OCT 22 2010

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Stuart Wright /S/
Deputy Inspector General
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SUBJECT: Memorandum Report: *Payment for Drugs Under the Hospital Outpatient Prospective Payment System*, OEI-03-09-00420

This memorandum report presents the results of our review comparing Medicare payment amounts for 32 selected separately payable drugs covered under the hospital Outpatient Prospective Payment System (OPPS) to hospital acquisition costs. Certain stakeholders[1] have expressed concerns about the OPPS payments for separately payable drugs, including that (1) Medicare payment amounts may substantially exceed acquisition costs for 340B hospitals, and (2) Medicare payment amounts may be lower than acquisition costs for non-340B hospitals.

We found that, in the aggregate, Medicare payments were 31 percent higher than acquisition costs among responding 340B hospitals and 1 percent higher than acquisition costs among responding non-340B hospitals for the selected separately payable drugs. For the individual drugs, the Medicare payment amounts for more than half exceeded non-340B hospital acquisition costs. The Medicare payment amounts for the remaining drugs purchased by non-340B hospitals were below average acquisition costs, albeit by a small amount (between 0.6 percent and 11 percent).

BACKGROUND

Medicare Part B Coverage of Prescription Drugs

Although Medicare Part D covers most outpatient prescription drugs, the Centers for Medicare and Medicaid Services (CMS) continues to cover a limited number of outpatient prescription drugs under its Part B benefit. Part B-covered drugs generally fall into the

[1] Examples of stakeholders expressing concern are: the American Hospital Association, the Alliance of Dedicated Cancer Centers, the New Jersey Hospital Association, and the Plasma Protein Therapeutics Association.

following categories: drugs furnished incident to a physician's service (e.g., injectable drugs used in connection with the treatment of cancer); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with durable medical equipment (e.g., inhalation drugs).[2] Medicare beneficiaries can receive Part B-covered drugs in several settings, including physician offices and hospital outpatient departments.

OPPS

Prior to 2000, Medicare largely based payments for hospital outpatient services on reasonable costs. Congress replaced the reasonable cost-based payment method with a prospective payment system in which Medicare pays a predetermined, fixed amount.[3, 4] In 2000, CMS implemented OPPS to pay hospitals for Part B outpatient services including, but not limited to, certain Part B-covered drugs.

OPPS Payment for Drugs

The OPPS payment for drugs is generally divided into two categories: separately payable drugs and packaged drugs.

Separately payable drugs. CMS makes a discrete payment for Part B-covered drugs when estimated per-drug, per-day costs are greater than $60 (for 2009).[5] CMS also makes separate payments for drugs with pass-through status, regardless of whether they exceed the packaging threshold of $60 per day per drug.[6, 7] Prior to 2010, CMS made separate payments for several antiemetic drugs (antinausea drugs typically administered to cancer patients) regardless of cost.[8]

For the purposes of this review, separately payable drugs generally refer to any drugs that Medicare made a separate payment for under the OPPS in 2009; i.e., drugs that have per-day costs above the $60 threshold, pass-through drugs, and certain antiemetics. Medicare and its beneficiaries paid approximately $3 billion for separately payable drugs provided in hospital outpatient departments in 2007.[9]

Packaged drugs. With certain exceptions, packaged drugs are inexpensive Part B-covered drugs that do not exceed the OPPS packaging threshold ($60 per day per drug in 2009) and

[2] 68 Fed. Reg. 50428, 50429 (Aug. 20, 2003).
[3] Section 1833(t) of the Social Security Act (the Act), 42 U.S.C. § 1395l(t); 42 CFR Part 419.
[4] Section 1833(t) of the Act, as added by the Balanced Budget Act of 1997, authorized OPPS. The CMS final rule implementing OPPS is at 65 Fed. Reg. 18434 (Apr. 7, 2000).
[5] See 73 Fed. Reg. 68502, 68642 (Nov. 18, 2008) for CMS's methodology for setting the packaging threshold.
[6] Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain new drugs.
[7] Section 1833(t)(6)(A) of the Act and 73 Fed. Reg. 68502, 68632 (Nov. 18, 2008).
[8] CMS removed this exemption from the packaging threshold in its rulemaking for 2010. 74 Fed. Reg. 60316, 60487 (Nov. 20, 2009).
[9] Medicare Payment Advisory Commission. *A Data Book: Healthcare Spending and the Medicare Program*. June 2009.

are not antiemetic or pass-through drugs. CMS does not make separate payment for packaged drugs; it includes (i.e., packages) payment for these drugs as part of the payment for the treatment during which the drug is administered.

