

M A Y 2 0 1 5

**REPORT TO THE CONGRESS**

---

Overview of the  
340B Drug  
Pricing Program

M A Y 2 0 1 5

**REPORT TO THE CONGRESS**

---

Overview of the  
340B Drug  
Pricing Program

**MEDPAC** Medicare  
Payment Advisory  
Commission

425 I Street, NW • Suite 701 • Washington, DC 20001  
(202) 220-3700 • Fax: (202) 220-3759 • [www.medpac.gov](http://www.medpac.gov)



## Acknowledgments

---

The Commission benefited from the individuals who generously offered their time and knowledge. Our thanks to the following: Gerardine Brennan, James Cosgrove, Beth Feldpush, Erin Hertzog, Krista Pedley, John Rigg, David Tawes, Maureen Testoni, and Laurel Todd. The Commission would also like to thank Hannah Fein, Mary Gawlik, and Melissa Lux for their help editing this report.



---

## **Executive summary**

---



## Executive summary

---

The 340B Drug Pricing Program allows certain hospitals and other health care providers (“covered entities”) to obtain discounted prices on “covered outpatient drugs” (prescription drugs and biologics other than vaccines) from drug manufacturers. Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid. The discounts are substantial. The Health Resources and Services Administration (HRSA), which manages the program, estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year 2013. According to HRSA, the intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients (Health Resources and Services Administration 2014e). HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. Although the ceiling prices are proprietary, we estimated that, on average, hospitals in the 340B program receive a minimum discount of 22.5 percent of the average sales price for drugs paid under the outpatient prospective payment system.

To be eligible for 340B discounted prices, a covered outpatient drug must be provided by a covered entity to its patients. Several types of hospitals as well as clinics that receive certain federal grants from the Department of Health and Human Services (HHS) (e.g., federally qualified health centers and Ryan White grantees) may enroll in the program as covered entities. Eligible hospitals include disproportionate share (DSH) hospitals, critical access hospitals (CAHs), rural referral centers, sole community hospitals, children’s hospitals, and freestanding cancer hospitals. Each eligible hospital must be owned by a state or local government, be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid. Each type of eligible hospital except for CAHs must have a minimum DSH adjustment percentage (which is based on the share of a hospital’s inpatients who are Medicaid and low-income Medicare patients).

The 340B program has grown substantially during the past decade. Covered entities and their affiliated sites spent over \$7 billion to purchase 340B drugs in 2013, three times the amount spent in 2005. The number of hospital organizations (a single organization includes a hospital and all of its eligible affiliated sites) participating in 340B grew from 583 in 2005 to 1,365 in 2010 and to 2,140 in 2014. The increase from 2010 to 2014 was driven by growth in the number of CAHs and other types of hospitals that became eligible for 340B in 2010 through the Patient Protection and Affordable Care Act of 2010 (PPACA). In 2014, about 45 percent of all Medicare acute care hospitals—including CAHs—participated in the 340B program.

Medicare Part B pays for certain 340B drugs provided by covered entities to beneficiaries, such as drugs used to treat cancer and rheumatoid arthritis. Medicare pays the same amounts for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to



purchase outpatient drugs at steep discounts. From 2004 to 2013, Medicare spending in nominal dollars for Part B drugs at hospitals that participate in 340B grew from \$0.5 billion to \$3.5 billion, or 543 percent. Hospitals in the 340B program accounted for 22 percent of Medicare spending for Part B drugs at all Medicare acute care hospitals in 2004, growing to 48 percent in 2013. Some of this growth was due to an increase in the number of participating hospitals as a result of PPACA, which expanded the types of hospitals eligible for 340B. However, most of the growth in Medicare spending occurred among hospitals that were in the 340B program before PPACA. For example, 733 hospitals in the 340B program received Medicare payments for separately payable Part B drugs in both 2008 and 2013. These hospitals accounted for 73 percent of the growth in Medicare spending for separately payable Part B drugs at all 340B hospitals from 2008 to 2013.

Covered entities are allowed to provide 340B drugs only to individuals who are “patients” of the entity, but the statute does not define who should be considered a patient of the entity. HRSA has outlined three criteria for who is an eligible patient, but some of these criteria are not clearly defined. As noted by the Government Accountability Office, the lack of specificity in the guidelines for who is an eligible patient makes it possible for covered entities to interpret this term either too broadly or too narrowly. HRSA plans to clarify the definition of eligible patients in proposed guidance in 2015.

Covered entities can purchase 340B drugs for all eligible patients, including patients with Medicare or private insurance, and generate revenue if the reimbursements for the drugs from payers exceed the discounted prices they pay for the drugs. Because the 340B statute does not restrict how covered entities can use this revenue, entities can use these funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose.<sup>1</sup> HRSA does not have statutory authority to track how covered entities use this revenue.

According to guidance issued by HRSA in 2010, a covered entity may provide 340B drugs through an in-house pharmacy and one or more community pharmacies that are not part of the entity (contract pharmacies). According to HRSA, 73 percent of entities dispense 340B drugs only through an in-house pharmacy; 27 percent contract with outside pharmacies to dispense these drugs. Subsequent to HRSA’s guidance, between 2010 and 2014, the number of unique pharmacies serving as 340B contract pharmacies increased by 154 percent (Clark et al. 2014).

In recent years, there has been a debate between 340B hospitals and drug manufacturers about the proper scope of the program. Manufacturers have questioned whether all of the hospitals in the program need discounted drugs and whether the criteria for hospitals to participate in the program—such as the DSH adjustment percentage—should be changed. Manufacturers seek to narrow the program’s focus to helping patients who are poor and uninsured gain access to outpatient drugs. In contrast, 340B hospitals seek to preserve the current criteria for eligibility for the program and their ability to use revenue generated through the program without restrictions. They argue that the program is essential for maintaining the full range of services they provide to low income and other patients in their communities. ■

---

**Overview of the  
340B Drug Pricing Program**

---



---

## **Description of the 340B program**

---

The 340B Drug Pricing Program (“340B program”) allows certain hospitals and other health care providers (“covered entities”) to obtain discounted prices on outpatient drugs from manufacturers. The program was created in 1992 after the adoption of the Medicaid Drug Rebate Program and is named for the provision in the Public Health Service Act that authorizes it. According to the Health Resources and Services Administration (HRSA), which administers the program, the intent of the 340B program is to allow covered entities to stretch scarce federal resources as far as possible to provide more care to more patients (Health Resources and Services Administration 2014e).<sup>2</sup>

Medicare Part B pays for certain 340B drugs provided by covered entities to beneficiaries; these are typically physician-administered drugs used to treat conditions such as cancer and rheumatoid arthritis. Under the outpatient prospective payment system (OPPS), Medicare’s payment rate for Part B drugs is the same for 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at steep discounts. Similarly, beneficiaries’ cost-sharing liability is the same at both types of hospitals. Medicare Part D plans also pay for some 340B drugs—typically oral drugs—dispensed to beneficiaries by covered entities and community pharmacies that contract with covered entities.

### **Program rules for drug manufacturers**

There are strong incentives for drug manufacturers to participate in the program. Manufacturers must offer 340B discounts to covered entities to have their drugs covered under Medicaid. Therefore, most manufacturers of outpatient drugs participate in the program (Government Accountability Office 2011). In addition to selling drugs to covered entities at a discounted price, manufacturers are prohibited from distributing drugs in ways that discriminate against covered entities. For example, manufacturers may not impose requirements on drug sales (such as minimum purchase amounts) that would discourage entities from participating in the program (Health Resources and Services Administration 2012). In addition, if there is a shortage of a particular drug, manufacturers must treat 340B providers the same as non-340B providers. In other words, they are not permitted to limit drug sales to 340B providers unless they also limit sales to other providers.

### **Program rules for covered entities**

The statute specifies which types of providers are eligible to participate in the 340B program (see text box, pp. 4–5). To participate, a provider must register with HRSA, be approved by the agency, and follow program requirements. Several types of hospitals as well as clinics that receive certain federal grants from the Department of Health and Human Services (HHS) are eligible for the program. All hospitals participating in 340B must have a minimum disproportionate share (DSH) adjustment percentage (except for critical access hospitals, or CAHs) and meet additional criteria. The DSH adjustment percentage is based on the share of a hospital’s inpatients who are Medicaid and low-income Medicare patients.

## Several types of providers are eligible to participate in the 340B program

Six types of hospitals and 10 types of clinics that receive certain federal grants (or “federal grantees”) are eligible by statute to participate in the 340B Drug Pricing Program. As of 2014, over 28,000 providers and affiliated sites participated in the program. A single provider (known as a “covered entity”) may have multiple sites that participate in the program as long as each site is an integral part of the covered entity, is registered with the Health Resources and Services Administration (HRSA), and follows the program’s rules. For example, a hospital may own and operate multiple satellite clinics that are not located in the main hospital building; these clinics can participate in 340B if they are an integral part of the hospital and are reimbursable sites on the hospital’s most recently filed Medicare cost report. However, if a single organization owns multiple hospitals and each hospital in the organization files its own Medicare cost report, each individual hospital must meet the program’s requirements, register separately with HRSA, and be approved by HRSA to participate in the program.

