

Another issue raised by stakeholders, including groups representing independent oncology practices and oncology providers, is that hospitals' participation in the 340B Program might contribute to a recent trend in hospital acquisition of oncology practices.<sup>6</sup> Because independent outpatient oncology practices are not eligible for the 340B Program, they cannot obtain oncology drugs at the 340B discounted rate. Some stakeholders argue that 340B hospitals are acquiring independent oncology practices, in part, to expand their outpatient base for 340B oncology drugs and thus generate higher revenue for these drugs.<sup>7</sup> They assert that this trend has negative implications for payers and patients, including the Medicare program and its beneficiaries, because payments for services provided in hospital outpatient departments are generally higher than they are for services provided in free-standing community

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<sup>6</sup>According to the Community Oncology Alliance, since 2008, 313 clinical treatment sites have closed, and 544 practices have been acquired by or otherwise entered into formal partnership agreements with hospitals.

<sup>7</sup>American Society of Clinical Oncology, "Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology," to be published in *Journal of Oncology Practice*, accessed May 7, 2014, <http://jop.ascopubs.org/content/early/2014/04/15/JOP.2014.001432.extract>.

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outpatient facilities. However, these stakeholders note that a variety of other factors could contribute to these acquisitions.

You asked us to examine hospitals' participation in the 340B Program and the potential implications for Medicare and its beneficiaries. In this report, we (1) compare 340B hospitals with non-340B hospitals in terms of financial and other characteristics and (2) examine how Medicare Part B drug spending at 340B hospitals, for all drugs and for oncology drugs, compares to spending at non-340B hospitals.

For both of our research objectives, we examined 2008 and 2012 data from the Health Resources and Services Administration's (HRSA) 340B Covered Entity Database to determine which hospitals participated in the 340B Program.<sup>8</sup> We focused our analysis on one of the six hospital types eligible for the program—disproportionate share hospitals (DSH)—because DSH hospitals account for the majority of drug purchases under the 340B Program.<sup>9</sup> To be eligible for the 340B Program, a DSH hospital must be a general acute care hospital that serves a disproportionate share of low-income patients—as generally indicated by a Medicare DSH adjustment percentage greater than 11.75—and that meets other specified criteria.<sup>10</sup> We compared characteristics and payments for these

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<sup>8</sup>We used 2012 data because it was the year in which all sources of data needed for our analysis were most complete. We chose 2008 data to capture any potential changes over time in hospitals' participation in the 340B Program.

<sup>9</sup>According to HRSA, as of January 2015, 978 340B DSH hospitals participated in the 340B Program and these hospitals accounted for 78 percent of total 340B drug purchases.

<sup>10</sup>A hospital's DSH adjustment percentage is used to determine the additional payment a hospital can receive from Medicare if it serves a disproportionate number of low-income Medicare and Medicaid beneficiaries in its inpatient department. An alternative method for meeting the DSH requirement to participate in the 340B Program applies to hospitals that are located in an urban area, have 100 or more beds, and can demonstrate that more than 30 percent of their total net inpatient care revenues come from state and local government sources for indigent care (other than Medicare and Medicaid). These hospitals—known as "Pickle" hospitals—are referred to in this report as meeting DSH alternative criteria. In addition to meeting the DSH adjustment percentage requirement, or the DSH alternative criteria, 340B DSH hospitals must be (1) owned and operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not entitled to Medicare or eligible for Medicaid. These hospitals must also not obtain covered outpatient drugs through a group purchasing organization. See 42 U.S.C. § 256b(a)(4)(L).



hospitals with those for two groups: non-340B DSH hospitals (hospitals that received DSH payments but did not participate in the 340B Program) and all other non-340B hospitals.<sup>11</sup> We excluded from all analyses the following types of hospitals: (1) hospitals located outside the 50 states and Washington, D.C., (2) hospitals that were not acute care, (3) hospitals paid under a Medicare system other than the prospective payment system (PPS),<sup>12</sup> and (4) hospitals that participated in the 340B Program on the basis of one of the other five hospital eligibility categories.<sup>13</sup> We also excluded outliers and hospitals for which data were missing or inconsistent. We also spoke with stakeholders, including officials from three groups representing drug manufacturers, three groups representing 340B hospitals, and two groups representing independent oncology practices and providers, to obtain their views on these issues and the 340B Program generally.

To compare financial and other characteristics of 340B hospitals with non-340B hospitals, we used 2012 Medicare hospital cost report data from the Centers for Medicare & Medicaid Services (CMS). We examined characteristics such as hospital size, teaching status (major teaching hospital, other teaching hospital, or nonteaching hospital),<sup>14</sup> ownership type (public, nonprofit, or for profit), location (urban or rural), DSH adjustment percentage (high or low),<sup>15</sup> and provision of charity care and

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<sup>11</sup>Over one-third of the hospitals in the non-340B DSH group had a DSH adjustment percentage greater than 11.75.

<sup>12</sup>Certain hospitals, including certain freestanding cancer hospitals, critical access hospitals, and hospitals located in Maryland that are paid under a cost containment waiver, are not paid under Medicare's PPS.

<sup>13</sup>Other types of hospitals that are eligible for the 340B program include children's hospitals, critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. In general, these hospitals must also meet certain DSH eligibility criteria. See 42 U.S.C. § 256b(a)(4)(M) – (O).

<sup>14</sup>We defined major teaching hospitals as those that had a resident-to-bed ratio greater than 0.25.

<sup>15</sup>We considered hospitals to have a high DSH adjustment percentage if this percentage was greater than 11.75 percent. We considered hospitals to have a low DSH adjustment percentage if this percentage was less than or equal to 11.75 percent.

uncompensated care (high or low).<sup>16</sup> We also examined whether hospitals with higher DSH adjustment percentages provided larger amounts of charity care and uncompensated care. We used the cost report data to examine hospitals' financial characteristics by calculating four types of hospital financial margins: (1) total facility margin, (2) total Medicare margin, (3) inpatient Medicare margin, and (4) outpatient Medicare margin.<sup>17</sup> In addition, we determined whether hospitals received the following Medicare payment adjustments and the size of each adjustment: (1) DSH adjustment, (2) indirect medical education (IME) adjustment, (3) direct graduate medical education (GME) payment, (4) outlier case adjustment, and (5) Medicare-dependent hospital (MDH) classification.<sup>18</sup> All of these adjustments apply to a hospital's inpatient payments. Only the GME and outlier case adjustments apply to a

<sup>16</sup>Uncompensated care includes charity care and bad debt, including costs not reimbursed by public payers (such as Medicaid). Charity care generally represents services for which a hospital demonstrates that a patient is unable to pay, and is based on a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria. Bad debt generally represents services for which a hospital determines that a patient has the financial capacity to pay, but is unwilling to do so. We considered hospitals to have provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis.

<sup>17</sup>Margins were calculated as revenue minus costs divided by revenue. The total facility margin included revenue and costs associated with all of a hospital's patients. The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency. According to the Medicare Payment Advisory Commission, acute inpatient and outpatient services account for over 90 percent of hospitals' Medicare revenues. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 14, 2014), 65.

<sup>18</sup>The MDH classification applies to small rural providers for which Medicare patients make up a significant percentage of inpatient days or discharges. We included the DSH, IME, GME, and outlier case adjustments in our analysis because these adjustments are most commonly received by hospitals. We included the MDH classification because although a low number of hospitals receive this adjustment, the proportion of total Medicare revenue accounted for by the adjustment is relatively large. We excluded adjustments that were time limited (e.g., payment incentives for implementing electronic health records) or were directly related to eligibility for the 340B program (e.g., rural referral center) from our analysis of payment adjustments.

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hospital's outpatient payments. There were 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals in our cost report analysis.<sup>19</sup>

To examine how Medicare Part B drug spending at 340B hospitals, for all drugs and for oncology drugs, compares with this spending at non-340B hospitals, we used CMS's 2008 and 2012 Medicare claims data combined with CMS's 2008 and 2012 Medicare hospital cost report data. For each year, we calculated per beneficiary Part B drug spending for separately payable outpatient drugs for each hospital that served at least one outpatient beneficiary during the year.<sup>20</sup> To examine oncology drug payments specifically, we identified separately payable Part B oncology drugs by Healthcare Common Procedure Coding System code. For each year we then calculated Part B oncology drug spending per Medicare oncology beneficiary for each hospital that received any of these payments.<sup>21</sup> For both the overall outpatient drug and the oncology drug spending analyses, we examined whether there were differences in Part B drug spending between 340B DSH and non-340B hospitals that could not be explained by factors outside of the 340B Program, such as hospital teaching status or patient health status. To examine differences in patient health status, for each year we calculated an average risk adjustment score for each hospital, based on the risk scores of the hospital's outpatient population or outpatient population that received an oncology drug, specifically. We excluded payments for vaccines because they are not eligible for discounts under the 340B Program.<sup>22</sup>

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<sup>19</sup>Because hospitals can have varying fiscal year start and end dates, the time periods covered by the cost reports in our analysis vary. All cost reports in our analysis cover at least 10, but not more than 14, months.