OPPS Payment Methodology

Since 2006, CMS has based the OPPS payment rate for separately payable drugs on average sales price (ASP).[10] The ASP is a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.[11] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[12]

For drugs administered in a physician's office, the Medicare payment amount is set by the Act at 106 percent of the ASP.[13] Although the OPPS also bases payment for separately payable drugs on ASP, the Act does not define a set payment methodology. Rather, CMS annually updates the payment methodology (i.e., the percentage added to or subtracted from the ASP) for separately payable drugs that are not pass-through drugs through the rulemaking process. After examining Medicare claims data to gauge hospital acquisition costs for the drugs and overhead costs, CMS set the 2009 Medicare payment amount for non-pass-through separately payable drugs at 104 percent of the ASP (see Table 1).[14] The payment amount for pass-through drugs paid under the OPPS is equal to the payment amount for drugs in the physician office setting (i.e., 106 percent of the ASP), according to CMS.[15] The Medicare payment amount for the OPPS is meant to cover both acquisition costs for the drugs and related overhead costs.[16]

In previous rulemakings, CMS proposed various approaches for gathering information on how overhead costs are allocated and accounted for among particular drugs in hospital

[10] 70 Fed. Reg. 68516, 68640 (Nov. 10, 2005); section 1833(t)(14)(A)(iii)(II) of the Act.
[11] Section 1847A(c) of the Act.
[12] See section 1847A(c)(2) of the Act. Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.
[13] Section 1847A(b)(1) of the Act.
[14] The method used to calculate Medicare payment amounts for separately payable drugs under OPPS did not change for 2010. See 73 Fed. Reg. 68502, 68651–68659 (Nov. 18, 2008) for an explanation of how CMS determined payment rates for 2009.
[15] The payment methodology is updated annually. However, Medicare payment amounts under OPPS are updated quarterly based on changes to the manufacturer-reported ASPs.
[16] 73 Fed. Reg. 68502, 68656 (Nov. 18, 2008).

outpatient pharmacies.[17] Hospitals claimed that all of these approaches would be administratively burdensome, and CMS did not implement any of them. Additionally, CMS does not specifically define what constitutes overhead costs.

Table 1: Medicare Payment Amounts for Drugs Under OPPS in 2009

Drug Type	OPPS Payment Amount for 2009
Separately payable drugs (drugs that exceed the $60 threshold and some antiemetics in 2009)	104 percent of ASP
Separately payable drugs (pass-through drugs)	106 percent of ASP
Packaged drugs	Not applicable; payment included in related service

Source: Office of Inspector General (OIG) analysis of Medicare payment under OPPS and 73 Fed. Reg. 68502 (Nov. 18, 2008).

340B Program

The Medicare payment amounts for drugs under the OPPS are the same for all types of hospital outpatient departments. However, hospital acquisition costs vary widely and certain hospitals are able to purchase drugs at reduced prices.

The 340B Drug Pricing Program (340B Program), overseen by the Health Resources and Services Administration (HRSA), was created to assist entities that provide services to disproportionately low-income, uninsured, and underinsured populations and allow them to purchase drugs at reduced prices. Under the 340B Program, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for certain sales to certain covered entities.[18] Therefore, eligible entities that participate in the 340B Program should have lower acquisition costs for many drugs. Eligible 340B entities include disproportionate share hospitals, Ryan White grantees, State-operated AIDS drug assistance programs, and black lung clinics, among others. As of March 2010, approximately 14,500 entities were enrolled in the 340B Program.[19, 20]

[17] See 74 Fed. Reg. 60316, 60499–60501 (Nov. 20, 2009) for a discussion of CMS's proposals for accurately paying overhead costs.
[18] The Veterans Health Care Act of 1992, P.L. No. 102-585, § 602, which is codified as section 340B of the Public Health Service (PHS) Act, established the 340B Program. See 42 U.S.C. § 256b.
[19] HRSA, *Covered Entity Database*. Accessed at http://www.hrsa.gov on April 29, 2010.
[20] Because the 340B Program requires each location to be registered individually in HRSA's Covered Entity database, and a 340B entity may have several satellite sites, the database includes multiple entity listings associated with the same organization.