In 2014, there were 14,061 hospitals and affiliated sites in the 340B program. These hospitals and affiliated sites comprised 2,140 hospital organizations (a hospital and all of its affiliated sites count as one hospital organization). Of the hospitals in 340B that year, 45 percent were disproportionate share (DSH) hospitals and 44 percent were critical access hospitals (CAHs). To qualify for 340B, DSH hospitals must have a DSH adjustment percentage greater than 11.75 and meet other criteria, described below.<sup>3</sup> Outpatient sites affiliated with a hospital do not affect the hospital’s DSH adjustment percentage because the percentage is based on a hospital’s mix of inpatients. CAHs are not required to have a minimum DSH adjustment percentage to qualify for 340B, but must meet other criteria, described below.<sup>4</sup>

*(continued next page)*

### **Type of drugs covered by program**

The 340B program applies to “covered outpatient drugs,” which are defined as prescription drugs and biologics other than vaccines (Social Security Act, Section 1927 (k)).<sup>5</sup> This term excludes inpatient drugs and drugs that are bundled with other services (such as physician and hospital outpatient services) for payment purposes. Hospitals that were added to the program by the Patient Protection and Affordable Care Act of 2010 (PPACA)—such as CAHs—are excluded by statute from purchasing orphan drugs (drugs designated by the Secretary for a rare disease or condition) under 340B. This provision does not apply to DSH hospitals or other covered entities that were eligible for the program before 2010. According to HRSA’s interpretation, this provision excludes orphan drugs only when they are used for the rare disease or condition for which they received an orphan designation (Health Resources and Services Administration 2014e). The provision does not apply when orphan drugs are used for other indications.<sup>6</sup>

## Several types of providers are eligible to participate in the 340B program (cont.)

In addition to DSH hospitals and CAHs, four other hospital types are eligible to participate in 340B:

- children's hospitals with a DSH adjustment percentage greater than 11.75,
- sole community hospitals with a DSH adjustment percentage equal to or greater than 8.0,
- rural referral centers with a DSH adjustment percentage equal to or greater than 8.0, and
- freestanding cancer hospitals with a DSH adjustment percentage greater than 11.75.

If the DSH adjustment percentage of a 340B hospital falls below the minimum, the hospital must inform HRSA and HRSA will terminate the hospital from the 340B program.

The Commission has found that the amount of Medicare DSH payments a hospital receives is not a good proxy for the amount of uncompensated care (charity care and bad debt) it provides (Medicare Payment Advisory Commission 2007). Our analysis showed that the top 10 percent of hospitals in terms of uncompensated care provided 41 percent of all uncompensated care but received only 10 percent of all DSH payments. By contrast, the bottom 10 percent of hospitals provided less than 2 percent of all uncompensated care but received about 8 percent of DSH payments.

All six hospital types must be owned by a state or local government, be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.<sup>7</sup>

In 2014, 14,211 federal grantees and affiliated sites participated in 340B. The most common types of federal grantees in the program are federally qualified health centers, which offer primary and preventive care, and family planning clinics (Government Accountability Office 2011). Other grantees include organizations that target specified diseases such as sexually transmitted diseases, tuberculosis, AIDS, and hemophilia. ■

Hospitals in the 340B program that are subject to the orphan drug exclusion are responsible for ensuring that orphan drugs purchased through the 340B program are not used for the rare condition or disease for which they received an orphan designation (Health Resources and Services Administration 2014g). These hospitals must maintain auditable records that track their use of orphan drugs by indication. Some hospitals subject to the orphan drug exclusion have decided not to purchase orphan drugs through the 340B program because they cannot or do not wish to maintain auditable records to demonstrate compliance with the exclusion.

## Formula for calculating 340B ceiling prices

The Health Resources and Services Administration (HRSA) calculates a 340B ceiling price for each covered outpatient drug as the difference between the drug's average manufacturer price (AMP) and its unit rebate amount (URA). HRSA calculates URAs using a statutory formula that is based on the formula used to calculate Medicaid drug rebates, which is specified in the Social Security Act (SSA), Section 1927. The basic formula for ceiling prices is:

$$\text{Ceiling price} = (\text{AMP} - \text{URA}) \times \text{drug package size.}$$

AMP represents the average price paid to a manufacturer by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from a manufacturer. AMP excludes prompt-pay discounts, bona fide services fees paid by manufacturers to wholesalers or retail pharmacies, direct sales to federal purchasers, and sales to 340B covered entities.<sup>8</sup> Manufacturers participating in Medicaid are required to report AMP to the Secretary, and these prices are confidential. The URA varies by type of drug.

- For single-source and innovator multiple-source drugs, the URA is the greater of (AMP – the “best price”) or (AMP × 23.1 percent).<sup>9</sup> The best price represents the best price available from the manufacturer to any wholesaler, retailer, provider,

*(continued next page)*

### 340B entities receive substantial discounts on drugs

The discounts available through the program for covered outpatient drugs are substantial. HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year 2013 (Health Resources and Services Administration 2015a).

The 340B ceiling price represents the maximum price a manufacturer can charge for a 340B drug. However, covered entities that participate in HRSA's Prime Vendor Program (PVP) often pay less than the ceiling price. HRSA calculates a 340B ceiling price for each covered outpatient drug as the difference between the drug's average manufacturer price (AMP) and its unit rebate amount (URA). HRSA calculates URAs using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The statutory formula for the URA varies based on whether the drug is a single-source or innovator, multiple-source drug (e.g., a brand-name drug); a noninnovator multiple-source drug (e.g., a generic drug); or a clotting factor or exclusively pediatric drug (see text box). According to statute, HRSA is allowed to disclose ceiling prices to covered entities but not to the general public.

Although the ceiling prices and key data used to calculate them are proprietary, we attempted to estimate the lower bound of the average discount that 340B hospitals receive for drugs paid under the OPDS (these are primarily physician-administered drugs used to treat conditions such



## Formula for calculating 340B ceiling prices (cont.)

HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, 340B-covered entities, Medicare Part D plans, and certain other purchasers. Manufacturers report best price data to the Secretary, and this information is confidential. If AMP has grown faster than the rate of inflation (as measured by the consumer price index for all urban consumers (CPI-U)) since the drug's market date, an additional rebate is applied to AMP. This inflation rebate ensures that the value of the rebate is not eroded by growth in the drug's price. According to the Congressional Budget Office (CBO), AMP and the average retail price of brand-name oral drugs generally rise faster than the CPI-U (Congressional Budget Office 2014).<sup>10</sup> CBO found that the inflation rebate accounts for about half of the total rebates for brand-name oral drugs in Medicaid. We do not have information on the inflation rebate's share of the total rebates for physician-administered drugs.

- For noninnovator multiple-source drugs, the URA equals  $AMP \times 13$  percent.
- For clotting factors or exclusively pediatric drugs, the URA is the greater of ( $AMP - \text{the best price}$ ) or ( $AMP \times 17.1$  percent). If AMP has grown faster than the rate of inflation since the drug's market date, an additional rebate is applied to AMP. ■

as cancer and rheumatoid arthritis). We estimate that the lower bound of the average discount is 22.5 percent of the average sales price for drugs paid under the OPPS. Appendix A describes our method for calculating this estimate (p. 25).

The 340B statute required HRSA to establish a PVP to distribute 340B drugs to covered entities; entities have the option to participate in the PVP. HRSA currently contracts with a company called Apexus to manage the PVP. By pooling the purchasing power of covered entities, Apexus negotiates subceiling prices on many 340B drugs with manufacturers, which allows covered entities to pay less than the ceiling price (Health Resources and Services Administration 2014d). By the end of fiscal year 2013, Apexus had over 7,000 drugs under contract, with an estimated average savings of 10 percent below the ceiling price (Department of Health and Human Services 2014). Apexus also negotiates discounts on other pharmacy products and services not eligible for 340B pricing, such as vaccines, billing software, and contract pharmacy vendors. As of April 2014, about 82 percent of covered entities participated in the PVP and accounted for \$5 billion in 340B drug purchases (Apexus 2014). DSH hospitals, children's hospitals, and freestanding cancer hospitals that participate in 340B are prohibited from purchasing covered outpatient drugs through a group purchasing organization.

### **Covered entities may provide 340B drugs only to eligible patients**

Covered entities are allowed to provide 340B drugs only to individuals who are eligible patients of the entity, but the statute does not define who should be considered "a patient of the entity."



HRSA's current guidance, released in 1996, states three criteria for individuals to be considered eligible patients:

- the covered entity must have a relationship with the individual, which HRSA defines as maintaining the individual's health care records;
- the individual receives health care services from a health care professional who is employed by the entity or who provides care under contractual or other arrangements (e.g., referral for consultation), such that responsibility for the individual's care remains with the entity;<sup>11</sup> and
- the individual receives a service or range of services from the covered entity that is consistent with the service or services for which grant funding or federally qualified health center look-alike status has been provided (this criterion does not apply to hospitals) (Health Resources and Services Administration 1996).