<sup>20</sup>We based per beneficiary Part B drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital in the respective year. We included only separately payable drugs because drugs paid as part of a bundled service under the PPS are not eligible for 340B discounts.

<sup>21</sup>We based per beneficiary Part B oncology drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital who received payment for at least one oncology drug in the respective year. It is possible that some of these beneficiaries received an oncology drug to treat a condition other than cancer.

<sup>22</sup>Our analysis was based on drugs identified by CMS as Part B drugs. According to HRSA, some Part B drugs may not be eligible for 340B discounts, such as certain skin substitutes; however, HRSA did not have a list of those drugs in 2008 and 2012.

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To assess the reliability of the data we used in our analysis, we reviewed related documentation, interviewed officials from HRSA and CMS, and performed appropriate electronic data checks. This allowed us to determine that the data were sufficiently reliable for our purposes.

We conducted this performance audit from March 2014 to June 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

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### 340B Program

The 340B Program, which is administered and overseen by HRSA, within HHS, is named for the statutory provision authorizing it, which was added to the Public Health Service Act in 1992.<sup>23</sup> Eligibility for the program is statutorily defined and is limited to entities that participate in specified federal programs and hospital types that meet certain eligibility criteria.<sup>24</sup> A clinic or other site affiliated with a hospital, but not located in the main hospital building, is eligible to participate in the 340B program if it is an

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<sup>23</sup>Pub. L. No. 102-585, 106 Stat. 4943, 4967 (adding § 340B to the Public Health Service Act) (codified as amended at 42 U.S.C. § 256b). Outpatient drugs covered under the 340B Program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, which can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

<sup>24</sup>Eligible entities include federally qualified health centers, urban Indian organizations, family planning clinics, sexually transmitted disease grantees, tuberculosis grantees, Native Hawaiian Health Centers, state-operated Ryan White AIDS Drug Assistance Programs, other Ryan White grantees, hemophilia treatment centers, and black lung clinics. Eligible hospitals include certain DSH hospitals, critical access hospitals, sole community hospitals, rural referral centers, freestanding cancer hospitals, and children's hospitals. Additionally, providers that meet all of the requirements for the federally qualified health centers program, but do not receive federal grants—referred to as federally qualified health center look-alikes—are eligible to participate in the 340B Program.

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integral part of the hospital, which HRSA has defined as a reimbursable facility, included on the eligible hospital's most recently filed Medicare cost report.<sup>25</sup> Independent physician-based practices that do not participate in the qualifying federal programs are not eligible to participate in the 340B Program.

Covered entities may use 340B drugs for patients whether or not they are low-income, uninsured, or underinsured, and covered entities may receive payments from health insurers, such as Medicare, that are higher than the drug's discounted price, generating revenue through the program. A statutory pricing formula determines the 340B price of a drug. The amount of the 340B discount ranges from an estimated 20 to 50 percent off what the entity would have otherwise paid.<sup>26</sup>

Throughout calendar year 2012, there were 10,622 unique covered entities that participated in the 340B program—an increase of 20 percent since 2008.<sup>27</sup> Approximately half of the increase in unique covered entities was among entities that became eligible for the program based on expanded eligibility criteria enacted by the Patient Protection and Affordable Care Act in 2010.<sup>28</sup> The remaining increase was among entity types that were eligible for the program in both 2008 and 2012, including 340B DSH hospitals. In 1992, the House Energy and Commerce Committee estimated that approximately 90 DSH hospitals would have

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<sup>25</sup>See 59 Fed. Reg. 47884 (Sep. 19, 1994). Institutional providers that render services to Medicare beneficiaries are required to submit cost reports annually. Among other things, these reports contain self-reported information on facility characteristics, utilization data, and financial statement data.

<sup>26</sup>In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. The average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies.

<sup>27</sup>These counts do not include counts of affiliated sites and clinics. In order to improve the accuracy of the 340B database, HRSA changed the way that it required covered entities to register these sites beginning in 2012. As a result, we could not definitively measure the change in the number of affiliated sites and clinics over time.

<sup>28</sup>Entities that became eligible for the 340B Program through the Patient Protection and Affordable Care Act include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7107(a), 124 Stat. 821 (codified at 42 U.S.C. § 256b(a)(4)(M) –(O)). The expansion of Medicaid under the Patient Protection and Affordable Care Act could also result in more hospitals meeting the minimum 340B DSH eligibility criteria.

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been eligible to participate in a 340B Program, had it been in effect at that time.<sup>29</sup> In 2012, 1,057 DSH hospitals participated in the program.

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## Medicare Payments to Hospitals

Medicare pays most hospitals through both the acute care inpatient prospective payment system (IPPS), which is covered by Medicare Part A, and the outpatient prospective payment system (OPPS), which is covered by Medicare Part B. Under these systems, Medicare pays providers a predetermined rate for a given service that is expected to cover the costs incurred by efficient providers. Within the OPPS, certain services, including most Part B drugs, are paid separately.

Payments under the IPPS are adjusted to account for the beneficiary's clinical condition and related treatment costs relative to the average Medicare case and payments under both the IPPS and the OPPS are adjusted for the market conditions in the hospital's location relative to national conditions. Hospitals may receive additional payments if they qualify for certain adjustments, such as:<sup>30</sup>

- **DSH adjustment:** The DSH adjustment generally provides supplemental payments for inpatient services to hospitals that treat a disproportionate number of low-income inpatients.<sup>31</sup> To qualify for this adjustment, a hospital's disproportionate patient percentage—the share of low-income patients treated by the hospital—must generally equal or exceed a specific threshold level determined by a statutory

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<sup>29</sup>See H.R. Rep. No. 102-384, Pt. 2 at 12 (1992) (discussing bill to amend the Social Security Act, containing language similar to what eventually became section 340B of the Public Health Service Act).

<sup>30</sup>Medicare also reimburses hospitals for 70 percent of bad debts resulting from beneficiaries' nonpayment of copayments and deductibles after a reasonable effort has been made to collect the unpaid amounts.

<sup>31</sup>See 42 U.S.C. § 1395ww(d)(5)(F).

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formula.<sup>32</sup> The amount of the DSH payment adjustment varies by hospital location and size.

- **GME and IME adjustments:** Medicare reimburses teaching hospitals and academic medical centers for both the direct and indirect costs of their residency training programs. GME payments cover the direct costs of resident training, such as salaries and benefits, for both inpatient and outpatient services. The IME adjustment applies only to inpatient services, and reflects the higher patient care costs associated with resident education. The size of the IME adjustment depends on the hospital's teaching intensity, which is generally measured by a hospital's number of residents per bed.
- **Outlier case payment:** The outlier case payment protects hospitals from large financial losses due to unusually costly inpatient and outpatient cases. A hospital's costs for the case must exceed a certain threshold amount and additional payments are based on a percentage of the costs above this threshold.
- **MDH classification:** The MDH classification allows small rural hospitals for which Medicare patients make up a significant percentage of inpatient days or discharges to receive adjustments to their IPPS rates.<sup>33</sup> To qualify as an MDH, a hospital has to meet various criteria regarding location, size, and patient mix.

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## Medicare Spending for Part B Drugs

In 2012, the Medicare program and its beneficiaries spent a total of \$6 billion for Part B drugs in the hospital outpatient setting. Part B drugs are typically administered by a physician or under a physician's close supervision in physicians' offices or hospital outpatient departments. Under the OPPS, Medicare reimburses all hospitals for separately

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<sup>32</sup>The disproportionate patient percentage is generally computed as the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income (the federal program that provides cash benefits to eligible low-income individuals who are aged, blind, or disabled) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A.

<sup>33</sup>Federal law refers to "Medicare-dependent small rural hospitals." See, e.g., 42 C.F.R. § 412.108 (2014). In this report, we refer to this category of rural providers as "Medicare-dependent hospitals" (MDH). Although the MDH program was originally enacted as a temporary program, it has been extended multiple times and is due to expire for discharges as of October 1, 2017.

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payable Part B drugs at rates determined by a statutorily defined formula regardless of the price the hospital pays for the drug. Medicare pays 80 percent of the payment rate for Part B drugs and the beneficiary is responsible for the remaining 20 percent. Typically, Part B drugs are provided with a physician service, which is also paid for by both Medicare and the patient. In general, spending for Part B drugs and other services has a financial impact on Medicare beneficiaries because monthly Part B premiums are set to cover 25 percent of total Part B expenditures.