Drugs purchased under the 340B Program by disproportionate share hospitals (hereinafter referred to as 340B hospitals) are paid for under the OPPS when administered to Medicare beneficiaries in an outpatient setting.[21] A 340B hospital is defined as:

- being owned or operated by a unit of State or local government, a public or private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, or a private nonprofit hospital which has a contract with a State or local government to provide services to low-income individuals;

- having a disproportionate share adjustment percentage[22] greater than 11.75 percent or being described in section 1886(d)(5)(F)(i)(II) of the Act; and

- not obtaining covered outpatient drugs through a group purchasing arrangement.[23]

Sales to covered entities through the 340B Program are not included in the calculation of the ASP.[24] If 340B sales were included, the ASPs would be lower because of 340B entities' eligibility for substantially lower drug prices. Medicare claims data from 340B hospitals are included when CMS determines the Medicare payment amount for separately payable non-pass-through drugs under the OPPS each year.

METHODOLOGY

Scope

We compared first-quarter 2009 Medicare payment amounts to first-quarter 2009 hospital acquisition costs for 33 separately payable drugs from 2 separate random samples of hospitals in the United States that participate in Medicare: 1 sample of 99 340B hospitals and another sample of 110 non-340B hospitals. This study includes only separately payable drugs; i.e., we excluded packaged drugs from our analysis because CMS does not calculate a separate Medicare payment amount. See Appendix A for a list of the drugs under review.

Data Sources and Collection

Drugs and Medicare payment amounts. Separately payable drugs are identified and billed using Healthcare Common Procedure Coding System (HCPCS) codes. Each HCPCS code defines the drug name and the dosage amount represented by the HCPCS code but does not specify manufacturer or package size information. We obtained a list of the top 30 separately

[21] Section 7101 of the Affordable Care Act extended participation in the 340B program to certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers. However, these changes took effect after the time period covered by this review.
[22] See section 1886(d)(5)(F) of the Act for the definition and calculation of the disproportionate share adjustment percentage.
[23] HRSA, *Introduction to 340B Drug Pricing Program*. Accessed at http://www.hrsa.gov on March 16, 2010. 42 U.S.C. § 256b(a)(4)(L).
[24] Sections 1847A(c)(2)(A) and 1927(c)(1)(C)(i)(I) of the Act.

payable HCPCS codes by Medicare expenditures in 2008 from CMS. We included 3 additional HCPCS codes at CMS's request for a total of 33 drugs.[25] We obtained first-quarter 2009 Medicare payment amounts under the OPPS for the selected drugs from CMS's Web site.

Hospital acquisition costs. We selected two random samples: one for 340B hospitals and one for non-340B hospitals. We obtained a list of 340B hospitals from HRSA's Covered Entity database in July 2009. This database contains the name and contact information for all 340B hospitals. From this list we selected a random sample of 100 340B hospitals.[26] We removed 1 of the selected hospitals because of an ongoing OIG investigation for a sample size of 99. To select the sample of non-340B hospitals, we obtained the Online Survey, Certification, and Reporting database. This database contains the names and contact information of hospitals participating in Medicare nationwide. We first removed 340B hospitals (as identified in the HRSA database) from this list and selected a random sample of 110 non-340B hospitals from the remaining facilities.[27]

In September 2009, we sent written surveys to the hospitals in our two samples. For each of the 33 drugs under review, we asked the hospitals to provide their first-quarter 2009 acquisition costs, any discounts or rebates for these purchases, the number of units purchased, and whether the purchases were made through the 340B Program. In addition, we asked hospitals to indicate whether the drugs were for outpatient use. We sent up to two written followup surveys to nonresponding hospitals in our samples between October and November 2009. Additionally, we conducted multiple followup phone calls with nonresponding hospitals to elicit a higher response rate. See Appendix B for a detailed methodology.