### **The 340B statute does not restrict how covered entities can use revenue from the 340B program**

Covered entities can purchase 340B drugs for all eligible patients, including patients with Medicare and private insurance, and generate revenue if the reimbursements for the drugs exceed the 340B prices they pay for the drugs. Because the 340B statute does not restrict how covered entities can use this revenue, entities can use these funds to expand the number of patients served, increase the scope of services offered to low-income and other patients, invest in capital, cover administrative costs, or for any other purpose.<sup>12</sup> HRSA does not have statutory authority to track how entities use this revenue.

In 2011, the Government Accountability Office (GAO) interviewed a sample of 29 covered entities about the extent to which they generated revenue from the 340B program (Government Accountability Office 2011). The sample was selected to represent five types of covered entities in five states and is not generalizable.<sup>13</sup> About half the entities interviewed by GAO reported that they generated revenue that exceeded their drug costs.<sup>14</sup> However, a few entities reported that their ability to generate revenue from private insurers (including Medicare Part D plans) was decreasing because some insurers were reducing their payment rates for drugs billed by 340B providers. The covered entities that generated revenue through the 340B program stated that they used it to serve more patients and provide additional services, such as additional locations, patient education programs, and case management. However, there is no statutory requirement for covered entities to document how they use revenue from the program.

The Safety Net Hospitals for Pharmaceutical Access (SNHPA), which represents hospitals participating in the 340B program, surveyed its member hospitals about how they used revenue generated through the program (Wallack and Herzog 2011). Hospitals stated that they used the revenue for a variety of purposes, such as reducing the price of drugs paid by patients, supporting medication therapy management programs, providing uncompensated care, and maintaining broader hospital operations.<sup>15</sup>

## **Covered entities must ensure that manufacturers do not provide duplicate discounts on the same drugs**

Covered entities must be able to ensure that manufacturers do not provide a discounted 340B price and a Medicaid drug rebate for the same drug (duplicate discounts) (Health Resources and Services Administration 2014f).<sup>16</sup> To avoid duplicate discounts, a covered entity chooses whether to “carve out” or “carve in” Medicaid patients. If the entity carves out Medicaid patients, it provides non-340B drugs to these patients and the state Medicaid program is permitted to claim rebates on the drugs.<sup>17</sup> If the entity carves in Medicaid patients, it provides 340B drugs to these patients and the state Medicaid program is not allowed to claim the rebates. HRSA maintains a file of covered entities that carve in Medicaid patients to help state Medicaid agencies identify claims for 340B drugs and prevent duplicate discounts.<sup>18</sup> In 2013, 65 percent of hospital sites and 37 percent of nonhospital sites carved in Medicaid patients (i.e., they provided 340B drugs to Medicaid patients).

State Medicaid programs have different reimbursement policies for covered entities that provide 340B drugs to Medicaid patients. According to interviews by GAO with 18 covered entities in 2011, most reported that Medicaid reimbursement for 340B drugs was based on their actual acquisition cost (AAC) of the drugs plus a dispensing fee (Government Accountability Office 2011). Meanwhile, some covered entities reported that they received Medicaid payment rates above AAC for 340B drugs; in essence, these providers retained some of their savings from 340B drugs and shared the rest with the state. In 2011, HHS’s Office of Inspector General (OIG) found that about half of states had policies that required covered entities to bill Medicaid at AAC for 340B drugs (Office of Inspector General 2011).<sup>19</sup>

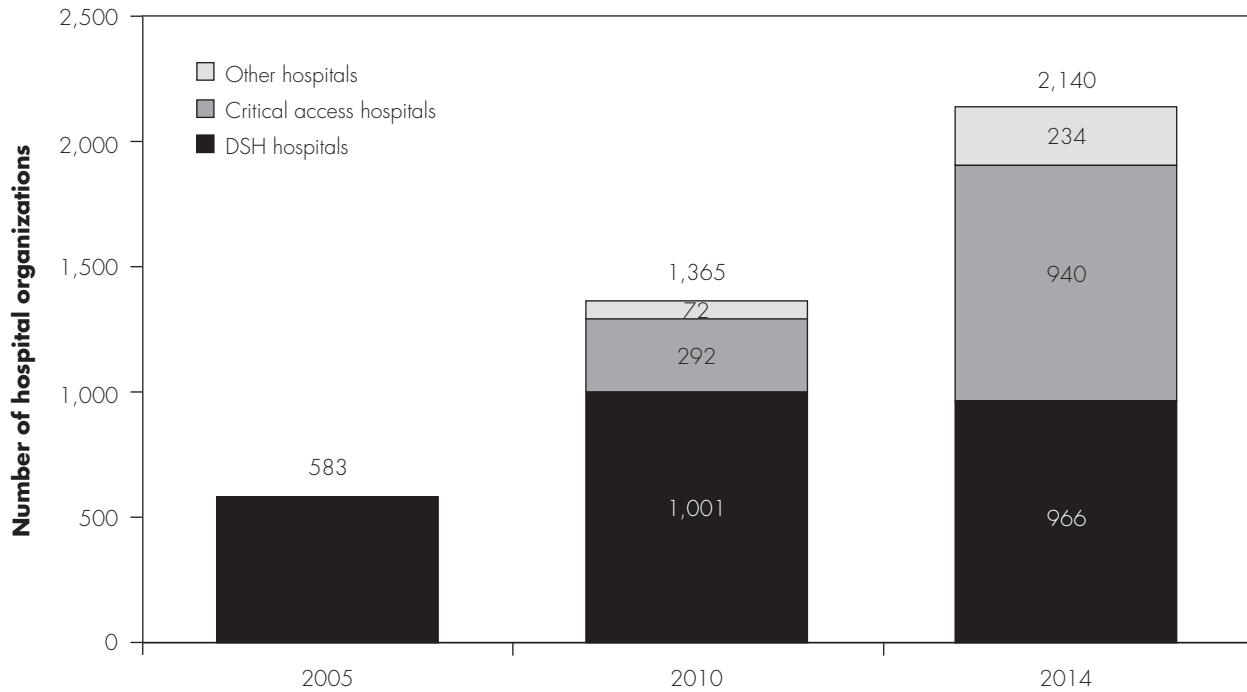
## **About one-quarter of covered entities use contract pharmacies to provide 340B drugs**

A covered entity may provide 340B drugs through an in-house pharmacy and one or more pharmacies that are not part of the entity (contract pharmacies). According to HRSA, 73 percent of entities dispense 340B drugs through an in-house pharmacy and 27 percent contract with outside pharmacies to dispense these drugs. Although the 340B statute does not explicitly mention contract pharmacies, HRSA has issued guidance on this topic. Until 2010, covered entities were allowed to provide 340B drugs only through an in-house pharmacy or a single outside pharmacy.<sup>20</sup> In 2010, however, HRSA changed its guidelines to state that covered entities could use multiple contract pharmacies to provide 340B drugs as long as the entities comply with program rules aimed at preventing the diversion of drugs to non-eligible patients and duplicate discounts (Health Resources and Services Administration 2010). HRSA’s rationale for permitting multiple contract pharmacies was to increase patient access to 340B drugs. The agency concluded that the prior guidelines limiting covered entities to either an in-house pharmacy or a single outside pharmacy restricted the flexibility of entities in meeting their patients’ needs.

Since HRSA changed its guidelines in 2010, there has been rapid growth in the number of contract pharmacies. Between 2010 and 2014, the number of unique pharmacies serving as contract pharmacies increased by 154 percent (Clark et al. 2014). By August 31, 2014, over 20 percent of retail pharmacies were acting as contract pharmacies (Clark et al. 2014). OIG found that contract pharmacy arrangements created difficulties for covered entities in preventing the diversion of drugs and duplicate discounts (Office of Inspector General 2014).

**Figure 1**

**The number of hospital organizations participating in the 340B program more than tripled, 2005–2014**



Note: DSH (disproportionate share). Although each hospital may include multiple sites, this figure counts only the number of unique hospital organizations. Other hospitals include freestanding cancer hospitals, children’s hospitals, rural referral centers, and sole community hospitals. Data are from the third quarter of each year.

Source: Health Resources and Services Administration database of 340B covered entities.