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### **340B DSH Hospitals Were Generally Larger and Had Lower Total Facility Margins, but Higher Medicare Margins Compared with Non-340B Hospitals**

In 2012, 340B DSH hospitals were generally larger and more likely to be teaching hospitals—especially major teaching hospitals—compared with non-340B hospitals. Although 340B DSH hospitals tended to have lower total facility margins compared with non-340B hospitals, they tended to have higher total Medicare margins. Lower total facility margins among 340B DSH hospitals could be partly attributable to the tendency for these hospitals to provide more charity care and uncompensated care compared with non-340B hospitals, although there were notable exceptions. Higher total Medicare margins among 340B DSH hospitals could be partly attributable to the receipt of more Medicare payment adjustments by these hospitals.

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### **340B DSH Hospitals Were Generally Larger and Many Provided More Charity Care and Uncompensated Care Compared with Non-340B Hospitals, with Notable Exceptions**

Compared with non-340B hospitals—including both non-340B DSH hospitals and other non-340B hospitals—340B DSH hospitals in our analysis tended to be larger in terms of annual total facility revenue, annual Medicare revenue, and the number of inpatient beds in 2012.<sup>34</sup>

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<sup>34</sup>Unless otherwise noted, when we refer to “non-340B hospitals,” we are referring to both non-340B DSH and other non-340B hospitals.



The differences between 340B DSH hospitals and non-340B hospitals were most pronounced among major teaching hospitals, and among the 279 major teaching hospitals, 189 (or nearly 70 percent) were 340B DSH hospitals (see table 1). Further, the median DSH adjustment percentage among 340B DSH hospitals in our analysis was twice as high as the median DSH adjustment percentage among non-340B DSH hospitals—18 percent compared with 9 percent. Among major teaching hospitals, the median DSH adjustment percentage was over three times as high—28 percent compared with 8 percent.

**Table 1: Median Value for Certain Characteristics of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, 2012**

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
<b>All hospitals</b>	<b>N=925</b>	<b>N=1,461</b>	<b>N=567</b>
Total facility revenue (annual)	\$221,798,171	\$124,953,410	\$86,558,543
Medicare revenue (annual)	\$47,056,462	\$27,095,156	\$17,989,741
Number of inpatient beds	200	131	79
DSH adjustment percentage	18%	9%	N/A
<b>Major teaching hospitals<sup>a</sup></b>	<b>N=189</b>	<b>N=73</b>	<b>N=17</b>
Total facility revenue (annual)	\$678,101,836	\$410,446,721	\$324,935,756
Medicare revenue (annual)	\$116,678,679	\$96,614,102	\$80,784,893
Number of inpatient beds	454	317	214
DSH adjustment percentage	28%	8%	N/A
<b>Other teaching hospitals</b>	<b>N=249</b>	<b>N=326</b>	<b>N=80</b>
Total facility revenue (annual)	\$374,066,746	\$261,520,835	\$232,492,533
Medicare revenue (annual)	\$76,816,940	\$60,156,029	\$56,697,908
Number of inpatient beds	311	241	203
DSH adjustment percentage	20%	9%	N/A
<b>Nonteaching hospitals</b>	<b>N=487</b>	<b>N=1,062</b>	<b>N=470</b>
Total facility revenue (annual)	\$98,120,109	\$90,166,366	\$68,088,170
Medicare revenue (annual)	\$20,721,543	\$19,403,494	\$13,698,803
Number of inpatient beds	109	102	64
DSH adjustment percentage	14%	9%	N/A

Legend: N/A = Not applicable.

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

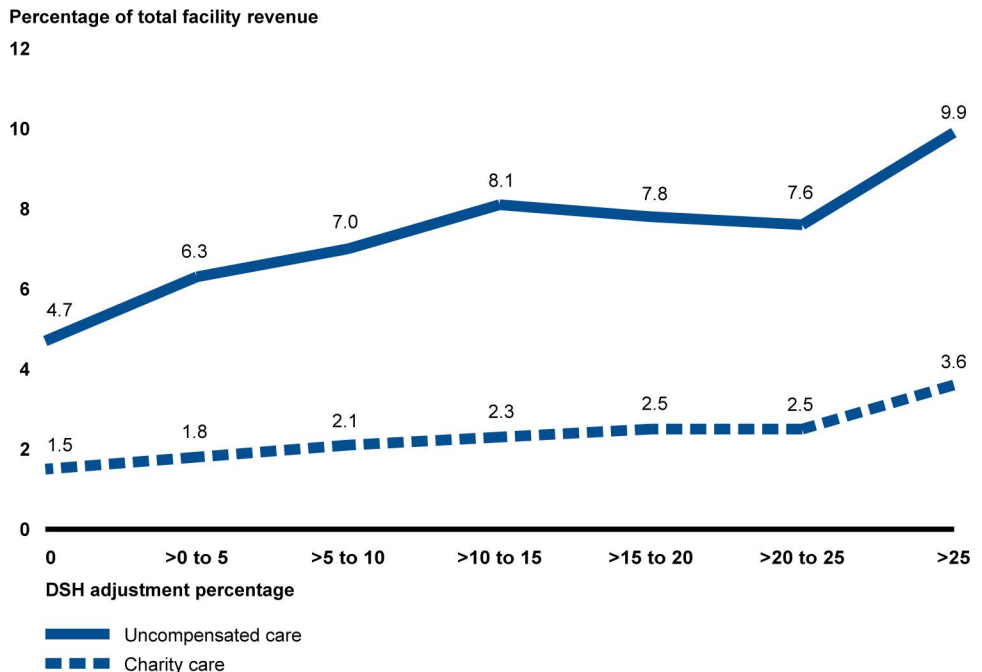
Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50

states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

<sup>a</sup>Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

Compared with non-340B hospitals, in 2012, 340B DSH hospitals generally provided more charity care and uncompensated care, as a proportion of total facility revenue—although there were notable exceptions. In addition, we found that higher DSH adjustment percentages were often, but not always, associated with provision of greater amounts of charity care and uncompensated care by hospitals. Across all hospitals in our analysis, as hospitals' DSH adjustment percentages increased, the average amount of charity care and uncompensated care they provided, as a proportion of total facility revenue, generally increased. (See fig. 1.)

**Figure 1: Average Amount of Uncompensated Care and Charity Care as a Percentage of Total Facility Revenue Provided by All Hospitals with Various Disproportionate Share Hospital (DSH) Adjustment Percentages, 2012**



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; or participated in the 340B Program in an eligibility category other than the DSH hospital eligibility category. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care.

The median amount of uncompensated care provided by 340B DSH hospitals was 1.4 percentage points greater than the median amount provided by non-340B DSH hospitals, and 3.6 percentage points greater than the median amount provided by other non-340B hospitals. The median amount of charity care provided by 340B DSH hospitals was 0.8 percentage points greater than the median amount provided by non-340B DSH hospitals, and 1.4 percentage points greater than the median amount provided by other non-340B hospitals. (See table 2.)

**Table 2: Median Amount of Uncompensated Care and Charity Care Provided by 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, as a Percentage of Total Facility Revenue, by Teaching Status, 2012**

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
<b>All hospitals</b>	<b>N=925</b>	<b>N=1,461</b>	<b>N=567</b>
Uncompensated care	7.4	6.0	3.8
Charity care	2.1	1.3	0.7
<b>Major teaching hospitals<sup>a</sup></b>	<b>N=189</b>	<b>N=73</b>	<b>N=17</b>
Uncompensated care	6.6	4.5	2.8
Charity care	2.5	1.1	1.4
<b>Other teaching hospitals</b>	<b>N=249</b>	<b>N=326</b>	<b>N=80</b>
Uncompensated care	6.4	5.2	3.9
Charity care	2.2	1.6	1.1
<b>Nonteaching hospitals</b>	<b>N=487</b>	<b>N=1,062</b>	<b>N=470</b>
Uncompensated care	7.9	6.4	3.8
Charity care	2.0	1.2	0.6

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care.

<sup>a</sup>Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

However, there were notable numbers of 340B DSH hospitals that provided low amounts of uncompensated care and charity care. For example, while we found that 340B DSH hospitals tended to provide a larger amount of charity and uncompensated care compared with non-340B hospitals, 12 percent of 340B DSH hospitals in our analysis were among the hospitals that provided the lowest amounts of charity care. We also found that 14 percent were among the hospitals that provided the

lowest amounts of uncompensated care across all hospitals in our analysis. Additionally, among 340B DSH hospitals, the median amount of uncompensated care provided by major teaching hospitals was less than the median amount provided by all hospitals in the group, despite the fact that the major teaching hospitals in this group tended to have the highest DSH adjustment percentages. Additionally, nearly one quarter of 340B DSH hospitals that were major teaching hospitals provided low amounts of uncompensated care. (See table 3.)