Between October and December 2009, 94 340B and 110 non-340B hospitals responded to our survey and 90 340B and 77 non-340B hospitals provided some acquisition cost data. Not all hospitals in the sample purchased all of the drugs under review. Therefore, the number of hospitals with acquisition cost data for each drug varied widely. For example, less than 10 hospitals in each sample reported any purchases for 6 of the drugs. See Appendix C for the number of hospitals providing data per drug.

We also asked hospitals to provide data on their pharmacy overhead costs. Per CMS's recommendation, we did not include a specific definition of overhead costs in our survey. Based on public comment, CMS believed that if OIG were to provide examples of overhead costs in its survey, responding hospitals might interpret the examples as legal definitions of overhead costs. Given that CMS itself has not explicitly defined these costs for individual

[25] Two of the thirty-three drugs had pass-through status in the first quarter of 2009. See Appendix A.
[26] As of July 2009, there were 2,541 340B hospitals listed in HRSA's Covered Entity Database. We identified and linked related entities into units we refer to as "purchasing agents" because we wanted our sampling units to be entities that purchase drugs either for themselves or on behalf of affiliated entities. This sample was drawn from a universe of 851 hospital purchasing agents.
[27] This sample was drawn from a universe of 5,305 hospitals.

drugs, we did not want to establish a definition that could be the source of future conflict between the agency and hospitals. Therefore, hospitals had minimal guidance in providing these data. Absent a consistent definition of overhead costs, we were not able to determine how these self-reported figures relate to any additional costs that are meant to be reimbursed under the payment amount for each individual drug.

Data Analysis

From the list of hospitals that provided acquisition cost data, we removed 1 340B hospital and 29 non-340B hospitals that did not participate in the OPPS.[28] Our subsequent analysis was based on these data reported by the remaining 89 340B hospitals and 48 non-340B hospitals. We excluded 1 drug (Q4101) from our analysis because of low reported utilization (one 340B and one non-340B hospitals reported purchasing Q4101), resulting in a total of 32 separately payable drugs under review.

For both hospital types (i.e., 340B and non-340B), we aggregated the hospitals' acquisition costs data by the appropriate HCPCS code. We then calculated volume-weighted average acquisition costs (hereinafter referred to as average acquisition costs) by totaling the acquisition costs, net of any discounts and rebates, for each drug and dividing them by the total units purchased among all facilities for each drug. We determined the percentage difference between CMS's first-quarter 2009 ASP-based Medicare payment amount for each drug and the average acquisition costs for both hospital types. To determine the aggregate difference between CMS's first-quarter 2009 ASP-based Medicare payment amounts and total acquisition costs among all 32 drugs for both 340B and non-340B hospitals, we:

- determined the total acquisition costs for the 32 drugs among each hospital type by summing the data reported by all respondents;

- multiplied the total units purchased for each drug, as reported by hospitals, by the drug's Medicare payment amount to calculate the total amount that hospitals would have paid for all selected drugs if their acquisition costs equaled Medicare payment amounts; and

- calculated the percentage difference between the total amount that would have been paid had the acquisition cost equaled Medicare payment amounts and the total amount paid for the 32 drugs, as reported by 340B and non-340B hospitals.

Limitations

The analysis and results in this report are based only on self-reported data received from responding hospitals in our sample. We were unable to make projections to the universe of hospitals because of the limited number of hospitals that purchased certain drugs as well as the large number of hospitals removed from our analysis.

[28] Examples of non-340B hospitals that are not paid under OPPS include critical access hospitals and hospitals in Maryland. 42 CFR § 419.20(b).