**The 340B program has grown substantially over the past decade**

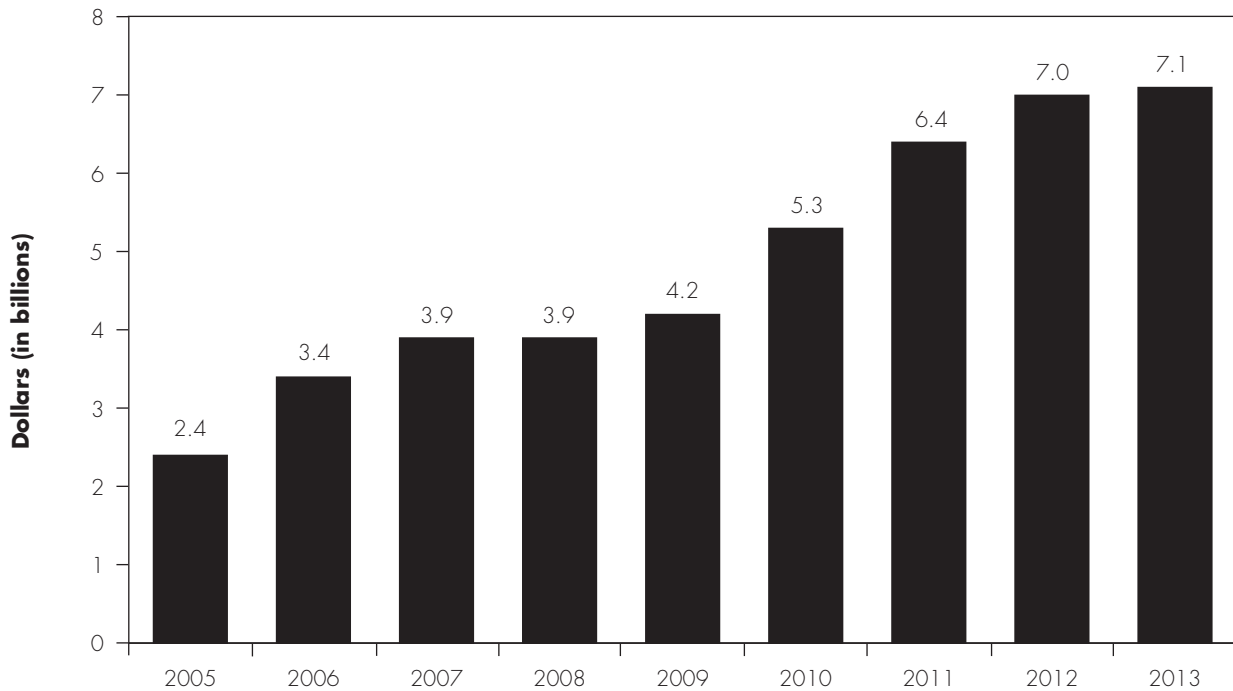
Since 2005, there has been a significant increase in the number of hospitals participating in the 340B program and the amount of money spent by covered entities to purchase 340B drugs. In addition, Medicare spending for Part B drugs at hospitals that participate in 340B has grown rapidly since 2004. In recent years, GAO and OIG have raised concerns about HRSA’s oversight of the program, especially given its growth over time (Government Accountability Office 2011, Government Accountability Office 2015, Office of Inspector General 2014). HRSA has improved its oversight but has not yet addressed some areas of concern. HRSA plans to issue proposed regulations and guidance in key areas in 2015.

**The number of hospitals in the 340B program more than tripled from 2005 to 2014**

From 2005 to 2010, the number of hospital organizations participating in the 340B program grew from 583 to 1,365 (134 percent) (Figure 1).<sup>21</sup> Most of this increase reflects growth during that period in the number of DSH hospitals, from 583 to 1,001. DSH hospitals must have a DSH

**Figure 2**

**Amount spent by covered entities on 340B drugs tripled, 2005–2013**



Note: Includes all 340B drugs purchased by covered entities from wholesalers and some (but not all) 340B drugs purchased directly from manufacturers. The Health Resources and Services Administration estimates that these numbers account for 90 percent to 95 percent of total 340B sales.

Source: Apexus.

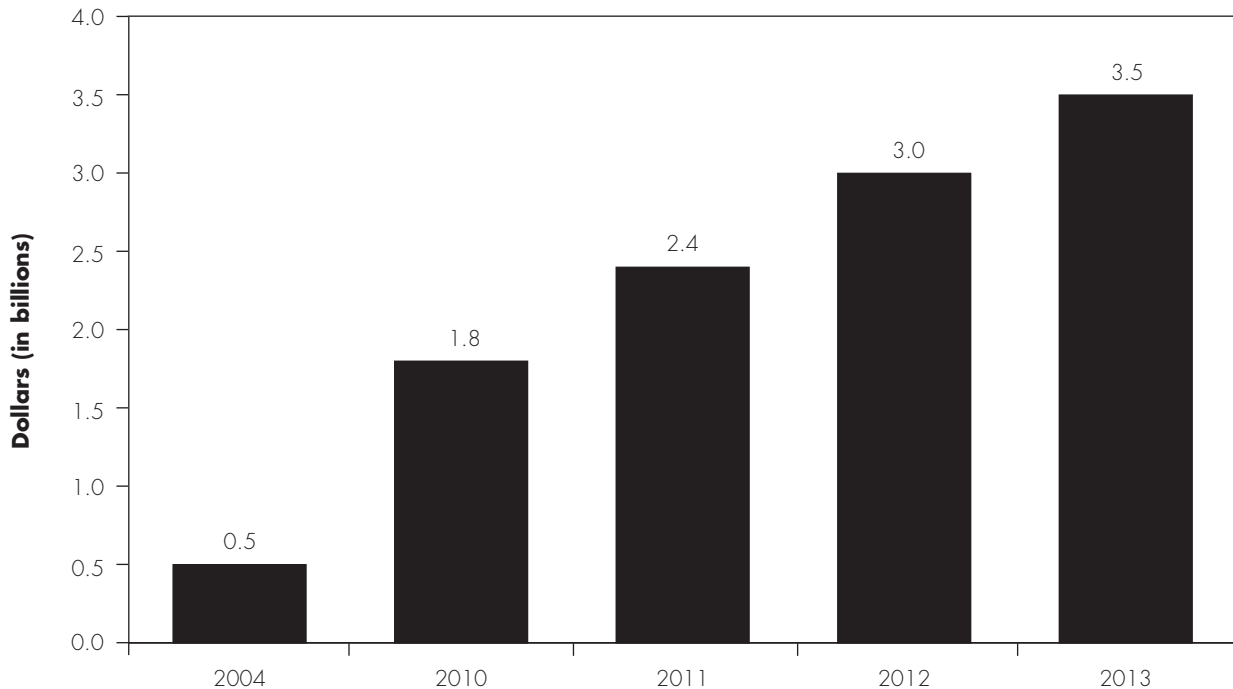
adjustment percentage greater than 11.75 and meet other criteria, described in the text box on pp. 4–5. From 2010 to 2014, the number of hospital organizations in the program grew by 57 percent to 2,140 (Figure 1). This increase was driven by growth in the number of CAHs and other types of hospitals (e.g., rural referral centers (RRCs) and sole community hospitals (SCHs)) that became eligible for 340B through PPACA in 2010.<sup>22</sup> The number of participating DSH hospitals declined slightly during this period from 1,001 to 966. In 2014, about 45 percent of all Medicare acute care hospitals participated in the 340B program, including 71 percent of CAHs. There are 340B hospitals in every state and the District of Columbia.

**The amount of money spent by covered entities on 340B drugs tripled from 2005 to 2013**

Covered entities and their affiliated sites spent over \$7 billion on 340B drugs in 2013, three times the amount spent in 2005 (Figure 2).<sup>23</sup> This figure includes both oral and physician-administered drugs and refers to the amount spent by covered entities to purchase 340B drugs, not the payments received by entities from Medicare, private insurers, and other payers for these drugs. It includes all covered entities (hospitals as well as clinics that receive certain federal grants

**Figure 3**

**Medicare spending on separately payable Part B drugs at hospitals that participate in the 340B program, 2004–2013**



Note: Includes total Medicare spending (program spending and beneficiary cost sharing) for separately payable Part B drugs. Because some 340B hospitals do not provide 340B drugs to Medicaid beneficiaries, we excluded spending for drugs provided to patients of these hospitals who were eligible for both Medicare and Medicaid (dual eligibles). Critical access hospitals and certain other hospitals that participate in 340B are excluded by statute from purchasing orphan drugs at 340B prices. According to the Health Resources and Services Administration’s (HRSA’s) interpretation of the statute, this provision excludes orphan drugs only when they are used for the rare disease or condition for which they received an orphan designation (the orphan drug exclusion). Because claims data do not identify the indication for which a drug was used, we could not determine whether an orphan drug used by one of these hospitals was eligible for 340B discounted prices. Therefore, we excluded spending for all orphan drugs used by hospitals that are subject to the orphan drug exclusion. We also excluded spending on vaccines because they are excluded from the 340B program.

Source: MedPAC analysis of Medicare claims data from CMS and HRSA’s database of 340B covered entities.

from HHS). By comparison, total U.S. drug spending grew by 33 percent from 2005 to 2013 (IMS Institute for Healthcare Informatics 2014, IMS Institute for Healthcare Informatics 2012). During that period, spending by covered entities on 340B drugs increased from 1.0 percent of total U.S. drug spending to 2.2 percent. As of the first quarter of 2015, DSH hospitals accounted for 78 percent of all spending by covered entities on 340B drugs (Health Resources and Services Administration 2015b).