**Table 3: Percentage of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Provided High and Low Amounts of Uncompensated Care and Charity Care, by Teaching Status, 2012**

Characteristic	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
<b>All hospitals</b>	<b>N=925</b>	<b>N=1,461</b>	<b>N=567</b>
High uncompensated care	37	23	11
Low uncompensated care	14	23	48
High charity care	36	22	14
Low charity care	12	26	43
<b>Major teaching hospitals<sup>a</sup></b>	<b>N=189</b>	<b>N=73</b>	<b>N=17</b>
High uncompensated care	32	11	6
Low uncompensated care	23	37	63
High charity care	41	20	6
Low charity care	12	25	19
<b>Other teaching hospitals</b>	<b>N=249</b>	<b>N=326</b>	<b>N=80</b>
High uncompensated care	31	16	1
Low uncompensated care	18	28	43
High charity care	36	24	17
Low charity care	12	17	28
<b>Nonteaching hospitals</b>	<b>N=487</b>	<b>N=1,062</b>	<b>N=470</b>
High uncompensated care	41	26	12
Low uncompensated care	8	20	49
High charity care	34	22	13
Low charity care	12	29	46

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care. We considered hospitals to have

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provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these reported amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis.

<sup>a</sup>Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

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## 340B DSH Hospitals Generally Had Lower Total Facility Margins than Non-340B Hospitals

Compared with non-340B hospitals, 340B DSH hospitals in our analysis generally had lower overall financial margins in 2012, as measured by their total facility margins. Specifically, the median annual total facility margin among 340B DSH hospitals (3.7) was 1.8 percentage points lower than the median annual total facility margin among non-340B DSH hospitals (5.5), and 3.3 percentage points lower than the median annual total facility margin among other non-340B hospitals (7.0). This finding was generally consistent when we looked at hospitals by characteristics such as teaching status (major teaching, other teaching, or nonteaching), ownership type (public, nonprofit, or for profit), and location (urban or rural). The lower total facility margins among 340B DSH hospitals could be attributable, in part, to the tendency for 340B DSH hospitals to provide a larger amount of charity care and uncompensated care, as a proportion of total facility revenue, compared with non-340B hospitals.

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## 340B DSH Hospitals Generally Had Higher Medicare Margins and Received More Medicare Payment Adjustments Compared with Non-340B Hospitals

Compared with non-340B hospitals, 340B DSH hospitals in our analysis generally had substantially higher (i.e., less negative) total Medicare margins and inpatient Medicare margins in 2012 (see table 4). The median annual total Medicare margin that year among 340B DSH hospitals was -2.7, which was 4.6 and 13.3 percentage points higher than the median annual total Medicare margin among non-340B DSH hospitals and other non-340B hospitals, respectively.<sup>35</sup> Similarly, the median annual

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<sup>35</sup>The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency.

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inpatient Medicare margin among 340B DSH hospitals was 0.2, which was 7.8 and 22.1 percentage points higher than the median annual inpatient Medicare margin among non-340B DSH and other non-340B hospitals, respectively.

**Table 4: Median Annual Medicare Margins for 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals, 2012**

Margin type	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
Total Medicare <sup>a</sup>	(2.7)	(7.3)	(16.0)
Inpatient Medicare	0.2	(7.6)	(21.9)
Outpatient Medicare	(10.0)	(8.2)	(8.3)

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system. Margins were calculated for each hospital and the median margin represents the median among all hospitals within each group.

<sup>a</sup>The total Medicare margin included revenue and costs associated with a hospital's acute inpatient and outpatient Medicare patients (including revenue and costs associated with a hospital's graduate medical education activities). It did not include revenue and costs associated with Medicare patients served by the hospital's inpatient rehabilitation facility, inpatient psychiatric facility, skilled nursing facility, or home health agency.

The higher total Medicare margins and higher inpatient Medicare margins for 340B DSH hospitals may be attributable, in part, to the amount of Medicare payment adjustments they received. The 340B hospitals in our analysis were more likely to receive Medicare payment adjustments and receive higher payment adjustment amounts compared with non-340B hospitals, which resulted in increased Medicare revenue for these hospitals. For example, in 2012, 340B DSH hospitals were more likely than non-340B DSH hospitals to receive three of the five payment adjustments we examined—IME, GME, and outlier case (see table 5).<sup>36</sup>

<sup>36</sup>Due to the way that we categorized hospitals for our analysis, all 340B DSH hospitals and all non-340B DSH hospitals received DSH payments and none of the other non-340B hospitals received DSH payments.

**Table 5: Percentage of 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Received Certain Medicare Payment Adjustments, 2012**

Payment adjustment	340B DSH hospitals	Non-340B DSH hospitals	Other non-340B hospitals
Indirect medical education <sup>a</sup>	47	27	17
Direct graduate medical education <sup>b</sup>	51	30	20
Disproportionate share adjustment <sup>c</sup>	100	100	N/A
Outlier case <sup>d</sup>	98	96	96
Medicare-dependent hospital <sup>e</sup>	1	5	3

Legend: N/A = Not applicable.

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This table is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

<sup>a</sup>Supplemental payments to cover the indirect costs of hospitals' medical education activities.

<sup>b</sup>Supplemental payments to cover the direct costs of hospitals' medical education activities.

<sup>c</sup>Supplemental payments for hospitals that treat a disproportionate number of low-income Medicare and Medicaid patients.

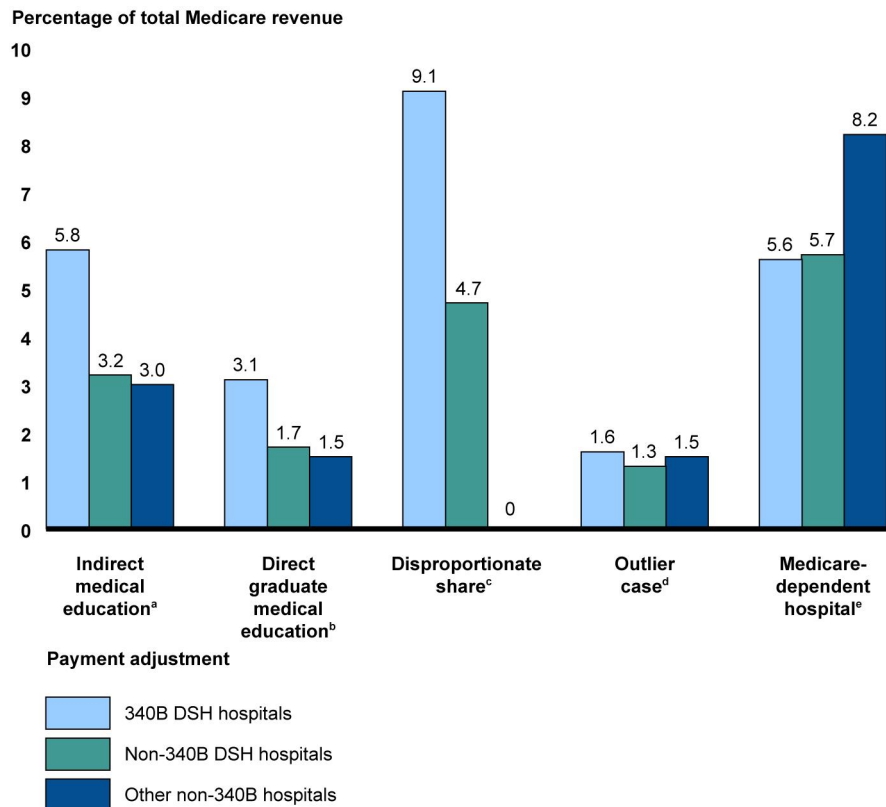
<sup>d</sup>Supplemental payments for unusually expensive cases.

<sup>e</sup>Supplemental payments for small rural hospitals for which Medicare patients make up a significant percentage of inpatient discharges.

Additionally, in 2012, 340B DSH hospitals received higher payment amounts, as a proportion of total Medicare revenue, for four of the five payment adjustments we examined—IME, GME, DSH, and outlier case adjustments—compared with non-340B hospitals (see fig. 2).



**Figure 2: Average Annual Medicare Payment Adjustment as a Percentage of Total Medicare Revenue for 340B Disproportionate Share Hospitals (DSH) and Non-340B Hospitals That Received Certain Adjustments, 2012**



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This figure is based on analysis of 2012 data from CMS's hospital cost reports and HRSA's 340B covered entity database. The analysis included 925 340B DSH hospitals, 1,461 non-340B DSH hospitals, and 567 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they either had a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; or were paid under a Medicare system other than the prospective payment system.

<sup>a</sup>Supplemental payments to cover the indirect costs of hospitals' medical education activities.

<sup>b</sup>Supplemental payments to cover the direct costs of hospitals' medical education activities.

<sup>c</sup>Supplemental payments for hospitals that treat a disproportionate number of low-income Medicare and Medicaid patients.

