CHAPTER 3

Part B drug payment policy issues

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Chapter summary

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments. It also covers certain drugs furnished by suppliers. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). In 2013, Medicare and its beneficiaries paid more than $19 billion dollars for Part B–covered drugs at ASP + 6 percent. This chapter explores two issues related to Medicare payment policy for Part B drugs.

The first issue relates to the general payment methodology for Part B drugs: ASP + 6 percent. ASP is the price realized by a manufacturer for its drug for sales to all purchasers (with certain exceptions), net of rebates, discounts, and price concessions. Medicare pays providers ASP + 6 percent for the drug regardless of the price a provider pays to acquire the drug. This formula gives the provider a financial incentive to seek the lowest available price for a given product.

However, concern has been expressed that the 6 percent add-on to the ASP may create incentives for use of higher priced drugs when lower priced alternatives are available. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. Currently, it is difficult to know

In this chapter

the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

Our work examines the mechanics of the ASP payment system and explores policy alternatives to the 6 percent add-on. In particular, we model two policy options that convert part or all of the 6 percent add-on to a flat-fee add-on for each day the drug is administered to a beneficiary. Our modeling demonstrates that a flat-fee add-on would increase payment rates for lower priced drugs and reduce payment rates for higher priced drugs compared with current policy.

Moving to a flat-fee add-on could have a number of effects. It might increase the likelihood that a provider would choose the least expensive drug in situations where differently priced therapeutic alternatives exist, potentially generating savings for Medicare and its beneficiaries. At the same time, a flat-fee add-on might create other incentives that could increase spending. For example, questions have been raised about whether increased payment rates for very inexpensive drugs might create incentives among some providers to overuse these drugs or spur manufacturers of low-priced drugs to raise their prices.

It would be important in structuring a flat-fee add-on to consider its effect on providers' ability to purchase drugs within the Medicare payment amount. A flat-fee add-on would reduce payment rates for very expensive drugs. With a flat-fee add-on, some providers might have difficulty purchasing very expensive drugs within the Medicare payment rate, but that would depend on how the policy is structured and how manufacturers' pricing decisions respond to the policy.

The second issue relates to the discount on Part B drugs received by certain hospitals and other providers under the 340B Drug Pricing Program. The 340B program allows certain providers ("covered entities") to obtain discounted prices on covered outpatient drugs (prescription drugs and biologics other than vaccines) from drug manufacturers. Under the outpatient prospective payment system (OPPS), Medicare pays for certain 340B drugs, such as drugs for cancer and rheumatoid arthritis, provided by hospitals in the 340B program. Medicare pays the same rates (ASP + 6 percent) for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at steep discounts. Similarly, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate for outpatient drugs, whether given at a 340B hospital or not.

The Health Resources and Services Administration (HRSA), which manages the 340B program, calculates a 340B ceiling price for each outpatient drug using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The 340B ceiling price represents the maximum price a manufacturer can

charge for a 340B drug. According to statute, HRSA is allowed to share these prices with covered entities but not with the general public.

Although 340B prices are proprietary, we estimate that the minimum discount that 340B hospitals receive for drugs paid under the OPPS is 22.5 percent of the drugs' ASP, on average. This figure represents a conservative estimate—a lower bound—of the actual discount. We also estimate that in 2013, 340B hospitals (excluding critical access hospitals, Maryland hospitals, and others for which we do not have data on Medicare revenue) received about $3.2 billion in Medicare revenue for drugs paid under the OPPS while acquiring them for at most $2.4 billion. Hospitals that qualify for 340B because they are disproportionate share hospitals accounted for nearly all of the Medicare revenue and acquisition cost for outpatient drugs among 340B hospitals.

An important policy question is whether Medicare should pay less than ASP + 6 percent for Part B drugs purchased by 340B hospitals since they are able to purchase outpatient drugs at a price that is, on average, at least 22.5 percent below ASP. It could be argued that, even if Medicare's program payment does not change, Medicare beneficiaries should pay lower cost sharing for drugs provided by 340B hospitals. Reducing Medicare's payment rates or beneficiary cost sharing for Part B drugs provided by 340B hospitals would save money for the Medicare program and beneficiaries, but it would decrease the revenue that hospitals receive through the 340B program, which may reduce their participation in 340B. ■

Background

Medicare Part B covers infusible and injectable drugs administered in physician offices and hospital outpatient departments. Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs). In accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays physicians and suppliers for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).[1] CMS, through regulation, has also established a payment rate of ASP + 6 percent for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS).[2] Like other Medicare services, Part B–covered drugs are subject to the budget sequester effective April, 1, 2013, through 2024.[3]

Medicare pays ASP + 6 percent for each drug and makes an additional separate payment for administration of the drug under the physician fee schedule or OPPS. Medicare also pays an additional dispensing or supplying fee to pharmacies that dispense inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs to beneficiaries and pays a furnishing fee to providers of clotting factors. The data presented in this chapter reflect only the ASP + 6 percent payments and do not include the drug administration payments or the supplying, dispensing, or furnishing fees. In 2013, Medicare spending (program payments and beneficiary cost sharing) on Part B–covered drugs paid ASP + 6 percent amounted to over $19 billion dollars (more than $15 billion of Medicare program payments and nearly $4 billion of beneficiary cost sharing). Of that spending, physician offices accounted for over $11 billion, hospital outpatient departments accounted for nearly $7 billion, and suppliers accounted for over $1 billion. In recent years, Medicare Part B drug spending has grown more rapidly for hospital outpatient departments than for physician offices and suppliers (average annual growth of roughly 20 percent and 5 percent, respectively, for the period between 2009 and 2012). Of Medicare Part B drug spending in outpatient hospitals in 2013, roughly half was attributable to hospitals that participate in the 340B Drug Pricing Program.

Medicare Part B covers drugs and biologics for a wide range of indications, although a small number of drugs and conditions account for a large share of spending. The top 10 drugs that account for the most Part B drug spending fall into 3 areas: cancer, rheumatoid arthritis, and macular degeneration (Table 3-1, p. 66). These 10 drugs account for 48 percent of Medicare spending on Part B drugs paid ASP + 6 percent. Part B, however, covers a number of other types of drugs, some of which are used by a much larger number of beneficiaries. The top 10 Part B drugs used by the most beneficiaries in 2013 include several corticosteroids, drugs used during stress tests or imaging, an anemia drug, an antibiotic, and an inhalation drug (Table 3-1). For 9 of these 10 most frequently used drugs, total Medicare payments ranged from $2 million to $21 million per drug, while the 10th drug accounted for payments of more than $240 million. The 10 most frequently used Part B drugs as a group accounted for less total spending than any 1 of the top 10 highest expenditure Part B drugs.