**Medicare spending for Part B drugs at hospitals that participate in 340B has grown rapidly since 2004**

From 2004 to 2013, Medicare spending in nominal dollars for Part B drugs at hospitals that participate in 340B grew from \$0.5 billion to \$3.5 billion, or 543 percent (Figure 3).<sup>24</sup> Hospitals in the 340B program accounted for 22 percent of Medicare spending for Part B drugs at all acute

care hospitals in 2004, growing to 41 percent in 2010 and 48 percent in 2013.<sup>25</sup> DSH hospitals that participate in 340B accounted for most of the Medicare payments for Part B drugs at 340B hospitals—\$3.4 billion in 2013. Other 340B hospitals received about \$100 million in payments for Part B drugs. These numbers include total Medicare spending (program spending and beneficiary cost sharing) for separately payable Part B drugs.<sup>26</sup> The text box (p. 14) compares spending growth for outpatient chemotherapy drugs at 340B hospitals and non-340B hospitals.

Some of the growth in Medicare spending for Part B drugs at 340B hospitals from 2004 to 2013 was due to an increase in the number of participating hospitals as a result of PPACA, which expanded the types of hospitals eligible for 340B. However, most of the growth in Medicare spending occurred among hospitals that were in the 340B program before PPACA. For example, 733 hospitals in the 340B program received Medicare payments for separately payable drugs in both 2008 and 2013. These hospitals accounted for 73 percent of the growth in Medicare spending for separately payable drugs at all 340B hospitals from 2008 to 2013.

### **Concerns about HRSA’s oversight of 340B program**

Concerns have been raised by GAO and OIG about HRSA’s oversight of the 340B program with regard to several key areas:

- the definition of a patient of a covered entity,
- the criteria for hospital eligibility for the program,
- the compliance of covered entities and manufacturers with program requirements, and
- the use of contract pharmacies by covered entities (Government Accountability Office 2015, Government Accountability Office 2011, Office of Inspector General 2015, Office of Inspector General 2014).<sup>27</sup>

HRSA has improved its oversight in the last few years but has not yet addressed some key issues. HRSA plans to issue proposed regulations and guidance in 2015 to clarify important requirements and strengthen program integrity.

### **Clarifying who is considered a patient of a covered entity**

Covered entities are allowed to provide 340B drugs only to individuals who are patients of the entity, but the statute does not define who should be considered “a patient of the entity.” HRSA’s guidance on who is considered an eligible patient is described on p. 8. According to part of the guidance, the individual must receive health care services from a health care professional who is employed by the entity or who provides care under contractual or other arrangements, such that responsibility for the individual’s care remains with the entity. However, HRSA has not clarified the meaning of “other arrangements” or “responsibility for the individual’s care.” The lack of specificity in the guidelines for who is an eligible patient makes it possible for covered entities to interpret this term either too broadly or too narrowly (Government Accountability Office 2011). For example, HRSA has expressed concern that some covered entities may consider individuals to be eligible patients even when the entity does not have actual responsibility for their care



## Medicare spending for outpatient chemotherapy drugs and drug administration services increased faster at 340B hospitals than non-340B hospitals

**W**e examined Medicare Part B spending for chemotherapy drugs and drug administration services provided in hospital outpatient departments (OPDs) at 340B hospitals and non-340B hospitals between 2008 and 2012.<sup>28</sup> To examine changes among 340B and non-340B hospitals, we compared hospitals that participated in the 340B program for all five years of the analysis (2008 through 2012) with hospitals that did not participate in 340B at any time during this period. Looking solely at hospitals that were in the 340B program for the entire five-year period allowed us to separate spending growth for the same set of hospitals from spending growth that reflects an increase in the number of hospitals participating in the 340B program. Medicare spending grew faster among hospitals that participated in the 340B program for all five years than among hospitals that did not participate in the 340B program at any time during this period (19.1 percent per year vs. 13.9 percent per year, respectively). Among all OPDs (whether or not they were part of a 340B hospital), spending for chemotherapy drugs and drug administration services grew by 16.1 percent per year. Meanwhile, spending for the same set of drugs and services provided in freestanding physicians' offices rose by only 1.1 percent per year.

Some stakeholders and researchers claim that the ability of 340B hospitals to purchase oncology drugs at significant discounts has led many of these hospitals to acquire community oncology practices and convert them to hospital-based settings (Conti and Bach 2014). There are other factors—besides the ability of 340B hospitals to purchase drugs at lower prices—that have likely influenced this trend. Under current policy, Medicare pays more for many services in OPDs than in physicians' offices. Although the payment rates for separately payable chemotherapy drugs are the same in OPDs and physicians' offices, Medicare pays more in OPDs than in offices for drug administration services, evaluation and management office visits, and many diagnostic tests. These payment differences create a financial incentive for hospitals to purchase physician practices and convert them to OPDs without changing their location or patient mix. In addition, the increase in hospital employment of physicians has contributed to the migration of services to OPDs (Medicare Payment Advisory Commission 2013). ■

(Government Accountability Office 2011). HRSA plans to issue proposed guidance during 2015 to clarify the definition of a 340B patient (Health Resources and Services Administration 2015a).

### Clarifying the criteria for hospital eligibility for the 340B program

To be eligible for the 340B program, a hospital must be (1) owned by a state or local government, (2) be a public or nonprofit hospital that is formally delegated governmental powers by a state or local government, or (3) be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.<sup>29</sup>

Regarding the third option for eligibility, HRSA has not specified criteria for contracts between nonprofit hospitals and state or local governments, such as the amount of care that a hospital must provide to low-income patients under such a contract (Government Accountability Office 2011).<sup>30</sup> Thus, hospitals with contracts to provide a relatively small amount of care to low-income individuals could be eligible for 340B discounts, which may not have been what HRSA intended. HRSA plans to issue proposed guidance during 2015 to clarify the hospital eligibility requirements (Health Resources and Services Administration 2015a).

### **Ensuring that covered entities and manufacturers are complying with 340B program requirements**

Concerns have been raised by GAO and OIG about HRSA's ability to ensure that covered entities and manufacturers comply with the 340B program's requirements, especially given the increased participation by hospitals and greater use of contract pharmacies by entities (Government Accountability Office 2011, Office of Inspector General 2014). The growth in the number of 340B hospitals and the increased use of contract pharmacies may lead to a greater risk that 340B drugs are provided to individuals who are not patients of the entity (such activity is called "diversion") (Government Accountability Office 2011). There is greater risk of diversion in hospitals than other types of covered entities because hospital pharmacies dispense both inpatient and outpatient drugs and must ensure that inpatients do not receive 340B drugs (the program covers only outpatient drugs). Moreover, in the case of hospitals that have multiple affiliated sites, it may be difficult for hospitals to ensure that each site complies with program rules and dispenses 340B drugs only to eligible patients (Government Accountability Office 2011).

Historically, HRSA primarily relied on covered entities and manufacturers to ensure their own compliance with the 340B program (Government Accountability Office 2011). Covered entities are required to develop safeguards to maintain compliance with program rules (such as mechanisms to prevent the diversion of 340B drugs to ineligible patients), keep auditable records to demonstrate compliance, and inform HRSA if they are no longer eligible for the program or have violated program rules. Manufacturers that participate in the 340B program are required to charge covered entities at or below the ceiling price for covered outpatient drugs. However, OIG found that 340B providers were overcharged by manufacturers in the past: 14 percent of drug purchases under the program in June 2005 exceeded the ceiling prices (Office of Inspector General 2006).

HRSA has improved its oversight of covered entities in recent years by requiring that all entities recertify their compliance with program requirements each year and conducting audits of selected entities (Health Resources and Services Administration 2014b). To recertify compliance with program rules, each covered entity must annually update its information in the 340B database and sign an attestation that it complies with the requirements. HRSA has completed 295 audits of covered entities since fiscal year 2012; as of March 2015, final results from 180 audits were on HRSA's website. HRSA's completed audits identified several instances of noncompliance, such as covered entities dispensing 340B drugs to individuals who were not eligible patients (Health Resources and Services Administration 2014h). In addition to identifying specific violations among covered entities, the agency believes that these audits have a sentinel effect of encouraging other entities to focus on compliance and correct violations



(Health Resources and Services Administration 2014c). It is unclear, however, whether the relatively small number of audits that HRSA has completed since fiscal year 2012 are sufficient to ensure compliance among the 11,000 covered entities that participate in the program. In fiscal year 2014, HRSA received an additional \$6 million appropriation to expand its program integrity and oversight activities (Health Resources and Services Administration 2014b). With these resources, HRSA is conducting additional audits of covered entities (Health Resources and Services Administration 2015a).

HRSA has begun to improve its oversight of manufacturers to ensure that they are selling drugs at or below ceiling prices to covered entities. HRSA is in the process of auditing one manufacturer (in partnership with OIG) and is developing a protocol to audit additional manufacturers (Health Resources and Services Administration 2015a). HRSA is also developing a secure website to share ceiling prices with 340B providers, which the agency expects will become operational during fiscal year 2015. Covered entities will be able to use this website to ensure that they are not overcharged by manufacturers (Health Resources and Services Administration 2015a).

HRSA plans to issue two proposed rules during 2015 to improve compliance by covered entities and manufacturers with program rules (Health Resources and Services Administration 2015a). The first proposal would implement a provision in statute that enables HRSA to impose civil monetary penalties on manufacturers that intentionally overcharge a covered entity. The second proposal would establish an administrative dispute resolution process to resolve claims by covered entities that they have been overcharged for drugs and claims by manufacturers that covered entities have violated program rules.