<sup>d</sup>Supplemental payments for unusually expensive cases.

<sup>e</sup>Supplemental payments for small rural hospitals for which Medicare patients make up a significant percentage of inpatient discharges.

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Despite their participation in the 340B Program, 340B DSH hospitals in our analysis generally had lower outpatient Medicare margins compared with non-340B hospitals. In 2012, the median annual outpatient Medicare margin among 340B DSH hospitals was 1.8 and 1.7 percentage points lower than that of non-340B DSH hospitals and other non-340B hospitals, respectively. Lower outpatient Medicare margins among 340B DSH hospitals were likely due to a variety of factors. One potential factor is that there are fewer Medicare payment adjustments for outpatient services. Among the five payment adjustments we examined, only two—GME and outlier case—apply to outpatient payments.

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## **Per Beneficiary Part B Drug Spending Was Substantially Higher at 340B DSH Hospitals, Which May Reflect Financial Incentives to Prescribe Outpatient Drugs**

In both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than non-340B hospitals. This indicates that, on average, Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals. The differences we found did not appear to be explained by the hospital or patient population characteristics we examined. Because Medicare pays hospitals at set rates for Part B drugs regardless of their costs for acquiring them, there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or prescribe more expensive drugs to Medicare beneficiaries. The substantially higher spending at 340B DSH hospitals may reflect a response to this incentive.

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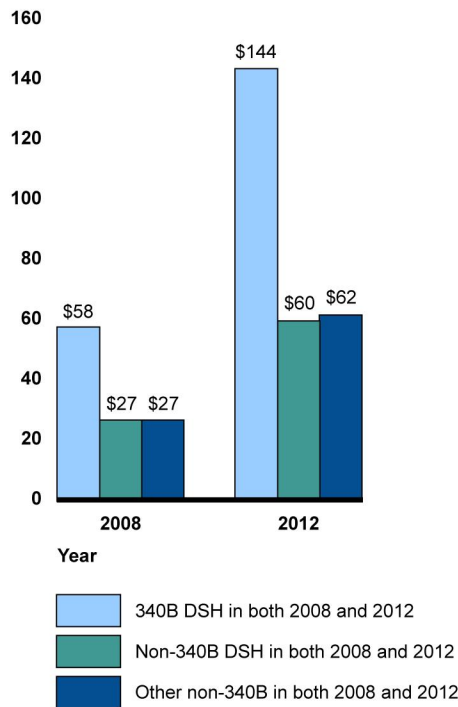
## **Per Beneficiary Part B Drug Spending Was Substantially Higher at 340B DSH Hospitals Compared with Non-340B Hospitals**

Among the hospitals in our analysis that provided outpatient services and whose 340B status did not change between 2008 and 2012, on average, per beneficiary Medicare Part B drug spending was substantially higher at 340B DSH hospitals compared with non-340B hospitals in both 2008 and 2012. For example, in 2012, average per beneficiary spending at 340B

DSH hospitals was \$144, compared to \$60 and \$62 at non-340B DSH and other non-340B hospitals, respectively.<sup>37</sup> (See fig. 3.) Because Medicare reimbursement rates for Part B drugs at all of the hospitals in our analysis were based on the same fee schedule, this indicates that, on average, Medicare beneficiaries at 340B DSH hospitals were prescribed more drugs or prescribed more expensive drugs, or both, than beneficiaries at the other hospitals in our analysis.

**Figure 3: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status**

Average per beneficiary Medicare spending for Part B drugs



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. The analysis included 645 340B DSH hospitals, 1,183 non-340B DSH hospitals, and 435 other non-340B hospitals. 340B DSH

<sup>37</sup>For each year, we calculated per beneficiary Part B drug spending for separately payable outpatient drugs for each hospital that served at least one outpatient beneficiary during the year. We based per beneficiary Part B drug spending on the number of unique outpatient Medicare beneficiaries served by each hospital in the respective year.

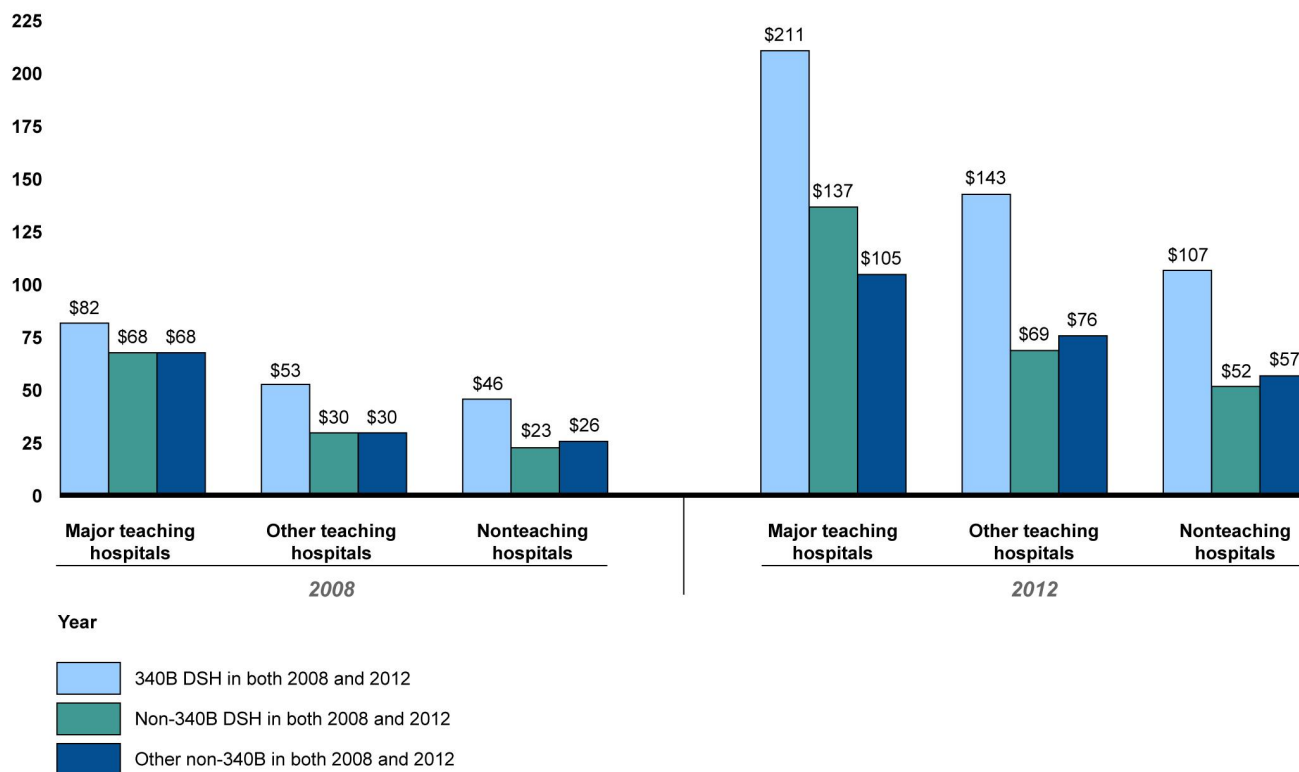
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hospitals qualified for the 340B Program because they had either a Medicare disproportionate share hospital (DSH) adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient beneficiary. Per beneficiary spending is based on the number of unique outpatient beneficiaries served by each hospital in each year. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

The spending differences between 340B DSH hospitals and non-340B hospitals remained even after we accounted for teaching status, ownership type, or location (i.e., urban or rural). For example, among both teaching and nonteaching hospitals, average per beneficiary Part B drug spending was much higher at 340B DSH hospitals than at non-340B hospitals. (See fig. 4.)