Across all Part B drugs paid ASP + 6 percent, the majority of drug administrations or prescriptions involved drugs that were relatively inexpensive, while a small share of drug administrations or prescriptions accounted for the vast majority of spending (Table 3-2, p. 67).[4] For about 60 percent of drug administrations, the ASP + 6 percent payment per administration was less than $50. These drugs accounted for just 1 percent of Part B drug spending. For example, 9 of the 10 Part B drugs used by the most beneficiaries had an average ASP + 6 percent payment per administration of $13 or less (Table 3-1, p. 66). By contrast, about 5 percent of drug administrations accounted for 50 percent of Part B drug spending, with Medicare paying $2,000 or more per administration (Table 3-2). The top 10 Part B drugs that accounted for the highest total Medicare expenditures provide some examples of high-cost drugs. The ASP + 6 percent payment per drug administration for these 10 drugs ranged from more than $1,200 to over $5,200 per administration (Table 3-1). In addition, since many of these drugs are typically administered multiple times to an individual patient over the course of a year, the average total payment per beneficiary over the year is higher than the average payment per administration (Table 3-1). (For additional data on the average cost per administration and per beneficiary for high expenditure or high frequency drugs, see the online Appendix 3-A to this report, available at http://www.medpac.gov).

TABLE 3–1

Top 10 Part B–covered drugs by total expenditures and by number of beneficiaries who used the drug, 2013

Drug		Indication or type of drug	Total Medicare payments in 2013 based on ASP + 6 percent (in millions)	Number of beneficiaries who used drug in 2013	Average ASP + 6 percent payment in 2013	
					Per administration	Per beneficiary
Top 10 drugs with the highest total expenditures						
J9310	Rituximab	Cancer, rheumatoid arthritis	$1,514	69,844	$5,136	$21,262
J2778	Ranibizumab	Macular degeneration	1,368	143,464	2,013	9,240
J1745	Infliximab	Rheumatoid arthritis	1,111	59,997	3,159	18,129
J2505	Pegfilgrastim	Cancer	1,101	100,753	2,978	10,611
J0178	Aflibercept	Macular degeneration	1,090	108,423	2,106	9,774
J9035	Bevacizumab	Cancer, macular degeneration	1,037	186,617	1,240	4,533
J0897	Denosumab	Osteoporosis, cancer	635	227,511	1,237	2,615
J9305	Pemetrexed	Cancer	548	22,947	5,250	23,281
J9355	Trastuzumab	Cancer	503	17,215	2,690	28,870
J9041	Bortezomib	Cancer	453	20,285	1,462	21,889
Top 10 drugs used by the most beneficiaries						
J3301	Triamcinolone acetate	Corticosteroid	$19	1,543,805	$7	$11
J2785	Regadenoson	Stress test	242	1,152,357	208	210
J1030	Methylprednisolone 40 mg	Corticosteroid	7	1,105,159	4	6
J1040	Methylprednisolone 80 mg	Corticosteroid	9	896,093	6	10
J1100	Dexamethasone sodium phosphate	Corticosteroid	2	893,340	1	2
Q9967	LOCM 300–399mg/ml iodine	Contrast agent for imaging	14	809,484	12	17
J0702	Betamethasone acetate and sodium phosphate	Corticosteroid	14	678,672	13	19
J3420	Vitamin B12	Anemia	3	602,049	1	4
J7613	Albuterol	Bronchodilator	21	552,876	11	35
J0696	Ceftriaxone sodium	Antibiotic	3	547,504	3	4

Note: ASP (average sales price), LOCM (low osmolar contrast material), mg (milligram), ml (milliliter). Average ASP + 6 percent payment per administration and per beneficiary are calculated at the drug billing code level. These averages are calculated after removing extreme values from the data (i.e., values that are less than the 1st percentile and greater than the 99th percentile for the Healthcare Common Procedure Coding System code). Because of the removal of extreme values, the average payment per beneficiary displayed in the chart will differ from the average payment per beneficiary calculated using the total payment amount and total beneficiary count displayed in the chart. Add-on payments received by the 11 cancer hospitals are not reflected in the data. "Indication or type of drug" reflects one or more common uses of the drug or the drug class. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

Average sales price payment system

ASP for a drug reflects the average price realized by the manufacturer. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.[5] Manufacturers report ASP data to CMS on a quarterly basis for each of their Part B drugs. Medicare pays providers ASP + 6 percent for the drug, regardless of the price a provider pays for the drug, giving the provider a financial incentive to seek the lowest available price for the product.

The Medicare Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set the ASP + 6 percent payment rate. That means, for example, the ASP + 6 percent payment rate for the third quarter of a year is based on ASP data from the first quarter of the year.[6] The two-quarter lag in the ASP + 6 percent payment rates may provide a disincentive for manufacturers to institute large, rapid price increases because they could cause providers' acquisition costs to exceed the Medicare payment rate and potentially affect providers' willingness to purchase the product.

Payment rates for single-source drugs and biologics and multiple-source drugs are set differently. Each single-source drug (i.e., a drug without generic substitutes) and biologic is paid based on 106 percent of its own ASP. For a multiple-source drug, both the brand and generic versions of the drug receive the same ASP + 6 percent payment rate based on the weighted average of ASPs for all equivalent brand and generic products. Under the Patient Protection and Affordable Care Act of 2010 (PPACA), a different approach is used for biosimilars. A biosimilar product is paid 100 percent of its own ASP, plus 6 percent of the ASP for the reference biologic. Thus, a lower priced biosimilar receives an add-on in excess of 6 percent because its add-on will be set equal to the 6 percent add-on for the more expensive reference biologic.

TABLE 3–2 **Low-priced drugs accounted for most Part B drug administrations, while high-priced drugs accounted for most Part B drug expenditures, 2013**

	Percent of:	
Medicare ASP + 6 percent payment per drug administered per day	**Drug administrations**	**Medicare Part B drug payments**
Less than $10	45%	0.3%
$10–49	16	0.7
$50–199	11	3
$200–399	10	6
$400–999	6	10
$1,000–1,999	7	27
$2,000–4,999	4	32
$5,000 or more	1	21

Note: ASP (average sales price). Analysis includes Part B–covered drugs that are paid ASP + 6 percent and furnished by physicians, hospital outpatient departments, and suppliers. We excluded from the analysis drugs billed under not-otherwise-classified Healthcare Common Procedure Coding System codes. For drugs furnished by suppliers, the data reflect each prescription rather than each day the drug was administered. Medicare payment amounts include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester. Add-on payments made to the 11 cancer hospitals are excluded from the data. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

Is the 6 percent add-on the provider's profit margin?

The margin an individual provider realizes on a specific Part B drug could be more or less than 6 percent (with negative margins also possible) because the price an individual provider pays for a drug may differ from the ASP used to establish the Medicare payment rate, for several reasons. Since ASP is an average across all purchasers, net of rebates, discounts, and price concessions, some providers will pay more and some will pay less than the average (unless the manufacturer has uniform pricing). For example, if manufacturers offer discounts or rebates based on volume, small purchasers may pay higher prices than large purchasers.