Standards

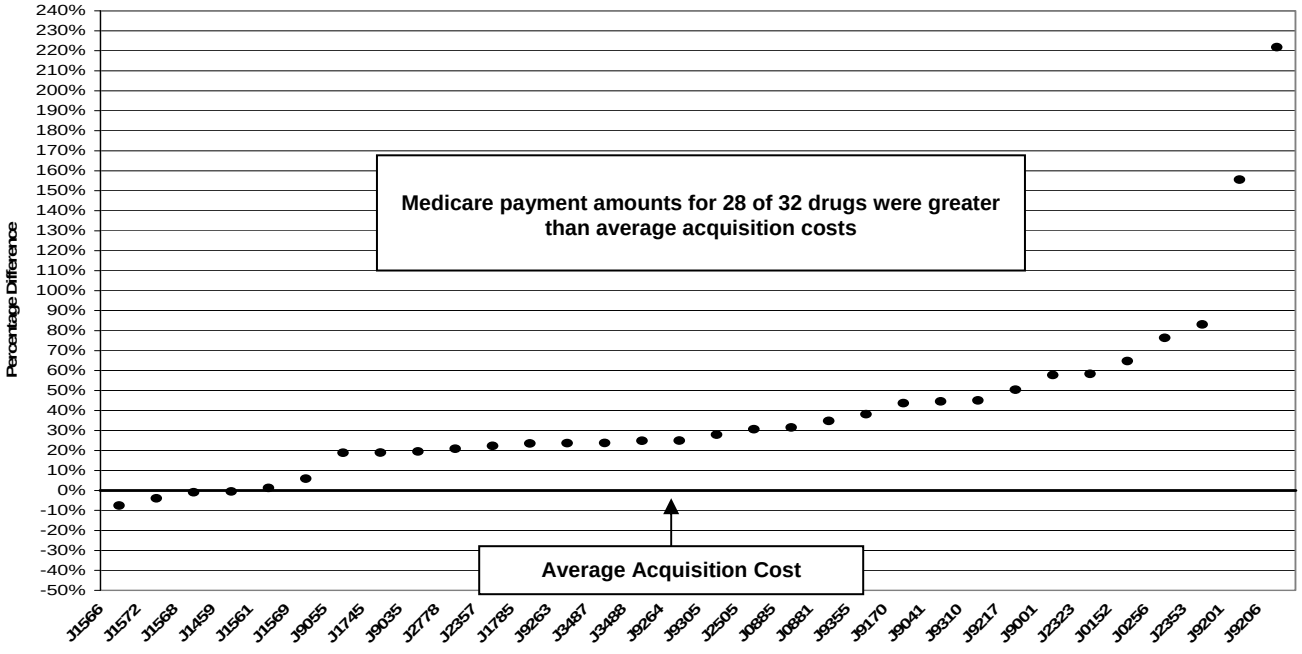
This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Medicare Payments to Responding 340B Hospitals for Separately Payable Drugs Were 31 Percent Higher Than Their Aggregate Acquisition Costs

In the first quarter of 2009, the aggregate Medicare payment amount was 31 percent higher than drug acquisition costs for 340B hospitals providing data. Despite stakeholder concerns, this is an expected result given the purpose of the 340B Program. In fact, for the 32 drugs under review, the Medicare payment amount exceeded acquisition costs for 89 percent of the drug purchases (by dollars) made by responding 340B hospitals. Medicare payment amounts for 28 drugs were between 1 percent and 222 percent higher than average acquisition costs. For the remaining four drugs, Medicare payment amounts were between 0.5 percent and 8 percent below acquisition costs. Chart 1 illustrates the range of differences between average acquisition costs and Medicare payment amounts for 340B hospitals. See Table D-1 in Appendix D for a comparison of Medicare payment amounts to average acquisition costs among 340B hospitals for each of the 32 drugs.

Chart 1. Comparison of Medicare Payment Amounts to Average Acquisition Costs for 340B Hospitals



Source: OIG analysis of 340B hospital acquisition cost data and first-quarter 2009 Medicare payment amounts. 2010.

A substantial majority of the drugs under review[29] have Medicare payment amounts that are higher than average acquisition costs because the 340B Program enables eligible entities (e.g., 340B hospitals) to purchase drugs at reduced prices based on the fact that the populations served by these entities are disproportionately low-income, uninsured, and underinsured. Furthermore, the lower sales prices to 340B entities are not included when manufacturers calculate ASPs (i.e., the basis of hospital payment for separately payable drugs is not reduced by the inclusion of 340B prices).