**Figure 4: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status, by Teaching Status**

Average per beneficiary Medicare spending for Part B drugs



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

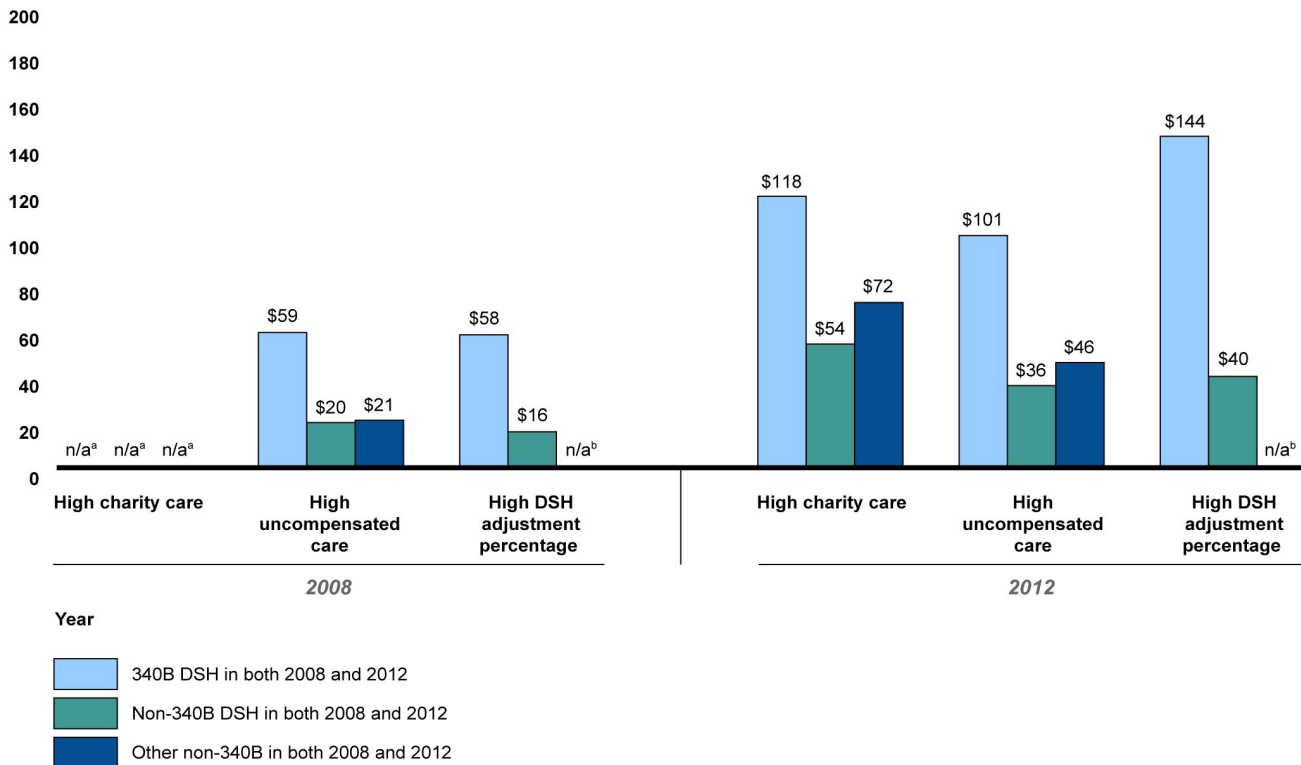
Notes: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. The analysis included 645 340B DSH hospitals, 1,183 non-340B DSH hospitals, and 435 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare disproportionate share hospital (DSH) adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient beneficiary. Per beneficiary spending is based on the number of unique outpatient beneficiaries served by each hospital in each year. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households. Major teaching hospitals had a resident-to-bed ratio greater than 0.25.

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Further, these differences were not explained by the factors we examined that might disproportionately affect hospitals that treat higher proportions of low-income patients. For example, among hospitals with high levels of charity care or high levels of uncompensated care, and among hospitals with a high DSH adjustment percentage—all indicators that these hospitals treat a higher proportion of low-income patients—Part B drug spending was much higher among 340B DSH hospitals in both 2008 and 2012. (See fig. 5.)

**Figure 5: Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012 among High Charity Care, Uncompensated Care, and Disproportionate Share Hospital (DSH) Adjustment Percentage Hospitals That Did Not Change 340B Status**

Average per beneficiary Medicare spending for Part B drugs



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Notes: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. The analysis included 645 340B DSH hospitals, 1,183 non-340B DSH hospitals, and 435 other non-340B hospitals. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare DSH adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient beneficiary. Per beneficiary spending is based on the number of unique outpatient beneficiaries served by each hospital in each year. Uncompensated care includes charity care and bad debt; therefore, charity care is a component of uncompensated care. We considered hospitals to have provided a high amount of charity care or uncompensated care if the amounts of charity care or uncompensated care that the hospital reported providing, as a proportion of total facility revenue, were within the top quartile across all hospitals in our analysis. We considered hospitals to have provided a low amount of charity care or uncompensated care if these reported amounts, as a proportion of total facility revenue, were within the bottom quartile across all hospitals in our analysis. We considered hospitals to have a high DSH adjustment percentage if this percentage was 11.75 or higher. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

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<sup>a</sup>Charity care was not reported in 2008 hospital cost reports; therefore, we could not analyze 2008 spending using this characteristic.

<sup>b</sup>No hospitals in this category had a high DSH adjustment percentage in 2008 or 2012.

Additionally, the differences we found were likely not explained by the health status of the outpatients served. Specifically, in 2008 and 2012, the health status of outpatient beneficiaries was generally similar at 340B and non-340B hospitals. For example, in 2012 the average risk score—a measure of relative health status—of these outpatient beneficiaries at 340B DSH hospitals was 1.50, while it was 1.45 at non-340B DSH hospitals and 1.36 at other non-340B hospitals.<sup>38</sup> Risk scores are based on overall health care spending and are not limited to drug spending. However, the difference between the risk scores of beneficiaries treated at 340B DSH hospitals and non-340B hospitals relative to these hospitals' Part B drug spending suggests that the substantially higher spending at 340B DSH hospitals may not be explained by differences in patient health status.

The relatively higher Part B drug spending at 340B DSH hospitals potentially could, in part, reflect a tendency for some beneficiaries to receive all of their Part B drugs in a hospital outpatient department instead of a physician's office. To the extent this occurs, some of the higher spending at 340B DSH hospitals may not be associated with increases in overall Medicare spending for Part B drugs. However, we found that, in 2012, among patients who received Part B drugs in hospital outpatient departments, the percentage of patients who only received drugs in that setting—meaning that they did not receive any Part B drugs at a physician's office—was only slightly higher at 340B DSH hospitals (59 percent) compared to non-340B DSH hospitals (54 percent), and other non-340B hospitals (54 percent). Moreover, when we limited our analysis to patients who only received Part B drugs in a hospital outpatient department, the substantially higher spending at 340B DSH hospitals persisted. Specifically, in 2012, average per beneficiary Part B drug spending for these patients was \$2,743 in 340B DSH hospitals,

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<sup>38</sup>A risk score is based on a beneficiary's characteristics, such as age and gender, and major medical conditions generally obtained from diagnoses on claims. A higher risk score indicates that a hospital cares for a sicker beneficiary population. A risk score of 1.0 represents the predicted health care costs of the average Medicare beneficiary. In 2008, the average risk score of outpatient beneficiaries was 1.45 at 340B DSH hospitals, 1.40 at non-340B DSH hospitals, and 1.33 at other non-340B hospitals.



compared to \$1,295 in non-340B DSH hospitals and \$1,634 in other non-340B hospitals.

### The Average Number of Oncology Patients Served Increased for All Hospital Groups from 2008 to 2012, but Increased the Most at 340B DSH Hospitals

Among the hospitals in our analysis that provided outpatient oncology services and whose 340B status did not change between 2008 and 2012, all three groups of hospitals served more oncology patients in 2012 compared to 2008. (See table 6).

**Table 6: Average Number of Medicare Outpatient Oncology Beneficiaries and Average Per Beneficiary Medicare Part B Oncology Drug Spending in 2008 and 2012 among Hospitals That Did Not Change 340B Status**

	340B Status					
	340B DSH in both 2008 and 2012 (N=645)		Non-340B DSH in both 2008 and 2012 (N=1,183)		Other non-340B in both 2008 and 2012 (N=435)	
	2008	2012	2008	2012	2008	2012
Percentage of hospitals treating oncology beneficiaries	84	89	65	66	59	61
Total number of outpatient oncology beneficiaries	44,853	68,576	24,795	33,886	10,172	13,398
Average number of outpatient oncology beneficiaries	83	120	32	43	40	51
Average per outpatient oncology beneficiary Part B spending for oncology drugs (\$)	4,779	7,801	3,632	5,432	3,539	5,904

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) data. | GAO-15-442

Note: This figure is based on analysis of 2008 and 2012 data from CMS's Medicare outpatient claims and hospital cost reports, and HRSA's 340B covered entity database. 340B DSH hospitals qualified for the 340B Program because they had either a Medicare disproportionate share hospital (DSH) adjustment percentage greater than 11.75 or met DSH alternative criteria and they met other specified criteria. Non-340B DSH hospitals received DSH payments, but did not participate in the 340B Program. Other non-340B hospitals did not receive DSH payments and did not participate in the 340B program. The analysis excluded hospitals that were located outside the 50 states and Washington, D.C.; were not an acute care hospital; were paid under a Medicare system other than the prospective payment system; changed participation groups between 2008 and 2012 (e.g., 340B DSH in 2008 but non-340B DSH in 2012); or did not serve at least one outpatient oncology beneficiary. Per outpatient oncology beneficiary spending is based on the number of unique outpatient oncology beneficiaries served by each hospital in each year. All spending is in 2012 dollars, adjusted using the consumer price index for all goods and services purchased for consumption by urban households.