Price changes can also affect the margin a provider realizes on a Part B drug. With the two-quarter lag in the ASP + 6 percent payment rate, a price increase lowers a provider's margin and a price decrease increases that margin temporarily until ASP catches up.[7] For example, when a drug first goes generic, the lag in ASP results in a large positive profit margin for providers because their payment for the generic drug is based on the brand price for at least two quarters (Office of Inspector General 2012, Office of Inspector General 2011a). For single-source drugs and biologics, there may be different pricing dynamics, depending on whether the drug or biologic faces competition from therapeutic alternatives. That is, the manufacturer of a single-source drug may increase prices with less concern about the effect it will have on providers' margins (and potentially the manufacturer's sales volume) if therapeutic alternatives do not exist for its drug. In contrast, if a single-source drug faces competition from other, therapeutically similar drugs, a manufacturer may have incentive to consider how its pricing decision affects providers' margins on its drug compared with competitor products.

Certain additional factors, such as prompt-pay discounts, wholesaler markups, and sales tax, can create a gap between manufacturers' reported ASP and the average purchase price across providers. For example, manufacturers may offer prompt-pay discounts to drug wholesalers who pay manufacturers for their purchases within a specified

time frame. These prompt-pay discounts lower ASP because they reduce the revenue the manufacturer receives for its products. Anecdotal reports from provider and pharmaceutical industry stakeholders suggest prompt-pay discounts paid by manufacturers to wholesalers may be in the range of 1 percent to 2 percent, although no data are available to verify these amounts. These discounts are reported to be an important source of revenue for wholesalers that are largely not passed on to final purchasers (e.g., physicians or hospitals). When these discounts are not passed on from wholesalers to providers, the average price paid by providers for a drug could end up higher than the manufacturer's reported ASP. Another factor that can affect providers' margin on a drug is wholesaler markup. Wholesalers may mark up the drug price they charge providers (e.g., for shipping or handling, or to generate profit). Wholesaler markup is not included in ASP because it does not affect the revenue earned by manufacturers. For some drugs, the average price paid by providers for a drug could be higher than ASP due to wholesaler markup. To the extent that wholesaler markup reflects fixed fees like shipping and handling, its effect may be most significant on provider margins for very inexpensive drugs (Medicare Payment Advisory Commission 2007). Another factor that can create a gap between ASP and providers' acquisition costs is sales tax. Many states and localities exempt providers' purchases of drugs from sales tax, but some may not. Since sales tax is not reflected in ASP, it could reduce providers' margins on drugs in areas charging sales tax.

What was the purpose of the 6 percent?

There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent is intended to cover drug storage and handling costs.[8] Others contend that the 6 percent is intended to maintain access to drugs for smaller practices and other purchasers who may pay above average prices for the drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (e.g., prompt-pay discounts). Another rationale for the percentage add-on may be to provide protection for providers when price increases occur and the payment rate has not yet caught up.

Does the percent add-on to ASP create an incentive to use high-cost drugs?

Providers' prescribing decisions may depend on a variety of factors. A number of clinical considerations may influence a provider's choice among therapeutic alternatives. For example, drugs may vary in terms of their effectiveness in treating patients with specific conditions or comorbidities, or they may have different side effects. In addition, providers may take into account whether a drug is on label or off label for a patient's condition or whether a drug is compounded. Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP may create an incentive to use higher priced drugs when cheaper therapeutic alternatives are available (Hutton et al. 2014, Sanghavi et al. 2014). At the same time, other factors may create financial incentives to use lower priced drugs in some situations. For example, when selecting a drug, a provider may take into account the cost sharing associated with each potential drug and the patient's ability to pay, which might lead to choosing a lower priced drug for some patients. Also, the capital cost associated with acquiring and keeping an inventory of a high-priced drug may be a disincentive for some providers to furnish expensive drugs.

The 6 percent add-on to ASP may create incentive to use higher priced drugs. Because 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs. However, few studies exist that examine whether the 6 percent add-on is influencing providers' choice of drugs. One study by Jacobson and colleagues (2010) of oncologists' prescribing patterns for lung cancer suggests that drug choice may to some degree be influenced by the higher add-on. Looking at five chemotherapy drugs for lung cancer, Jacobson and colleagues found a modest increase in use of the most expensive cancer drug after Medicare began paying for Part B drugs based on ASP + 6 percent in January 2005 (9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, whereas 11.0 percent of beneficiaries used that drug in the 10 months after). A study by the Office of the Inspector General reported some movement toward higher priced drugs among a group of therapeutically similar prostate cancer drugs. When the least costly alternative policy for certain prostate cancer drugs was removed in 2010 and the products began to be paid based on 106 percent of their own ASPs, OIG found a shift from the lowest priced prostate cancer drug toward higher priced competitor products (Office of Inspector General 2012).

For the 6 percent add-on to create the incentive to use a higher priced drug, there must be alternative drugs with different prices available to treat a particular patient's condition. Researchers have not quantified the amount of total Part B drug spending accounted for by drugs for which differently priced substitutes are available. This calculation would be challenging because the drugs used as substitutes may vary depending on the patient's condition, and clinical guidelines on comparable therapies change over time. Also, the existence of multiple-drug regimens makes identification of drug substitutes more complex. Thus, it is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels.

Policy analysis

We explored the idea of converting the 6 percent add-on to ASP to an unvarying—that is, flat—fee, which would help minimize financial incentives to use a more expensive product. To explore the implications of a flat-fee add-on to ASP, we developed two policy options.[9] These options are estimated to be budget neutral in aggregate relative to the current payment rate of 106 percent of ASP (i.e., ASP + 6 percent). We model budget neutrality under the assumption of no change in utilization (which is an unlikely outcome). All estimates are based on current Medicare law, meaning that the estimates are based on figures calculated before the application of the sequester. The two options modeled are:

- ***Option 1:*** 100 percent of ASP + $24 per drug per administration day
- ***Option 2:*** 102.5 percent of ASP + $14 per drug per administration day

Option 1 fully replaces the 6 percent add-on with a $24 flat fee per drug per day administered. However, as discussed subsequently, because full elimination of a percentage add-on might result in very expensive drugs being difficult to acquire at the Medicare payment amount, we also modeled a hybrid approach—a reduced percentage add-on plus fixed fee (102.5 percent of ASP + $14). In the hybrid model, the 2.5 percent add-on to ASP is intended to be illustrative. Because our model is budget neutral, the lower the percentage add-on, the higher the flat fee. Our goal was to select an add-on percentage that would not be systematically unprofitable and would generate a substantial flat fee. We chose a percentage add-on that was slightly higher than the 1 percent to 2 percent prompt-pay discounts manufacturers reportedly pay to wholesalers, which lower ASP but are largely not passed on to providers. Models with other budget-neutral combinations of percentage and flat-fee add-ons could be explored. In addition, other structures for the add-on could be considered—for example, tiered flat-fee add-ons or percentage add-ons (or a combination) based on the ASP for the drug.