### **Concerns about the growing use of contract pharmacies by covered entities**

The number of contract pharmacies has grown rapidly: Between 2010 and 2014, the number of unique pharmacies serving as contract pharmacies increased by 154 percent (Clark et al. 2014). According to GAO and OIG, the growth of contract pharmacy arrangements has increased the risk of diversion of 340B drugs to ineligible patients because contract pharmacies are more likely to serve patients of covered entities as well as other providers (Government Accountability Office 2011, Office of Inspector General 2014).

To prevent diversion, covered entities must identify which prescriptions filled at their contract pharmacies are considered 340B eligible. Covered entities often hire companies that use sophisticated software to identify 340B-eligible prescriptions through a variety of data sources such as patient lists, prescriber lists, clinical information, lists of eligible sites, and patient encounter data. OIG interviewed 30 covered entities and found that these providers and their vendors used different types of data and methods to identify prescriptions that were 340B eligible. As a result, different covered entities categorized similar types of prescriptions differently (i.e., as 340B eligible or non-eligible). OIG concluded that these inconsistencies in determining which prescriptions are 340B eligible may stem from a lack of clarity in HRSA's definition of which patients are eligible for 340B drugs (Office of Inspector General 2014). HRSA plans to issue proposed guidance during 2015 to clarify the definition of a 340B patient

(Health Resources and Services Administration 2015a). In addition, HRSA reviews contract pharmacy arrangements when it audits covered entities.

## **Debate about the scope of the 340B program**

In recent years, there has been a debate between 340B hospitals and drug manufacturers about the proper scope of the program. About 45 percent of all Medicare acute care hospitals participated in 340B in 2014. In addition, hospitals in 340B accounted for 48 percent of Medicare spending for Part B drugs at all acute care hospitals in 2013, up from 22 percent in 2004. There is a concern that the increase in the number of drug sales that are subject to 340B discounts will lead manufacturers to raise prices for other purchasers (Conti and Bach 2013, Government Accountability Office 2011, Hirsch et al. 2014). Manufacturers have questioned whether all of the hospitals in the program need discounted drugs and whether the criteria for hospitals to participate in the program—such as the DSH adjustment percentage—should be changed (Government Accountability Office 2011). Manufacturers seek to narrow the program’s focus to helping patients who are poor and uninsured gain access to outpatient drugs.

In contrast, 340B hospitals seek to preserve the current criteria for program eligibility and their ability to use revenue generated through the program without restrictions. They argue that the program is essential for maintaining the full range of services they provide to low-income and other patients in their communities. As support for their position, they cite the conference report that accompanied the bill that eventually became the 340B statute, which stated that the program’s intent is to enable covered entities “. . . to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” (U.S. House of Representatives 1992). ■

## Endnotes

---

- 1 Although there are no requirements under the 340B statute for how 340B revenue can be used, covered entities that are federal grantees (such as federally qualified health centers) may be required to use 340B revenue in ways that are consistent with their grant requirements. In addition, nonprofit hospitals are required to conduct a community needs assessment and document their community benefits in Internal Revenue Service tax filings.
- 2 HRSA cites language from a House Energy and Commerce Committee report on legislation that eventually became section 340B of the Public Health Service Act (U.S. House of Representatives 1992).
- 3 For 340B hospitals, the relevant part of the formula for the DSH adjustment percentage is  $5.88\% + (0.825 \times (DSH \text{ patient percentage} - 20.2\%))$ ; the DSH patient percentage is the sum of the percentage of Medicare inpatient days for patients eligible for Supplemental Security Income and the percentage of total inpatient days for patients enrolled in Medicaid. About 33 percent of hospitals paid under the inpatient prospective payment system in 2012 had a DSH adjustment percentage greater than 11.75 and were government owned or nonprofit.
- 4 About 94 percent of CAHs were government owned or nonprofit in 2012.
- 5 Covered outpatient drugs include over-the-counter drugs if they are prescribed by a physician and covered by a state Medicaid program.
- 6 HRSA issued a final rule with this interpretation on July 23, 2013, which was challenged in court by the Pharmaceutical Research and Manufacturers of America (PhRMA). On May 23, 2014, a U.S. District Court issued a ruling that vacated the orphan drug rule on the grounds that HHS lacks the authority to issue the rule as a substantive rule (*PhRMA v. HHS*, No. 13–01501 (D.D.C. May 23, 2014)). However, HRSA maintains that the decision did not invalidate HHS’s interpretation of the orphan drug exclusion. Therefore, on July 21, 2014, HRSA issued an “interpretive rule” reiterating its interpretation of the exclusion (Health Resources and Services Administration 2014e). On October 9, 2014, PhRMA filed suit challenging HRSA’s interpretive rule. This litigation is pending.
- 7 According to HRSA, a hospital is formally delegated governmental powers when a state or local government delegates a power usually exercised by the state or local government—such as the power to tax or issue government bonds—to the hospital (Health Resources and Services Administration 2013).
- 8 AMP also excludes payments from and rebates to pharmacy benefit managers, HMOs, mail-order pharmacies, insurers, hospitals, and clinics. However, if the drug is inhaled, infused, instilled, implanted, or injected and is not generally dispensed by a retail community pharmacy, the AMP includes payment from and rebates to these entities.

- 9 A single-source drug is typically a brand-name product with no available generic versions (SSA, Section 1927(k)(7)(A)). An innovator multiple-source drug is typically a brand-name product that has generic versions. A noninnovator, multiple-source drug is a generic version of any multiple-source product.
- 10 For example, between 2007 and 2010, the average retail price of brand-name drugs in Part D grew by 8.5 percent per year, on average, compared with growth of 1.7 percent per year in the CPI-U.
- 11 The individual is not considered a patient if the only service that he or she receives from the entity is the dispensing of a drug for subsequent self-administration or administration in a home setting.
- 12 Although there are no requirements under the 340B statute for how 340B revenue can be used, covered entities that are federal grantees (such as federally qualified health centers) may be required to use 340B revenue in ways that are consistent with their grant requirements. In addition, nonprofit hospitals are required to conduct a community needs assessment and document their community benefits in Internal Revenue Service tax filings.
- 13 GAO's sample included 5 DSH hospitals and 22 nonhospital providers (e.g., federally qualified health centers and family planning clinics) located in Illinois, Massachusetts, Tennessee, Texas, and Utah. GAO also interviewed two additional DSH hospitals located in other states. Entities were selected based on the types of services they provided and their level of participation in the 340B program.
- 14 GAO did not separately report its findings by type of covered entity.
- 15 SNHPA defines uncompensated care as including charity care and bad debt as well as public-payer shortfalls, which represent the loss incurred by hospitals in treating patients covered by Medicaid, State Children's Health Insurance Programs, and other state and local government indigent care programs (Safety Net Hospitals for Pharmaceutical Access 2015).
- 16 This prohibition applies to patients who are eligible for both Medicare and Medicaid because state Medicaid programs are allowed to claim rebates for these patients if they cover their Medicare cost-sharing amounts.
- 17 Some state programs require covered entities to carve out Medicaid patients so they can claim the Medicaid rebates for these patients. Most states, however, allow entities to choose whether to carve out or carve in Medicaid patients.
- 18 This file applies to drugs covered under Medicaid fee-for-service programs but not Medicaid managed care organizations (MCOs) (Health Resources and Services Administration 2014a). HRSA is working with CMS to develop policies to prevent duplicate discounts under MCOs.

- 19 This study excluded physician-administered drugs.
- 20 Before 2010, HRSA operated a demonstration program that allowed a small number of sites to use multiple outside pharmacies.
- 21 A hospital and all of its affiliated sites count as one hospital organization. Each hospital that files its own Medicare cost report must register separately with HRSA and counts as a unique organization.
- 22 Between 2010 and 2014, the number of CAHs in the 340B program increased from 292 to 940; the number of SCHs grew from 30 to 135; the number of RRCs increased from 10 to 50; and the number of freestanding cancer hospitals increased from 1 to 3.
- 23 These data are from Apexus and include all 340B drugs purchased by covered entities from wholesalers and some (but not all) 340B drugs purchased directly from manufacturers. HRSA estimates that this figure accounts for 90 percent to 95 percent of total purchases of 340B drugs.
- 24 We attempted to identify Medicare spending for 340B drugs at 340B hospitals. Because some 340B hospitals do not provide 340B drugs to Medicaid beneficiaries, we excluded Medicare spending for Part B drugs provided to patients of these hospitals who were eligible for both Medicare and Medicaid (dual eligibles). We also excluded spending on vaccines because they are excluded from the 340B program. CAHs and certain other hospitals that participate in 340B are excluded by statute from purchasing orphan drugs at 340B prices. According to HRSA's interpretation of the statute, this provision excludes orphan drugs only when they are used for the rare disease or condition for which they received an orphan designation (the orphan drug exclusion). Because claims data do not identify the indication for which a drug was used, we could not determine whether an orphan drug used by one of these hospitals was eligible for 340B discounted prices. Therefore, we excluded spending for all orphan drugs used by hospitals that are subject to the orphan drug exclusion.
- 25 Medicare spending for Part B drugs (excluding vaccines) at all acute care hospitals includes CAHs, SCHs, RRCs, freestanding cancer hospitals, and children's hospitals.
- 26 Separately payable Part B drugs in the OPPS are those that have pass-through status or had an estimated cost per day of more than \$90 in 2014. The cost per day threshold was \$80 in 2013 and \$75 in 2012.
- 27 In 2011, GAO also raised concerns that HRSA's nondiscrimination guidance, which prohibits manufacturers from distributing drugs in ways that discriminate against covered entities, was not specific enough (Government Accountability Office 2011). In response, HRSA issued updated guidance in 2012 on this topic. OIG has expressed concern about the lack of transparency in 340B ceiling prices, which prevents 340B providers and Medicaid from ensuring that they have paid the correct amount for 340B drugs (Office of Inspector

General 2015). In response, HRSA plans to develop a website to share ceiling prices with 340B providers. However, HRSA lacks statutory authority to share ceiling prices with state Medicaid programs.