For both years, average per beneficiary Medicare Part B oncology drug spending was highest at 340B DSH hospitals. Higher average per

beneficiary spending at 340B DSH hospitals compared to non-340B hospitals persisted regardless of teaching status or patient health status.<sup>39</sup> For example, in 2008 and 2012, the health status of outpatient oncology beneficiaries that received a Part B drug was similar at 340B and non-340B hospitals. In 2012, the average risk score of these outpatient oncology beneficiaries at 340B DSH hospitals was 2.29, while it was 2.11 at non-340B DSH hospitals and 2.14 at other non-340B hospitals.<sup>40</sup> Risk scores are based on overall health care spending and are not limited to oncology drug spending specifically. Nevertheless, the difference between the risk scores of beneficiaries treated at 340B and non-340B hospitals relative to these hospitals' Part B oncology drug spending suggests that the substantially higher Part B spending at 340B DSH hospitals may not be explained by differences in patient health status. Because Medicare reimbursement rates for Part B oncology drugs at all of the hospitals in our analysis were based on the same fee schedule, this indicates that, on average, Medicare beneficiaries at 340B DSH hospitals were prescribed more oncology drugs, or prescribed more expensive oncology drugs, than beneficiaries at the other hospitals in our analysis.

The average number of oncology patients served increased among all three of our hospital groups between 2008 and 2012, but 340B DSH hospitals saw the greatest increase in such patients served (83 to 120, or 45 percent). The increase across all three hospital groups in the number of oncology patients served may reflect recent trends in oncology treatment, such as where patients are treated, and could be due to multiple factors, including factors outside of the 340B program. For example, stakeholders that we spoke with noted that there is a larger trend toward integration in the health care industry. However, 340B DSH hospitals were much more likely to treat oncology patients compared with non-340B hospitals. In addition, there was a 5 percentage point increase from 2008 to 2012 in the percentage of 340B DSH hospitals that treated oncology patients, while the increases for non-340B DSH and other non-340B hospitals were 1 and 2 percentage points, respectively.

<sup>39</sup>Additionally, median Medicare spending per oncology beneficiary at 340B DSH hospitals was higher than average spending per oncology beneficiary in 2008 and 2012, indicating that Part B per beneficiary oncology spending at 340B DSH hospitals tended to be at the higher end of the spending distribution.

<sup>40</sup>In 2008, the average risk score of outpatient oncology beneficiaries was 2.083 at 340B DSH hospitals, 1.960 at non-340B DSH hospitals, and 1.939 at other non-340B hospitals.

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## Differences in Per Beneficiary Part B Drug Spending at 340B and Non-340B Hospitals May Reflect Responses to Incentives in the 340B and Medicare Programs

Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs, and the 340B statute does not restrict covered entities from using drugs purchased at the 340B discounted price for Medicare Part B beneficiaries. Consequently, there is a financial incentive at these hospitals to prescribe more drugs and more expensive drugs to Medicare beneficiaries in order to maximize the revenue generated by the difference between the cost of the drug and Medicare's reimbursement. The substantially higher per beneficiary Medicare spending for Part B drugs at 340B DSH hospitals, which did not appear to be explained by hospital characteristics or patient health status, may reflect responses to this incentive. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs, and higher Part B premiums that reflect the increases in Medicare spending for those drugs. Moreover, there are potential concerns about the appropriateness of the health care provided to Medicare beneficiaries if it is overly influenced by financial incentives to prescribe outpatient drugs.

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## Conclusions

Certain providers, including hospitals that serve a disproportionate number of low-income patients, have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program. Currently, approximately 40 percent of all U.S. hospitals participate in the program, including approximately 1,000 DSH hospitals. Because DSH hospitals account for nearly 80 percent of all 340B drug purchases, it is important to understand the characteristics of the population that is served by these hospitals in order to evaluate the impact of the 340B program on hospitals and their patients. We found that 340B DSH hospitals generally provided more charity care and uncompensated care compared with non-340B hospitals. However, there were notable exceptions to this pattern. Specially, 12 percent of the 340B DSH hospitals reported providing relatively small amounts of charity care and 14 percent reported providing relatively small amounts of uncompensated care.

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The financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns. Our work suggests that 340B DSH hospitals may be responding to this incentive to maximize Medicare revenues. On average, per beneficiary Medicare spending on Part B drugs in 2008 and 2012 was substantially higher at 340B DSH hospitals compared with non-340B hospitals—yet we did not find that these differences could be readily explained by hospital characteristics or patients’ health status. While hospitals may be financially benefitting—which is not inconsistent with the legislative design of the 340B Program—this poses potentially serious consequences to the Medicare program and its beneficiaries. Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has direct financial effects on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries. Absent a change in financial incentives, potentially inappropriate spending on drugs may continue. While limiting hospitals’ Medicare Part B reimbursement for 340B discounted drugs or eliminating the 340B discount for drugs provided by hospitals to Medicare Part B beneficiaries could diminish the incentive to prescribe more drugs or more expensive drugs than necessary at 340B hospitals, CMS and HRSA are unable to take such actions because they do not have the statutory authority to do so.

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## Matter for Congressional Consideration

To help ensure the financial sustainability of the Medicare program, protect beneficiaries from unwarranted financial burden, and address potential concerns about the appropriateness of the health care provided to Part B beneficiaries, Congress should consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals.

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## Agency and Third Party Comments and Our Evaluation

We provided a draft of this report for review to HHS and received written comments that are printed in appendix I. Because of the focus on 340B

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hospitals in this report, we also provided 340B Health (formerly Safety Net Hospitals for Pharmaceutical Access) an opportunity to review a draft of this report and we have summarized the comments we received below. HHS and 340B Health also provided technical comments, which we incorporated, as appropriate. Following is our summary of and response to comments from HHS and 340B Health.

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## HHS Comments

In its comments, HHS stated that our examination of Medicare Part B outpatient drug spending is a useful initial analysis of differences in spending between 340B DSH hospitals and non-340B hospitals. HHS also noted concerns related to some of our conclusions; however, we believe our methods and findings were robust and appropriately support our conclusions, as discussed below.

First, HHS noted that although we examined differences in per beneficiary spending by hospital type, we did not examine differences in patient outcomes or quality. HHS acknowledged that higher spending for Part B drugs at 340B hospitals could represent unnecessary or excess spending for these drugs. However, HHS stated that it is also possible that a higher volume of physician-administered drugs could lead to better clinical outcomes. While we did not attempt to evaluate health outcomes as part of our analysis, we have no evidence to suggest that non-340B hospitals had an incentive to provide a lower volume of Part B drugs than required to achieve positive clinical outcomes. In particular, we believe that because Medicare reimbursed all hospitals in our analysis—including non-340B hospitals—based on the drug's average sales price plus a fixed percentage above the drug's average sales price, non-340B hospitals would have no incentive to underprescribe Part B drugs.

Second, HHS questioned our interpretation of the differences between the average risk scores among the three hospital groups (1.50 for 340B DSH hospitals vs. 1.45 and 1.36 for non-340B DSH and other non-340B hospitals, respectively). HHS believes that the differences in risk scores could represent a meaningful difference in the health status of beneficiaries. We acknowledge that the differences in risk scores could represent a difference in the health status of the beneficiaries served by each hospital group. However, we believe that the relative difference between the risk scores and the per beneficiary Part B drug spending at 340B DSH and non-340B hospitals indicates that the substantially higher spending at 340B DSH hospitals may not be explained by differences in

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patient health status. For example, based on the risk scores, overall health care spending for beneficiaries who received Part B drugs at 340B DSH hospitals in 2012 would have been expected to be, on average, 3.4 percent higher than overall health spending that year for beneficiaries who received Part B drugs at non-340B DSH hospitals. In contrast, spending for Part B drugs at 340B DSH hospitals was substantially higher—140 percent higher—than spending at non-340B DSH hospitals. While the spending expectation from the risk scores applies to overall health care spending, not just Part B drug spending, the relative percentage differences suggest that the higher spending at 340B DSH hospitals may not be explained by differences in patient health status.

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### 340B Health Comments

340B Health noted several concerns related to the methodologies we used for our analysis. However, we believe that our methods were sound, as described below.

340B Health expressed concerns about the methodology we used to examine the amount of charity care and uncompensated care provided by hospitals. In particular, 340B Health stated that the data from worksheet S-10 in the Medicare hospital cost reports that we used for this analysis are too unreliable to serve as the basis for policy conclusions because the data are not used by CMS to determine Medicare payments. However, before we conducted our analysis, we confirmed with CMS that the agency did not have any concerns about our use of the data in the S-10 worksheet for our analysis. In addition, we performed our own data reliability assessment and concluded that the cost report data were sufficiently reliable for our study. The Medicare cost report is collected annually from all institutional providers that render services to Medicare beneficiaries. Among other things, these reports contain self-reported information on facility characteristics, utilization data, and financial statement data. We used these data to describe various characteristics of hospitals, including hospitals' self-reported levels of charity care and uncompensated care.