To illustrate the effect of the two policy options, Table 3-3 (p. 70) displays the payment rate under current policy (106 percent of ASP) compared with the two policy options for a variety of differently priced drugs (as measured by ASP). Both policy options increase reimbursement for lower priced drugs (ASP per administration less than $400) and decrease reimbursement for higher priced drugs (ASP per administration more than $400) compared with current policy. For example, a drug that had an ASP of $10 per administration would be paid more under Options 1 and 2 ($34 and $24.25, respectively) than under current policy ($10.60). In contrast, a drug with a $5,000 ASP per administration would be paid more under current policy ($5,300) compared with Option 1 ($5,024) and Option 2 ($5,139).

The changes in payment rates under a flat-fee add-on—the increase in payment rates for inexpensive drugs and decrease for expensive drugs—could have a number of effects. In situations where different Part B drugs exist to effectively treat a patient's condition, moving to a flat-fee add-on might increase the likelihood that a provider would choose the least expensive drug. To the extent that this type of substitution occurred and changed utilization patterns, a flat-fee add-on might have potential to generate savings for both the Medicare program and beneficiaries. However, a flat-fee add-on might also create financial incentives for the administration of drugs in smaller, more frequent doses since more administrations would generate more add-on fees. Such more frequent administration of drugs among some providers could result in higher spending.

A flat-fee add-on may help address concerns about reimbursement for very inexpensive drugs, where a 6 percent add-on may be quite small in dollar terms. In that sense, a flat-fee add-on would increase reimbursement for low-priced, generic drugs. However, for very inexpensive drugs, a flat-fee add-on would represent a relatively large payment increase (e.g., a drug with an ASP per administration of $5 would be paid $29 under Option 1 and about $19 under Option 2). There is a question of whether this increase in payment rates for very inexpensive drugs may incentivize overuse among

TABLE 3–3

Drug payment rates under current policy and two alternative policy options by ASP of the drug

	Drug payment amount in dollars			Drug payment amount expressed as percentage of ASP		
ASP per drug administered	Current payment rate (106% ASP)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day	Current payment rate (106% ASP)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day
$5	$5.30	$29.00	$19.13	106.0%	580.0%	382.5%
$10	10.60	34.00	24.25	106.0	340.0	242.5
$50	53.00	74.00	65.25	106.0	148.0	130.5
$100	106.00	124.00	116.50	106.0	124.0	116.5
$400	424.00	424.00	424.00	106.0	106.0	106.0
$1,000	1,060.00	1,024.00	1,039.00	106.0	102.4	103.9
$2,500	2,650.00	2,524.00	2,576.50	106.0	101.0	103.1
$5,000	5,300.00	5,024.00	5,139.00	106.0	100.5	102.8
$10,000	10,600.00	10,024.00	10,264.00	106.0	100.2	102.6

Note: ASP (average sales price). "ASP per drug administered" is defined as the ASP unit price times the number of units of the drug administered to the patient on a particular day. Under the two policy options, the flat-fee add-on is paid per drug per administration day (regardless of the number of units of the drug furnished to the patient that day). For drugs furnished by suppliers, the data reflect ASP per prescription rather than ASP per administration. Medicare payment amounts include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester.

Source: MedPAC analysis.

some providers. Also, uncertainty exists about how manufacturers of low-priced drugs might respond to the higher Medicare payment rates for their products resulting from a flat-fee add-on. Would manufacturers of low-priced drugs respond by increasing their prices, or would competition among generic manufacturers serve as a check against substantial price increases?

Another important question is what the effect would be of either policy option on providers' ability to purchase drugs at a price within the Medicare payment rate. Under Option 1, expensive drugs with an ASP of $2,500 to $10,000 per day would be paid at a rate equivalent to between 100.2 percent and 101 percent of ASP (Table 3-3). In light of the prompt-pay discount potentially resulting in the average purchase price across providers being above ASP by possibly 1 percent or 2 percent, very expensive drugs could be systematically unprofitable for providers under Option 1. Option 2, which combines a reduced percentage add-on and a moderate flat fee, attempts to address this issue. Under Option 2, drugs with an ASP per administration of between $2,500 and $10,000 per day would receive payments equivalent to 102.6 percent to 103.1 percent of ASP. With these payment rates, it would be less likely that expensive drugs would be systematically unprofitable across providers. However, variation in drug acquisition prices across providers would likely mean that some providers, especially small providers, would not be able to purchase some expensive drugs at prices within the Medicare reimbursement amount. When Medicare began paying 106 percent of ASP (instead of a share of the average wholesale price) in 2005, manufacturers responded by reducing the variation in prices across purchasers (Medicare Payment Advisory Commission 2006). It is possible that reducing the ASP add-on percentage could have a similar effect, spurring manufacturers to further reduce the variation in prices across purchasers, which could make these drugs available to more providers at a price within the Medicare payment amount. Alternatively, it is possible that price variation across purchasers would persist and that smaller oncology practices, for example, might decide to send patients to the larger oncology practices or hospital outpatient departments for certain expensive drugs. If these types of shifts in site of care occurred, the effect on beneficiaries (e.g., in terms of travel time to a provider) is unknown.

Application of the sequester to our calculations would reduce payment rates by about 1.6 percent, which may make it difficult for many purchasers to obtain the most expensive drugs within the Medicare reimbursement amount under either option. If the Congress wished to pursue a policy like Option 2 in the context of the sequester, it could consider a modified Option 2 that has a higher percentage add-on and lower flat fee. Alternatively, the Congress could choose to adopt a policy like Option 2 and override the sequester for Part B drugs, but that would increase Medicare program spending.

Changing a portion or all of the 6 percent add-on to a flat fee would redistribute revenues across providers. As expected, the revenue redistribution is larger under Option 1 (100 percent of ASP + $24) than Option 2 (102.5 percent of ASP + $14). Under both options, Medicare payments for Part B drugs would increase for physicians and suppliers and would decline for hospital outpatient departments (Table 3-4, p. 72). Although Part B drug revenues to physicians as a whole would increase, some of the physician specialties that account for a sizable portion of Part B drug spending would see Part B drug revenues decline—specifically, oncologists, ophthalmologists, and rheumatologists. In contrast, specialties that have lower Part B drug spending, such as primary care, infectious disease, and other specialties, would see Part B drug revenue increases of 5 percent or more. The percentage changes (increases and decreases) in revenues that result from these policy options are smaller when viewed in the context of providers' total Medicare revenues for all services rather than providers' Part B drug revenues only.

Paying for Part B drugs provided by hospitals in the 340B Drug Pricing Program

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 (see text box, pp. 74–75). The program is administered by the Health Resources and Services Administration (HRSA). Covered outpatient drugs include over-the-counter drugs if they are prescribed by a physician and covered by a state Medicaid program, and they exclude inpatient drugs and drugs that are bundled with other services (such as physician and hospital outpatient services) for payment purposes. To have their drugs covered under Medicaid, manufacturers must offer 340B discounts to covered entities. The discounts available through the 340B program for covered outpatient drugs are comparable with Medicaid drug rebates. In fiscal year 2013, covered entities saved about $3.8 billion on outpatient drugs through the program (Health Resources and Services Administration 2015).