- 28 Medicare spending includes program spending and beneficiary cost sharing for separately payable Part B chemotherapy drugs and drug administration services. The analysis includes hospitals paid under the outpatient prospective payment system as well as critical access hospitals, but excludes hospitals in Maryland.
- 29 In addition, hospitals (except CAHs) must have a minimum DSH adjustment percentage to be eligible for 340B.
- 30 HRSA requires a state or local government official and a hospital executive to certify that a contract exists, but does not require the hospital to submit it to HRSA for review.

## References

---

Apexus. 2014. 340B University: Las Vegas edition. Presentation. May 31.

Clark, B. L., J. Hou, C. H. Chou, et al. 2014. The 340B discount program: Outpatient prescription dispensing patterns through contract pharmacies in 2012. *Health Affairs* 33, no. 11 (November): 2012–2017.

Congressional Budget Office. 2014. *Competition and the cost of Medicare's prescription drug program*. Washington, DC: CBO.

Conti, R. M., and P. B. Bach. 2014. The 340B Drug Discount Program: Hospitals generate profits by expanding to reach more affluent communities. *Health Affairs* 33, no. 10 (October 1): 1786–1792.

Conti, R. M., and P. B. Bach. 2013. Cost consequences of the 340B drug discount program. *Journal of the American Medical Association* 309, no. 19 (May 15): 1995–1996.

Department of Health and Human Services. 2014. *Fiscal year 2015 Health Resources and Services Administration justification of estimates for appropriations committees*. Washington, DC: HHS.

Government Accountability Office. 2015. Drug discount program: Status of GAO recommendations to improve 340B Drug Pricing Program oversight. Statement of Debra Draper, Director of Health Care, Government Accountability Office, before the Subcommittee on Health, Committee on Energy and Commerce, U. S. House of Representatives. March 5.

Government Accountability Office. 2011. *Drug pricing: Manufacturer discounts in the 340B Program offer benefits, but federal oversight needs improvement*. GAO–11–836. Washington, DC: GAO.

Health Resources and Services Administration. 2015a. Statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration, before the Subcommittee on Health, Committee on Energy and Commerce, U. S. House of Representatives. March 5.

Health Resources and Services Administration, Department of Health and Human Services. 2015b. Personal communication with HRSA staff, April 16.

Health Resources and Services Administration, Department of Health and Human Services. 2014a. 340B Drug Pricing Program notice. Release no. 2014–1. Clarification on use of the Medicaid Exclusion File. December 12.

Health Resources and Services Administration, Department of Health and Human Services. 2014b. 340B staffing investments: Office of Pharmacy Affairs update. <http://www.hrsa.gov/opa/updates/june2014.html>.



Health Resources and Services Administration, Department of Health and Human Services. 2014c. Audit results: Office of Pharmacy Affairs update. <http://www.hrsa.gov/opa/updates/140509auditresults.html>.

Health Resources and Services Administration, Department of Health and Human Services. 2014d. FAQs: 340B Drug Pricing Program. <http://www.hrsa.gov/opa/faqs/index.html>.

Health Resources and Services Administration, Department of Health and Human Services. 2014e. *Interpretive rule: Implementation of the exclusion of orphan drugs for certain covered entities under the 340B program*. Rockville, MD: HRSA.

Health Resources and Services Administration, Department of Health and Human Services. 2014f. Medicaid exclusion/Duplicate discount prohibition. <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html>.

Health Resources and Services Administration, Department of Health and Human Services. 2014g. Orphan drugs exclusion. <http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html>.

Health Resources and Services Administration, Department of Health and Human Services. 2014h. Program integrity: Audit results. <http://www.hrsa.gov/opa/programintegrity/auditresults/results.html>.

Health Resources and Services Administration, Department of Health and Human Services. 2013. 340B Drug Pricing Program notice. Release no. 2013–3. Clarification of eligibility for hospitals that are not publicly owned or operated. March 7. <http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf>.

Health Resources and Services Administration, Department of Health and Human Services. 2012. 340B Drug Pricing Program notice. Release no. 2011–1.1. Clarification of non-discrimination policy. May 23. <http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf>.

Health Resources and Services Administration, Department of Health and Human Services. 2010. Notice regarding 340B Drug Pricing Program—Contract pharmacy services. Final notice. *Federal Register* 75, no. 43 (March 5): 10272–10279.

Health Resources and Services Administration, Department of Health and Human Services. 1996. Notice regarding Section 602 of the Veterans Health Care Act of 1992 patient and entity eligibility. Final notice. *Federal Register* 61, no. 207 (October 24): 55156–55158.

Hirsch, B. R., S. Balu, and K. A. Schulman. 2014. The impact of specialty pharmaceuticals as drivers of health care costs. *Health Affairs* 33, no. 10 (October 1): 1714–1720.

IMS Institute for Healthcare Informatics. 2014. IMS health study: Spending growth returns for U.S. medicines. News release. April 15.



IMS Institute for Healthcare Informatics. 2012. *The use of medicines in the United States: Review of 2011*. Parsippany, NJ: IMS Institute for Healthcare Informatics.

Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

Office of Inspector General. 2015. Examining the 340B Drug Pricing Program. Testimony of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, Department of Health and Human Services, before the Subcommittee on Health, Committee on Energy and Commerce, U. S. House of Representatives. March 5.

Office of Inspector General, Department of Health and Human Services. 2014. Memorandum report from Stuart Wright, Deputy Inspector General, to Mary K. Wakefield, Administrator, Health Resources and Services Administration. *Contract pharmacy arrangements in the 340B Program*, OEI-05-13-00431. February 4.

Office of Inspector General, Department of Health and Human Services. 2011. *State Medicaid policies and oversight activities related to 340B-purchased drugs*. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2006. *Review of 340B prices*. OEI-05-02-00073. Washington, DC: OIG.

Safety Net Hospitals for Pharmaceutical Access. 2015. Analysis: 340B DSH hospitals have high low-income patient loads and provide significant uncompensated care. <http://www.snhpa.org/340b-resources/why-340b-matters/340b-dsh-hospital-safety-net-role>.

U.S. House of Representatives. 1992. *The Medicaid drug rebate amendments of 1992*. Report 102-384, part 2. 102nd Cong., 2nd sess.

Wallack, M. C., and S. B. Herzog. 2011. *Demonstrating the value of the 340B Program to safety net hospitals and the vulnerable patients they serve*. Perspectives from SNHPA members. Washington, DC: Safety Net Hospitals for Pharmaceutical Access.

A P P E N D I X

# A

---

**Method for estimating the discount  
on drugs paid under the  
outpatient prospective payment system  
to hospitals that participate  
in the 340B program**

---



The 340B ceiling prices represent the maximum prices that manufacturers can charge covered entities for 340B drugs. Therefore, they approximate the actual prices paid by covered entities and influence the discounts that covered entities receive on 340B drugs. Because key data (such as the average manufacturer price and best price) used to calculate the 340B ceiling prices are confidential, we are not able to calculate those prices precisely. Instead, we estimated the lower bound of the average discount received by 340B hospitals for drugs paid under the outpatient prospective payment system (OPPS).

Our estimate includes all drugs separately paid under the OPPS except for vaccines, which are not eligible for 340B prices. We also excluded orphan drugs provided by critical access hospitals (CAHs), freestanding cancer hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs).<sup>1</sup> The data we used in our analysis are from 2013 and include information from hospital outpatient Medicare claims and information from the Health Resources and Services Administration on which hospitals participate in the 340B program. We excluded CAHs from our analysis because Medicare payments to these hospitals for drugs provided in the outpatient setting are based on cost. In contrast, payments to all other hospitals in the 340B program are based on average sales price (ASP). Because our simulations are based on ASP, they are inapplicable to CAHs.