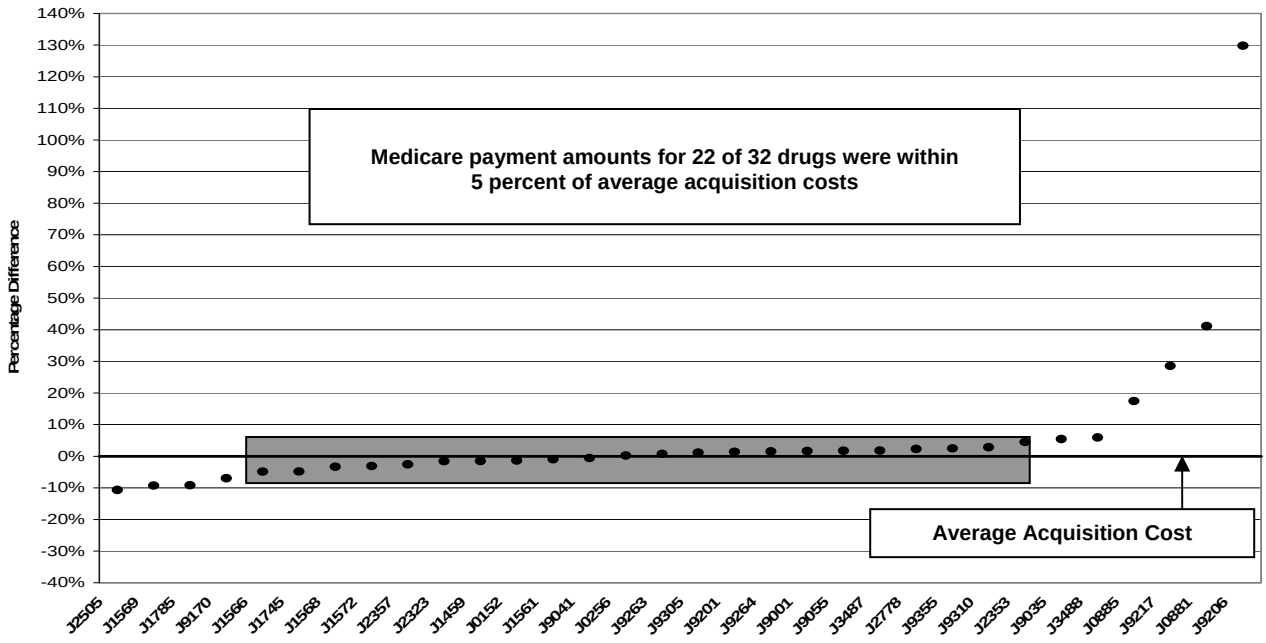
Medicare Payments to Responding Non-340B Hospitals for Separately Payable Drugs Were 1 Percent Higher Than Their Aggregate Acquisition Costs

In the first quarter of 2009, the aggregate Medicare payment amount was 1 percent higher than drug acquisition costs for non-340B hospitals providing data. For the 32 drugs under review, the Medicare payment amount exceeded acquisition costs for slightly more than half of the drug purchases (by dollars) by responding non-340B hospitals (54 percent).

The Medicare payment amount for more than half of the selected drugs (18 of 32) exceeded hospitals' acquisition costs by between 0.3 percent and 130 percent. The Medicare payment amounts for the remaining drugs (14 of 32) were below average acquisition costs, albeit by a small amount (between 0.6 percent and 11 percent). For non-340B hospitals, the difference between Medicare payment amounts and average acquisition costs was less than 5 percent for 22 of the 32 drugs under review. The lack of substantial differences is an expected result given that these hospitals do not have access to the reduced prices of the 340B program. Chart 2 illustrates the range of differences between average acquisition costs and Medicare payment amounts for non-340B hospitals. See Table D-2 in Appendix D for a comparison of Medicare payment amounts to average acquisition costs for non-340B hospitals for each of the 32 drugs.

[29] The four drugs with Medicare payment amounts below average acquisition costs are intravenous immune globulin products. According to hospital responses, a substantial majority of the purchases for these drugs were not made through the 340B Program.

Chart 2. Comparison of Medicare Payment Amounts to Average Acquisition Costs for Non-340B Hospitals



Source: OIG analysis of non-340B hospital acquisition cost data and first-quarter 2009 Medicare payment amounts, 2010.

CONCLUSION

In this report, we compared Medicare payment amounts under the OPPS to hospital acquisition costs. We found that, in the aggregate, Medicare payment amounts were (1) substantially higher than acquisition costs for 340B hospitals and (2) similar to acquisition costs for non-340B hospitals. This is an expected result given the purpose of the 340B Program.