Medicare Part B pays for certain 340B drugs that covered entities provide to beneficiaries, such as drugs used to treat cancer and rheumatoid arthritis.[10] Covered entities can purchase any Part B drug (except vaccines) at the 340B discounted price for an eligible patient. However, hospitals that were added to the program by PPACA—such as critical access hospitals (CAHs)—are excluded by statute from purchasing orphan drugs (drugs designated by the Secretary for a rare disease or condition) under 340B.[11] 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 2014b). The provision does not apply when orphan drugs are used for other indications.

From 2004 to 2013, Medicare spending in nominal dollars for separately payable Part B drugs at hospitals that participate in 340B grew from $0.5 billion to $3.5 billion, or 543 percent.[12] 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 the growth in Medicare spending at 340B hospitals during this period was due to an increase in the number of participating hospitals. In 2010, PPACA allowed additional types of hospitals to participate in the 340B program (see text box, pp. 74–75). However, most of the growth in Medicare spending occurred among hospitals that were in the 340B program before the PPACA expansion. 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.

Under the outpatient prospective payment system (OPPS), Medicare pays 340B hospitals and non-340B hospitals the same payment rates for Part B drugs, even though 340B hospitals are able to purchase outpatient drugs at steep

TABLE 3–4 **Impact of flat-fee add-on options on Part B drug revenues by type of provider**

	Medicare payments for:		Aggregate percent change in: Part B drug payments under alternate policies		Aggregate percent change in: Total Medicare payments for all types of services under alternate policies	
	Part B drugs paid 106% ASP in 2013 (in billions)	All types of services in 2013 (in billions)	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day	Option 1: 100% ASP + $24 per drug per day	Option 2: 102.5% ASP + $14 per drug per day
Physicians	$11.6	$56.0	1.3%	0.8%	0.3%	0.2%
Oncology	5.5	8.1	–1.5	–0.9	–1.0	–0.6
Ophthalmology	2.4	5.3	–3.9	–2.2	–1.7	–1.0
Rheumatology	1.1	1.6	–2.5	–1.4	–1.6	–1.0
Primary care	0.6	11.1	14.8	8.6	0.9	0.5
Urology	0.3	2.1	0.3	0.2	0.1	0.0
Infectious disease	0.1	0.3	13.4	7.8	2.5	1.5
Other specialties	1.6	27.4	16.9	9.8	0.9	0.5
Hospitals	6.7	162.6	–3.8	–2.2	–0.2	–0.1
Urban	5.9	137.0	–3.8	–2.2	–0.2	–0.1
Rural	0.8	22.7	–3.6	–2.1	–0.1	–0.1
Nonprofit	5.1	115.7	–3.8	–2.2	–0.2	–0.1
For profit	0.5	23.8	–3.2	–1.9	–0.1	0.0
Government	1.1	21.4	–3.9	–2.3	–0.2	–0.1
Major teaching	2.1	39.2	–4.1	–2.4	–0.2	–0.1
Minor teaching	2.1	55.1	–3.7	–2.2	–0.1	–0.1
Nonteaching	2.4	66.5	–3.6	–2.1	–0.1	–0.1
<100 beds	0.8	15.2	–3.6	–2.1	–0.2	–0.1
101–250 beds	1.7	46.9	–3.6	–2.1	–0.1	–0.1
251–500 beds	2.2	55.9	–3.8	–2.2	–0.1	–0.1
501+ beds	2.0	42.9	–4.0	–2.3	–0.2	–0.1
Suppliers	1.2	3.4	7.7	4.5	2.8	1.6

Note: ASP (average sales price). Policy options are modeled to apply to all Part B–covered drugs that are currently paid ASP+6 percent, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. For drugs provided by suppliers, the models assume the flat fee is per prescription. Estimates of Medicare payments for all types of services by type of provider exclude providers who did not bill for at least one Part B–covered drug. Medicare payments include Medicare program payments and beneficiary cost sharing and are calculated before application of the sequester. Add-on payments made to the 11 cancer hospitals for outpatient services (including outpatient drugs) are excluded from the data. Data for critical access hospitals, Maryland hospitals, and beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data for physicians, hospitals, and suppliers.

discounts. Similarly, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate for outpatient drugs received at both types of hospitals.[13] By contrast, many state Medicaid programs pay 340B hospitals their actual cost of acquiring outpatient drugs. In 2011, the Department of Health and Human Services Office of Inspector General found that about half of states had policies that required covered entities to bill Medicaid at their actual acquisition cost (AAC) for 340B drugs (Office of Inspector General 2011b). According to

interviews conducted by the Government Accountability Office (GAO) with 18 covered entities in 2011, most of the entities that used 340B drugs for Medicaid patients reported that Medicaid reimbursement for 340B drugs was based on the AAC plus a dispensing fee (Government Accountability Office 2011).[14] Although discounts for 340B drugs are probably substantial, the 340B prices are proprietary, and we do not have access to the data that would enable us to precisely calculate them. Instead, we developed an estimate of the minimum discount for Part B drugs paid under the OPPS.

Calculating prices for 340B drugs

HRSA calculates a 340B ceiling price for each covered outpatient drug using a statutory formula that is based on the formula used to calculate Medicaid drug rebates. The formula 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); a clotting factor; or an exclusively pediatric drug.[15] According to statute, HRSA is allowed to share these prices with covered entities but not with the general public. 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) may pay less than the ceiling price. 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. By pooling the purchasing power of entities, the prime vendor (Apexus) negotiates subceiling prices on 340B drugs with manufacturers (Health Resources and Services Administration 2014a). Although there is no public information on the discounts negotiated by Apexus for specific drugs, the average savings was 10 percent below the ceiling price in fiscal year 2013 (Department of Health and Human Services 2014).

Formula for calculating 340B ceiling prices

The formula for calculating 340B ceiling prices is based on the Medicaid drug rebate formula, which is specified in the Social Security Act (SSA), Section 1927. The basic formula is as follows:

ceiling price = (average manufacturer price (AMP) – the unit rebate amount (URA)) × 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.[16] Manufacturers participating in Medicaid are required to report AMP to the Secretary, but these prices are confidential.

The URA is specified in Section 1927 of the SSA and 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)*. "Best price" represents 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, Medicaid programs, Medicare Part D plans, and certain other entities. Manufacturers report best-price data to the Secretary of Health and Human Services, but 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 first quarter in which the drug was marketed, an additional rebate is applied to AMP. This inflation rebate ensures that the inflation-adjusted prices paid by Medicaid programs and 340B-covered entities for drugs do not increase over time. According to the Congressional Budget Office, AMPs of brand-name oral drugs generally rise faster than the CPI–U (Congressional Budget Office 2014). 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 × 13 percent*.
- For clotting factors or exclusively pediatric drugs, the URA is the greater of *(AMP – the best price)* or *(AMP × 17.1 percent)*. If AMP has grown faster than the rate of inflation since the first quarter in which the drug was marketed, an additional rebate is applied to AMP.

Because data on AMP and best price are confidential, we were not able to precisely calculate the Medicaid drug rebates or 340B ceiling prices. Instead, we estimated the minimum discount received by 340B hospitals for drugs paid under the OPPS.