340B Health also questioned whether our methods controlled for certain reasons it might be appropriate for Medicare Part B spending to be significantly higher at 340B hospitals. For example, they noted that 340B hospitals are larger, more likely to be teaching hospitals, and more likely to treat cancer patients or otherwise higher-risk patients. Our analyses controlled for each of these characteristics. To control for the size of each

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hospital, we calculated Part B drug spending at the per beneficiary level. To control for the effect of teaching hospital status, we examined Part B drug spending by teaching hospital level (major teaching, other teaching, and nonteaching) and we found substantially higher Part B drug spending at 340B DSH hospitals regardless of teaching status. To control for the possibility that 340B DSH hospitals were more likely to treat cancer patients, we conducted a separate analysis of Part B spending for oncology drugs at 340B DSH and non-340B hospitals and found similar results in spending.

Although controlling for teaching status and conducting separate analyses of oncology drug spending may have in part controlled for the treatment of higher risk patients, we also conducted analyses to determine whether patient health status at 340B DSH hospitals may explain the substantially higher Part B drug spending at these hospitals. 340B Health expressed concerns about the methodology we used in this analysis, noting that the patient risk scores we used were not intended to predict Part B drug spending—which was a limitation we noted in our report. However, the risk scores we used are an indication of the expected overall health care spending for the beneficiaries served by the hospitals in our analysis, and we found small differences in expected overall health care spending across the hospital groups. As we noted above, we believe that the relative difference between the risk scores and the per beneficiary Part B drug spending at 340B DSH and non-340B hospitals indicates that the substantially higher spending at 340B DSH hospitals may not be explained by differences in patient health status. Additionally, in expressing concerns about the risk score measures, 340B Health referred to a Medicare Payment Advisory Commission report that questioned the usefulness of these measures for assessing expected spending for individual beneficiaries.<sup>41</sup> However, the same report also stated that, on average, the risk scores are accurate predictors of patient health status, and for our report, we calculated an average risk score for each hospital group.

340B Health also questioned whether our exclusion of a group of hospitals—smaller, mostly nonteaching DSH hospitals that were in the 340B Program in 2012, but not in 2008—from our spending analysis

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<sup>41</sup>Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 13, 2014), 25.

might have skewed our findings. Our discussion in the report focused on our analysis of hospitals that participated in the 340B program in both 2008 and 2012 to ensure a like-to-like comparison. However, although we did not include a discussion of it in the report, we did separately examine Part B drug spending at DSH hospitals that participated in the 340B Program in 2012 but not in 2008. For example, we found that, in 2008, Part B drug spending at these hospitals was similar to spending at other non-340B DSH hospitals. However, in 2012, after the hospitals joined the 340B Program, Part B drug spending at these hospitals was 53 percent higher than spending at non-340B DSH hospitals (and among the nonteaching hospitals, spending at 340B DSH hospitals was 73 percent higher than non-340B DSH hospitals). Furthermore, although spending was higher at these 340B DSH hospitals in 2012, the average risk score of patients treated at these hospitals (1.41) was slightly lower than the average risk score of patients treated at non-340B DSH hospitals (1.45). These findings indicate that, like those we included in our report, these newer participants in the 340B program may have been responding to the financial incentives in the program.

Finally, 340B Health expressed concern that we did not attempt to review patient outcomes or otherwise evaluate the quality of care provided to beneficiaries at 340B DSH hospitals compared with non-340B hospitals and cited research that found that increased use of outpatient drugs can reduce spending on health services.<sup>42</sup> However, the research 340B Health cited was not focused on Part B drugs—which are generally drugs administered by a physician in a clinical setting—but rather on the effects of insurance coverage for prescription drugs on medical costs, so is not directly relevant to our analysis. In addition, as we noted above, while we did not attempt to evaluate health outcomes as part of our analysis, we have no evidence to suggest that non-340B hospitals had an incentive to provide a lower volume of Part B drugs than required to achieve positive clinical outcomes due to the structure of Medicare’s payment for Part B drugs.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the

<sup>42</sup>J. Christian-Herman, M. Emons, and D. George, “Effects of Generic-only Drug Coverage in a Medicare HMO,” *Health Affairs* web exclusive, accessed May 21, 2015, <http://content.healthaffairs.org/content/early/2004/09/29/hlthaff.w4.455.full.pdf+html>.



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Secretary of Health & Human Services and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staffs have any questions regarding this report, please contact me at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.

A handwritten signature in black ink, appearing to read 'James Cosgrove', with a large, stylized initial 'J'.

James Cosgrove  
Director, Health Care

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*List of Requesters*

The Honorable Orrin G. Hatch  
Chairman  
Committee on Finance  
United States Senate

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Charles E. Grassley  
Chairman  
Committee on the Judiciary  
United States Senate

The Honorable Joseph R. Pitts  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
House of Representatives

The Honorable Michael B. Enzi  
United States Senate

## Appendix I: Comments from the Department of Health & Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

MAY 12 2015

James C. Cosgrove  
Director, Healthcare  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"MEDICARE PART B DRUGS: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals"* (GAO-15-442).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE HEALTH AND HUMAN SERVICES (HHS) ON THE  
GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT: MEDICARE PART  
B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVE TO PRESCRIBE 340B  
DRUGS AT PARTICIPATING HOSPITALS (GAO-15-442)**

The U.S. Department of Health and Human Services (HHS) has reviewed the draft for report GAO-15-442, and appreciates the opportunity to review and comment.

The intent of the 340B Drug Pricing Program (340B Program) should be clearly highlighted within the GAO report. Based on Congressional report language,<sup>1</sup> the program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as “covered entities” in order to stretch scarce federal resources. HHS’s authority regarding the 340B Program is limited by statute and focuses on ensuring covered entities and manufacturers comply with program requirements.

GAO’s examination of Medicare Part B outpatient drug spending is a useful initial analysis of differences in spending between 340B disproportionate share hospitals (DSH) and non-340B hospitals. However, we are concerned that the report characterizing spending on Part B in 340B DSH hospitals as “excess,” “potentially inappropriate,” and “more...than necessary to treat Medicare Part B beneficiaries” is not supported by the study methodology. GAO’s study, which only examined average differences in per-beneficiary spending by hospital type, did not examine any patient differences in terms of outcomes or quality. While we acknowledge that one possible interpretation for higher spending in 340B hospitals is (as asserted by GAO) that the higher spending may be unnecessary or excess, it is also possible that higher volume of physician-administered drugs can lead to better clinical outcomes. To identify whether patients did or did not receive the necessary level of care would require further analysis that accounts for patient-level characteristics and examines outcomes and quality of care.

GAO’s study looked at average risk scores of patients at 340B DSH and non-340B hospitals to examine if differences in spending may be related to differences in the health status of beneficiaries. The study found that “the health status of outpatient beneficiaries was generally similar at 340B and non-340B hospitals...the average risk score...of these outpatient beneficiaries at 340B DSH hospitals was 1.50, while it was 1.45 at non-340B DSH hospitals and 1.36 at other non-340B hospitals.” Based on this analysis GAO’s study states that “the differences we found were likely not explained by the health status of the outpatients served.” HHS has concerns that this claim is not supported by the analysis for two reasons. First, the average risk scores were higher at 340B DSH hospitals (1.50 vs. 1.45 and 1.36). HHS believes that this could represent a meaningful difference in health status of beneficiaries. Second, based on the initial findings of differences in average risk scores, further analysis of the differences in spending by risk score seems warranted (e.g., stratifying drug spending by risk score at 340B and non-340B hospitals). Without additional examination of differences in risk scores of patients at 340B and non-340B hospitals, thus differences in spending were not explained by differences in patient health status.

<sup>1</sup> The H. Report for the 340B Program states the following intent: “[i]n giving these ‘covered entities’ access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

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## Appendix II: GAO Contact and Staff Acknowledgments

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### GAO Contact

James Cosgrove, (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov)

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### Staff Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Gerardine Brennan, Assistant Director; George Bogart; Lori Fritz; Daniel Lee; Elizabeth T. Morrison; Aubrey Naffis; and Daniel Ries.

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## Appendix III: Accessible data

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### Agency Comment Letter

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Text of Appendix I: Comments from the Department of Health & Human Services

Page 1

James C. Cosgrove Director, Healthcare

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548

Dear Mr. Cosgrove:

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The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim Esquea

Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS OF THE HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT: MEDICARE PART B DRUGS: ACTION NEEDED TO REDUCE FINANCIAL INCENTIVE TO PRESCRIBE 340B DRUGS AT PARTICIPATING HOSPITALS (GAO-15-442)

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## Public Affairs

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