As a basis for estimating the costs that 340B hospitals incur to acquire drugs covered under the OPPS, we used the basic formula for calculating the 340B ceiling price: *(average manufacturer price (AMP) – unit rebate amount (URA)) × drug package size*, which is described in the text box on pp. 6–7. For single-source and innovator multiple-source drugs, the URA is the greater of *(AMP – “the best price”)* or *(AMP × 23.1 percent)*, where the best price is the best price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, 340B-covered entities, Medicare Part D plans, and certain other purchasers. Also, if AMP for a sole-source or innovator multiple-source drug has grown at a faster rate than the consumer price index for all urban consumers (CPI-U) since the drug’s market date, an additional rebate is applied to AMP. For noninnovator multiple-source drugs, the URA is *AMP × 13 percent*.

Data limitations required us to modify how we estimated ceiling prices. One such limitation was that we did not have access to AMP data, so we used each drug’s ASP as a proxy for AMP. In most cases, ASP is slightly lower than AMP because ASP includes all discounts and rebates, while AMP does not include prompt-pay discounts. The Office of Inspector General found that in 2011, the difference between ASP and AMP was 3 percent at the median, with ASP generally lower than AMP (Office of Inspector General 2013). A second limitation was that we were not able to determine whether the ASP for most drugs has risen faster than the consumer price index for all urban consumers (CPI-U) since the drug’s market date because ASP data do not exist before 2005 and most drugs in our analysis have a market date earlier than 2005. Consequently, we were not able to determine whether an inflation rebate should be applied. A third limitation was that we did not have data on the best price of each drug.

Because of these data limitations, our estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. The formula we used to estimate ceiling prices for noninnovator multiple-source drugs is *ASP – (ASP × 13 percent)*; the formula for

single-source or innovator multiple-source drugs is  $ASP - (ASP \times 23.1 \text{ percent})$ . The method we used to estimate 340B hospitals' costs to acquire drugs is:

- **for noninnovator multiple-source drugs:**  $(1 - 0.13) \times (\text{Medicare payment indicated on a claim}) / 1.06$ .
- **for sole-source and innovator, multiple-source drugs:**  $(1 - 0.231) \times (\text{Medicare payment indicated on a claim}) / 1.06$ .

The reason we divided the Medicare payment on a claim by 1.06 is that the OPPS payment rate for all separately paid drugs is 106 percent of the drug's ASP.<sup>2</sup> This adjustment eliminated the 6 percent add-on from our calculation of ceiling prices.

We measured the discount received by 340B hospitals for each unit of a drug as the difference between the drug's ASP and the ceiling price we estimated for the drug. The aggregate discount for all 340B hospitals is the sum of these unit discounts across all drug units furnished. We estimate that the lower bound of the average discount on OPPS-covered drugs for 340B hospitals (excluding CAHs) is 22.5 percent of the drugs' ASPs. ■

## Endnotes

---

- 1 According to the Health Resources and Services Administration's interpretation of the 340B statute, CAHs, cancer hospitals, RRCs, and SCHs are prohibited from using orphan drugs under 340B when the drugs are used for the rare disease or condition for which they received an orphan designation (the orphan drug exclusion). Because claims data do not identify the indication for which a drug was used, we could not determine whether an orphan drug used by one of these hospitals was eligible for 340B discounted prices. Therefore, we excluded all orphan drugs used by these types of hospitals.
- 2 When the sequester began in April 2013, it reduced the amount that Medicare paid for all services by 2 percent. For separately payable drugs in the OPPS, Medicare normally pays 80 percent of  $1.06 \times ASP$ , but the sequester reduces this to 80 percent of  $1.039 \times ASP$ . At the same time, Medicare beneficiaries are responsible for 20 percent of  $1.06 \times ASP$ , and the sequester has no effect on the beneficiary's portion of the payment. The net effect of the sequester is to reduce the combined payment from Medicare and beneficiaries for separately payable drugs in the OPPS from 106 percent of ASP to 104.3 percent of ASP. For OPPS-covered drugs provided after the start of the sequester, we divided Medicare payments by 1.043 (rather than 1.06) to estimate the hospital acquisition cost.

## References

---

Office of Inspector General, Department of Health and Human Services. 2013. *Comparison of average sales prices and average manufacturer prices: An overview of 2011*. OEI-03-12-00670. Washington, DC: OIG.

---

## **About MedPAC**

---



## The Commission

---

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105–33) to advise the U.S. Congress on issues affecting the Medicare program. In addition to advising the Congress on payments to health plans participating in the Medicare Advantage program and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

The Commission’s 17 members bring diverse expertise in the financing and delivery of health care services. Commissioners are appointed to three-year terms (subject to renewal) by the Comptroller General and serve part time. Appointments are staggered; the terms of five or six Commissioners expire each year. The Commission is supported by an executive director and a staff of analysts who typically have backgrounds in economics, health policy, and public health.

MedPAC meets publicly to discuss policy issues and formulate its recommendations to the Congress. In the course of these meetings, Commissioners consider the results of staff research, presentations by policy experts, and comments from interested parties. (Meeting transcripts are available at [www.medpac.gov](http://www.medpac.gov).) Commission members and staff also seek input on Medicare issues through frequent meetings with individuals interested in the program, including staff from congressional committees and the Centers for Medicare & Medicaid Services (CMS), health care researchers, health care providers, and beneficiary advocates.

Two reports—issued in March and June each year—are the primary outlets for Commission recommendations. In addition to annual reports and occasional reports on subjects requested by the Congress, MedPAC advises the Congress through other avenues, including comments on reports and proposed regulations issued by the Secretary of the Department of Health and Human Services, testimony, and briefings for congressional staff.

The Commission’s goal is to achieve a Medicare program that ensures beneficiary access to high-quality care, pays health care providers and health plans in a manner that is fair and rewards efficiency and quality, and spends tax dollars responsibly.

## Commission members

---

**Glenn M. Hackbarth, J.D., chairman**

Bend, OR

**Jon B. Christianson, Ph.D., vice chairman**

*School of Public Health at the University of Minnesota*  
Minneapolis, MN

*Term expires April 2015*

**Alice Coombs, M.D.**

*Milton Hospital and South Shore Hospital*  
Weymouth, MA

**Glenn M. Hackbarth, J.D.**

**Jack Hoadley, Ph.D.**

*Health Policy Institute, Georgetown University*  
Washington, DC

**David Nerenz, Ph.D.**

*Henry Ford Health System*  
Detroit, MI

**Rita Redberg, M.D., M.Sc.**

*University of California at San Francisco Medical Center*  
San Francisco, CA

**Craig Samitt, M.D., M.B.A.**

*Oliver Wyman*  
Paradise Valley, AZ

*Term expires April 2016*

**Scott Armstrong, M.B.A., F.A.C.H.E.**

*Group Health Cooperative*  
Seattle, WA

**Katherine Baicker, Ph.D.**

*Harvard School of Public Health*  
Boston, MA

**Jon B. Christianson, Ph.D.**

**Herb B. Kuhn**

*Missouri Hospital Association*  
Jefferson City, MO

**Mary Naylor, Ph.D., F.A.A.N., R.N.**

*University of Pennsylvania, School of Nursing*  
Philadelphia, PA

**Cori Uccello, F.S.A., M.A.A.A., M.P.P.**

*American Academy of Actuaries*  
Washington, DC

*Term expires April 2017*

**Kathy Buto, M.P.A.**

Arlington, VA

**Francis "Jay" Crosson, M.D.**

Palo Alto, CA

**Bill Gradison Jr., M.B.A., D.C.S.**

McLean, VA

**William J. Hall, M.D., M.A.C.P.**

*University of Rochester School of Medicine*  
Rochester, NY

**Warner Thomas, M.B.A.**

*Ochsner Health System*  
New Orleans, LA

## Commission staff

---

**Mark E. Miller, Ph.D.**

*Executive director*

**James E. Mathews, Ph.D.**

*Deputy director*

*Analytic staff*

.....  
Catherine Bloniarz, M.S.  
Stephanie Cameron, Sc.M.  
Carol Carter, Ph.D.  
Evan Christman, M.P.Aff.  
Zachary Gaumer, M.P.S.  
David V. Glass, M.S.  
Scott Harrison, Ph.D.  
Kevin Hayes, Ph.D.  
Andrew Johnson, Ph.D.  
Dana Kelley, M.P.A.  
Julie Lee, Ph.D.  
Craig K. Lisk, M.S.  
Kim Neuman, M.A.  
Nancy Ray, M.S.  
John Richardson, M.P.P.  
Rachel Schmidt, Ph.D.  
Julie Somers, Ph.D.  
Jeffrey Stensland, Ph.D.  
Shinobu Suzuki, M.A.  
Ariel Winter, M.P.P.  
Daniel Zabinski, Ph.D.

*Research assistants*

.....  
Anna Harty  
Katelyn Smalley

*Policy and communications associate*

.....  
Emily Johnson

*Administrative staff*

.....  
Reda H. Broadnax, B.S.  
*Deputy director of finance  
and operations*  
Wylene Carlyle  
Paula Crowell  
Timothy Gulley  
Tina Jennings, MTESL  
Cynthia Wilson

*Staff consultants*

.....  
Julian Pettengill  
Joan Sokolovsky, Ph.D.  
Carlos Zarabozo, A.B.