The 340B Drug Pricing Program

The 340B Drug Pricing Program ("340B program") was created in 1992 after the adoption of the Medicaid Drug Rebate Program. This text box contains a brief description of the program; for more information, see the report *Overview of the 340B Drug Pricing Program*, available at http://www.medpac.gov. According to the Health Resources and Services Administration (HRSA), which administers the program, 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 2014b).[17] The program is named for the provision in the Public Health Service Act of 1992 that authorizes it. To have their drugs covered under Medicaid, manufacturers must offer 340B discounts to the providers that participate in the 340B program ("covered entities"). Therefore, most manufacturers of outpatient drugs participate in the program (Government Accountability Office 2011).

The statute specifies which types of providers are eligible to participate in the 340B program. Several types of hospitals as well as certain clinics that receive grants from the Department of Health and Human Services (e.g., federally qualified health centers and family planning clinics) are eligible for the program. There are six types of eligible hospitals: disproportionate share (DSH) hospitals, critical access hospitals (CAHs), rural referral centers (RRCs), sole community hospitals (SCHs), 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) to qualify for the program.[18]

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. 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 public and private payers and patients for these drugs. 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.

From 2005 to 2010, the number of hospital organizations in the 340B program grew from 583 to 1,365 (134 percent).[19] Most of this increase reflects growth in the number of DSH hospitals during that period, from 583 to 1,001. From 2010 to 2014, the number of 340B hospitals grew by 57 percent to 2,140. This increase was driven by growth in the number of CAHs and other types of hospitals (e.g., RRCs and SCHs) that became eligible for 340B through the Patient Protection and Affordable Care Act of 2010.[20] In 2014, about 45 percent of all Medicare acute care hospitals participated in the 340B program.

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 is defined 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;[21] 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

(continued next page)

The 340B Drug Pricing Program (cont.)

or federally qualified health center look-alike status has been provided (this criterion does not apply to hospitals) (Health Resources and Services Administration 1996).

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 entities might consider individuals to be eligible patients even when the entity does not have actual responsibility for their care (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 2015).

Covered entities can use 340B drugs for all eligible patients, including patients with Medicare or private insurance, and generate revenue if the reimbursements from payers exceed the discounted prices they pay for the drugs. 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.[22] About half the entities interviewed by GAO reported that they generated revenue that exceeded their drug costs.[23] These entities stated that they used the revenue to serve more patients and to provide additional services, such as additional locations, patient education programs, and case management.

However, the 340B statute does not restrict how covered entities can use revenue generated through the program. Therefore, 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.[24] HRSA does not have statutory authority to track how entities use this revenue.

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—for instance, 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. ■

Estimating 340B hospitals' revenue and costs of 340B drugs and savings on 340B drugs

This section includes the following:

- Estimates of the Medicare revenue that 340B hospitals receive on 340B drugs that are separately paid under the OPPS (These are primarily physician-administered drugs).[25] We included all drugs that are separately paid except for vaccines, which are not eligible for discounted prices. We also excluded orphan drugs that are provided by CAHs, cancer hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs).[26]
- An estimate of an upper bound of the cost that 340B hospitals incur to acquire the drugs that are separately paid in the OPPS.
- Estimates of the average minimum discounts (savings) that 340B hospitals receive on separately paid OPPS-covered drugs.

We used data from 2013 for our analysis and included information from hospital outpatient claims and

information on hospitals' participation in the 340B program.

We estimated the Medicare revenue that 340B hospitals receive for OPPS-covered drugs that are paid separately by summing Medicare payments for drugs that are reported on hospital outpatient claims. This revenue includes both payments from the Medicare program and beneficiaries' cost-sharing obligations. We excluded from this analysis hospitals that are not paid on the basis of ASP + 6 percent for drugs provided in hospital outpatient departments (OPDs)—CAHs and hospitals in Maryland—and hospitals for which we did not have data on overall Medicare revenue.

As a basis for estimating the costs that 340B hospitals incur to acquire drugs covered under the OPPS, we estimated the ceiling price for each drug, *(AMP – URA) × drug package size*. Data limitations required us to modify how we estimated ceiling prices. One 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 Department of Health and Human Services 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 ASPs for most drugs have risen faster than the CPI–U since the drug's market date because ASP payment was introduced in 2005 and most drugs in our analysis have a market date earlier than 2005. Consequently, we were not able to determine whether to apply inflation rebates. A third limitation was that we did not have data on the best price of the drugs.

Because of these data limitations, our estimates of ceiling prices are conservative and likely higher (possibly much higher) than what 340B hospitals actually pay. 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 × 23.1 percent*. The method we used to estimate 340B hospitals' costs to acquire drugs is:

- ***for noninnovator multiple-source drugs:*** *(1 – 0.13) × (Medicare payment indicated on a claim) / 1.06*
- ***for sole-source and innovator, multiple-source drugs:*** *(1 – 0.231) × (Medicare payment indicated on a claim) / 1.06*

We divided the Medicare payment on a claim by 1.06 because the OPPS payment for all separately payable drugs is 106 percent of the drug's ASP. This adjustment resulted in our calculations of ceiling prices being based on ASP alone.[27]

This method was a simplification from the method HRSA uses to determine ceiling prices because it omitted best price and inflation rebates and used ASP as a proxy for AMP. Consequently, our method provides an upper-bound estimate of ceiling prices paid by 340B hospitals and a lower-bound estimate of the discounts they received through the 340B program, meaning that we have likely overstated costs and understated discounts.

We estimate that in 2013, 340B hospitals (excluding CAHs, Maryland hospitals, and others for which we do not have overall Medicare revenue data) received about $3.2 billion in Medicare revenue for separately payable drugs in the OPPS.[28] We estimate an upper-bound cost of acquiring these drugs of $2.4 billion (Table 3-5). Disproportionate share (DSH) hospitals accounted for nearly all of the revenue and acquisition cost for these 340B hospitals. However, the Medicare revenue and acquisition cost for the non-DSH hospitals are underrepresented because orphan drugs, which we excluded from our estimates, are a substantial share of the OPPS-covered drugs provided by non-DSH hospitals added by PPACA: CAHs, cancer hospitals, RRCs, and SCHs.

We also estimated Medicare revenue and acquisition costs for several categories of 340B hospitals: urban or rural; major teaching, other teaching, and nonteaching; nonprofit or government owned; and number of beds. The estimates varied among categories.[29] Urban hospitals accounted for about 91 percent of total revenue and acquisition costs among 340B hospitals; major teaching hospitals accounted for about 43 percent; nonprofit hospitals accounted for about 76 percent; and hospitals that have 250 or more beds accounted for about 77 percent (percentages not shown in table).

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 discount on OPPS-covered drugs for 340B hospitals

TABLE 3–5

Medicare revenue, estimated drug acquisition cost, and differences between revenue and acquisition cost for 340B hospitals for OPPS-covered drugs

Type of hospital	OPPS drug revenue (in millions)	OPPS drug cost (in millions)	OPPS drug revenue – drug cost		
			Dollars (in millions)	Percent OPD Medicare revenue	Percent overall Medicare revenue
DSH 340B hospitals	$3,185	$2,357	$828	4.8%	1.1%
Other 340B hospitals	60	44	16	0.9	0.3
Urban	2,958	2,189	769	4.7	1.1
Rural	287	212	74	3.0	1.0
Major teaching	1,384	1,024	360	5.8	1.3
Other teaching	1,112	823	289	4.3	1.0
Nonteaching	744	551	193	3.4	0.9
Nonprofit	2,451	1,814	637	4.4	1.1
Government	794	588	207	4.8	1.2
≤ 50 beds	58	43	15	3.0	1.2
≤ 100 beds	187	138	48	3.1	1.1
101–250 beds	564	418	146	3.7	1.0
251–500 beds	1,080	799	281	3.9	0.9
> 500 beds	1,414	1,046	368	6.1	1.3

Note: OPPS (outpatient prospective payment system), OPD (hospital outpatient department), DSH (disproportionate share). DSH hospitals are eligible for the 340B program on the basis of their Medicare disproportionate share adjustment percentage and other criteria. Other 340B hospitals include cancer hospitals, pediatric hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs). This analysis excludes critical access hospitals and Maryland hospitals that participate in the 340B program and orphan drugs that are used by cancer hospitals, RRCs, and SCHs. It also excludes hospitals for which we do not have data on Medicare revenue.

Source: MedPAC analysis of 100 percent outpatient standard analytic file from 2013; file of 340B-covered entities from the Health Resources and Services Administration.

included in our analysis was 22.5 percent of the drugs' ASP. Each hospital category had similar discounts on 340B drugs (results not shown). We viewed these discount estimates as a lower bound on the actual discounts.

We also measured the difference between how much these 340B hospitals receive in Medicare revenue from OPPS-covered drugs and how much they pay to acquire them. This difference between revenue and acquisition cost is the estimated discount plus 6 percent of each drug's ASP. In aggregate, this difference is about $0.8 billion and is 1.1 percent of the overall Medicare revenue and 4.4 percent of the OPD Medicare revenue for these hospitals (Table 3-5).

For most of the hospital categories, the difference between revenue and acquisition cost as a share of overall Medicare revenue is close to the 1.1 percent for all hospitals. However, revenue minus acquisition cost as a share of OPD Medicare revenue varies among hospital categories from 3 percent for rural hospitals and hospitals that have 50 or fewer beds to about 6 percent for major teaching hospitals and hospitals that have more than 500 beds. The reason we see wider variation among OPD revenue than overall Medicare revenue is because OPD revenue is a relatively large share of overall Medicare revenue for rural hospitals and hospitals that have 50 or fewer beds, but a relatively small share of overall Medicare revenue for major teaching hospitals and hospitals that have more than 500 beds.

Should Medicare pay lower rates for Part B drugs provided by 340B hospitals?

An important policy question is whether Medicare should pay less than ASP + 6 percent for Part B drugs purchased at 340B discounted prices by 340B hospitals.[30] Even though 340B hospitals are able to purchase outpatient

drugs at a price that is, on average, at least 22.5 percent below ASP, Medicare pays ASP + 6 percent to 340B hospitals that are paid under the OPPS. In addition, beneficiaries have a cost-sharing liability of 20 percent of Medicare's payment rate; their cost sharing exceeds 20 percent of 340B hospitals' estimated costs to acquire these drugs.

Reducing the payment rates for Part B drugs provided by 340B hospitals would save money for both the Medicare program and beneficiaries but would reduce the revenue from Part B drugs that 340B hospitals receive through the 340B program. Because the 340B statute does not restrict how covered entities can use this revenue, 340B hospitals 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. If 340B hospitals lose all or a significant share of the revenue from Part B drugs that they receive through the 340B program, they may decide to reduce their participation in the program. Therefore, if policymakers decide to reduce Medicare's payment rates for Part B drugs furnished by 340B hospitals, policymakers may want to allow these hospitals to retain a share of the funds they receive through the 340B program. Under this option, 340B hospitals would retain at least some revenue from the 340B program to support their mission, giving them an incentive to continue to participate in the program.

Another consideration is whether to reduce Medicare's total payment rate (program payment plus beneficiary cost sharing) for Part B drugs provided by 340B hospitals or just beneficiaries' cost-sharing liability. It could be argued that, even if Medicare's program payment does not change, Medicare beneficiaries should pay lower cost sharing for drugs provided by 340B hospitals. ■

Endnotes

1 Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent. Our work in this report excludes these drugs and focuses only on drugs paid ASP + 6 percent.

2 Under the OPPS, Medicare pays separately for drugs that have an estimated average cost per day that exceeds a packaging threshold. That threshold is $95 in 2015 and was $80 in 2013 (the period of the data analysis). Payment for drugs with an estimated average cost per day less than the threshold are packaged into payment for other separately payable services on the claim (e.g., drug administration).

3 The sequester reduces payments providers receive for Part B–covered drugs by 1.6 percent, which results in a net payment equivalent to ASP plus 4.3 percent. Unless otherwise noted, our analysis focuses on the pre-sequester ASP + 6 percent payment rate because that is the rate specified in the Medicare statute for most Part B–covered drugs provided by physicians and suppliers.

4 For drugs provided by suppliers (e.g., inhalation, oral anticancer, oral antiemetic, and immunosuppressive drugs), the data reflect the ASP + 6 percent per prescription rather than ASP + 6 percent per administration. For ease of syntax, we use the term *drug administration* to refer to a drug administration by a physician or hospital outpatient department or a full prescription provided to a beneficiary by a supplier.

5 Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and sales that are exempt from the determination of Medicaid best price (e.g., sales to other federal programs, 340B-covered entities, state pharmaceutical assistance programs, and Medicare Part D plans). The types of discounts that must be netted from ASP include volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and chargebacks and rebates (other than rebates under the Medicaid program). Bona fide services fees—for example, fees for services paid by manufacturers to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and that are for services the manufacturer would otherwise perform in the absence of the service arrangement—are not considered price concessions for the purposes of ASP.

6 For example, the manufacturer submits its first-quarter ASP data within 30 days after the close of a quarter. CMS then has 60 days to calculate the new payments rates and update the claims processing systems so that the new payments rates can be effective in the third quarter.

7 Other technical aspects of the ASP methodology (how lagged price concessions and bundled price concessions are reflected in ASP, for example) can increase or decrease the margin on a drug.

8 For drugs provided by hospital outpatient departments, some portion of the drug payment amount is intended to cover pharmacy overhead. Specifically with respect to payment for separately paid drugs under the OPPS, CMS has stated that the drug payment rate (currently ASP + 6 percent; in prior years, as low as ASP + 4 percent) includes payment for drug acquisition costs and pharmacy overhead (Centers for Medicare & Medicaid Services 2012).

9 Inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs provided by suppliers are paid ASP + 6 percent plus a flat dispensing or supplying fee. Our model does not alter these dispensing or supplying fees, but one question that could be explored is whether those fees remain necessary if ASP + 6 percent were replaced with a payment formula that included a fixed add-on.

10 Medicare Part D plans pay for 340B drugs covered under Part D that are dispensed to beneficiaries by 340B providers or community pharmacies that contract with 340B providers. Part D drugs are primarily oral drugs.

11 This provision does not apply to disproportionate share hospitals or other covered entities that were eligible for the 340B program before 2010.

12 Because some 340B hospitals do not provide 340B drugs to Medicaid beneficiaries, we excluded spending for drugs provided to patients of these hospitals who are eligible for both Medicare and Medicaid (dual-eligible beneficiaries). We also excluded spending on vaccines because they are excluded from the 340B program and spending for all orphan drugs used by hospitals that were added to the program by PPACA because claims data do not identify the indication for which an orphan drug was used.

13 In 2010, 86 percent of beneficiaries in fee-for-service Medicare had supplemental coverage, which can cover all or part of their Part B cost-sharing liabilities (Medicare Payment Advisory Commission 2014).

14 According to GAO, state Medicaid agencies may reimburse covered entities at AAC because states cannot claim Medicaid rebates for drugs when entities decide to use drugs purchased at 340B prices for Medicaid patients. GAO interviewed

entities located in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah. Therefore, these findings may not be generalizable to all states.

15 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.

16 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.

17 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).

18 The minimum DSH adjustment percentage varies by type of hospital. The formula for the DSH adjustment percentage is complicated, but the part that is relevant for 340B hospitals equals *5.88 percent + [0.825 × (DSH patient percentage – 20.2 percent)]*. The DSH patient percentage is the sum of the percentage of Medicare inpatient days for patients who are eligible for Supplemental Security Income and the percentage of total inpatient days for patients on Medicaid.

19 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.

20 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.

21 The individual is not considered a patient if the only service he or she receives from the covered entity is the dispensing of a drug for subsequent self-administration or administration in the home.

22 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.

23 GAO did not separately report its findings by type of entity.

24 Nonprofit hospitals, however, are required to conduct a community needs assessment and document their community benefits in Internal Revenue Service tax filings.

25 In the OPPS, the costs of some drugs are packaged into the cost of the service they are provided with, and others are paid separately. Separately paid drugs either have pass-through status in the OPPS or their cost per day exceeds a threshold, which was $80 in 2013 (the year of the data we are analyzing) and is $95 for 2015.

26 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.

27 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 × ASP*, but the sequester reduces this amount to 80 percent of *1.039 × ASP*. At the same time, Medicare patients are responsible for 20 percent of *1.06 × ASP*, and the sequester has no effect on the patient's part of the payments. The net effect of the sequester is to reduce the combined revenue from Medicare and patients for separately payable drugs in the OPPS from ASP + 6 percent to ASP + 4.3 percent. For OPPS-covered drugs provided after the start of the sequester, we divide Medicare payment by 1.043 (rather than 1.06) to estimate acquisition cost.

28 On page 71, we reported that Medicare spending on separately payable Part B drugs in 340B hospitals was $3.5 billion in 2013. This amount is greater than the $3.2 billion amount on page 76 because the amount from page 71 includes all 340B hospitals, and the amount on page 76 excludes CAHs, Maryland hospitals, and hospitals for which we do not have overall Medicare revenue data.

29 When MedPAC analyzes hospitals by ownership status, we normally use nonprofit, for-profit, and government-owned categories. However, for-profit hospitals cannot participate in the 340B program, so this analysis uses nonprofit and government owned as categories for ownership status.

30 In the final rule on the OPPS for 2009, CMS requested comments that address 10 issues related to the topic of the influence of 340B hospitals in setting payment rates for separately payable drugs. Two of these issues pertained to whether 340B hospitals should be paid for drugs under the

OPPS at different rates than non-340B hospitals (Centers for Medicare & Medicaid Services 2008). In the final rule on the OPPS for 2010, CMS said that many commenters on the issues posed in the 2009 final rule were generally opposed to differential payment rates for hospitals based on their 340B status. CMS considered these differential payment rates alongside a question of whether claims from 340B hospitals should be excluded from calculating payment rates for separately payable drugs in the OPPS. CMS decided that there should not be different payment rates based on 340B status and concluded that it was not appropriate to exclude the claims from the 340B hospitals in the context of a policy that pays all hospitals the same rate for separately payable drugs (Centers for Medicare & Medicaid Services 2009).

References

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2012. Medicare and Medicaid Programs: Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; electronic reporting pilot; inpatient rehabilitation facilities quality reporting program; revision to quality improvement organization regulations. Final rule. *Federal Register* 77, no. 221 (November 15): 68210–68565.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2009. Medicare program; changes to the hospital outpatient prospective payment system and CY 2010 payment rates; changes to the ambulatory surgical center payment system and CY 2010 payment rates. Final rule. *Federal Register* 74, no. 223 (November 20): 60315–60983.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2008. Medicare program: changes to the hospital outpatient prospective payment system and CY 2009 payment rates; changes to the ambulatory surgical center payment system and CY 2009 payment rates; requirements for approval and re-approval of transplant centers to perform organ transplants—clarification of provider and supplier termination policy Medicare and Medicaid programs: changes to the ambulatory surgical center conditions for coverage. Final rule. *Federal Register* 73, no. 223 (November 18): 68501–69380.

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

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. 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. 2015. 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. 2014a. FAQs: 340B Drug Pricing Program. http://www.hrsa.gov/opa/faqs/index.html.

Health Resources and Services Administration, Department of Health and Human Services. 2014b. *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. 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.

Hutton, D., P. A. Newman-Casey, M. Tavag, et al. 2014. Switching to less expensive blindness drug could save Medicare Part B $18 billion over a ten-year period. *Health Affairs* 33, no. 6 (June): 931–939.

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.

Jacobson, M., C. C. Earle, M. Price, et al. 2010. How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment. *Health Affairs* 29, no. 7 (July): 1391–1399.

Medicare Payment Advisory Commission. 2014. *A data book: Health care spending and the Medicare program.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2007. *Report to the Congress: Impact of changes in Medicare payments for Part B drugs.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2006. *Report to the Congress: Effects of Medicare payment changes on oncology.* Washington, DC: MedPAC.

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.

Office of Inspector General, Department of Health and Human Services. 2012. *Least costly alternative policies: Impact on prostate cancer drugs covered under Medicare Part B.* OEI–12–12–00210. Washington, DC: OIG.

Office of Inspector General, Department of Health and Human Services. 2011a. *Medicare payments for newly available generic drugs.* OEI–03–09–00510. Washington, DC: OIG.

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

Sanghavi, D., K. Patel, K. Samuels, et al. 2014. *Transforming cancer care and the role of payment reform: Lessons from the New Mexico Cancer Center.* Engleberg Center for Health Care Reform at Brookings. Washington, DC: The Brookings Institution.

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