The Medicare payment amount for separately payable drugs under the OPPS is based on manufacturer-reported ASPs. Because ASPs do not reflect 340B prices (which are generally lower than other sales prices), a substantial majority of the drugs purchased by 340B hospitals have Medicare payment amounts that are higher than average acquisition costs. Similarly, because non-340B hospitals do not have access to reduced prices, the ASP-based Medicare payment amounts are closer to their acquisition costs. Although for some individual drugs the Medicare payment amount was slightly below average acquisition costs at non-340B hospitals, the fact that overall payment levels exceeded costs leads us to conclude that stakeholder concerns about underpayment were unfounded.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-03-09-00420 in all correspondence.

APPENDIX A

Table A-1. Drugs Under Review

HCPCS Code[1]		
J0152	Adenosine injection	30 mg[2]
J0256	Alpha 1 proteinase inhibitor	10 mg
J0881	Darbepoetin alfa, non-ESRD[3]	1 mcg[2]
J0885	Epoetin alfa, non-ESRD	1000 units
J1459[4, 5]	Privigen injection	500 mg
J1561	Gamunex injection	500 mg
J1566	Immune globulin, powder	500 mg
J1568[4]	Octagam injection	500 mg
J1569	Gammagard liquid injection	500 mg
J1572	Flebogamma injection	500 mg
J1745	Infliximab injection	10 mg
J1785	Injection Imiglucerase /unit	1 unit
J2323	Natalizumab injection	1 mg
J2353	Octreotide injection, depot	1 mg
J2357	Omalizumab injection	5 mg
J2505	Injection, pegfilgrastim	6 mg
J2778	Ranibizumab injection	0.1 mg
J3487	Zoledronic acid	1 mg
J3488[5]	Reclast injection	1 mg
J9001	Doxorubicin HCl liposome injection	10 mg
J9035	Bevacizumab injection	10 mg
J9041	Bortezomib injection	0.1 mg
J9055	Cetuximab injection	10 mg
J9170	Docetaxel	20 mg
J9201	Gemcitabine HCl	200 mg
J9206	Irinotecan injection	20 mg
J9217	Leuprolide Acetate suspension	7.5 mg
J9263	Oxaliplatin	0.5 mg
J9264	Paclitaxel protein bound	1 mg
J9305	Pemetrexed injection	10 mg
J9310	Rituximab injection	100 mg
J9355	Trastuzumab	10 mg
Q4101[4, 6]	Apligraf skin sub	1 sq cm[2]

Source: Centers for Medicare & Medicaid Services (CMS) first-quarter 2009 Addendum B pricing file.

[1] Healthcare Common Procedure Coding System.

[2] mg=milligram; mcg=microgram; cm=centimeter.

[3] ESRD is end stage renal disease.

[4] Denotes HCPCS codes included in the review at CMS's request.

[5] Denotes HCPCS codes for pass-through drugs.

[6] This code was excluded from our analysis because of the low response rate.

APPENDIX B – Detailed Methodology

340B Sample Selection

We obtained a complete list of 340B hospitals from the Health Resources and Services Administration's (HRSA) Covered Entity database. Because the 340B Program requires each location to be registered individually in HRSA's Covered Entity database, and a 340B entity may have several satellite sites, the database includes multiple entity listings associated with the same organization. We identified and linked related entities into units we refer to as "purchasing agents" because we wanted our sampling units to be entities that purchase drugs either for themselves or on behalf of affiliated entities.

We used the HRSA-assigned unique 340B identification number to group affiliated entities by purchasing agent. This identification number consists of three segments: first, a letter prefix that indicates the entity type; second, numbers assigned at HRSA's discretion; and third, if a site is related to another site, a terminal letter suffix. An example of the unique identification number would be DSH1234A. Using this number, we grouped entities together if their HRSA identification numbers differed only by letter suffix and counted each grouping as one purchasing agent. For example, to link DSH1234A to other entities, we would have grouped it with DSH1234B and DSH1234C. Each group of entities was counted as one purchasing agent. Entities with no listed affiliates were each counted as one purchasing agent. We selected a random sample of 100 340B purchasing agents.[30, 31] For the purposes of this report, we refer to the purchasing agent and related satellite sites as a single 340B hospital. We removed 1 340B purchasing agent because of an ongoing OIG investigation for a sample size of 99.

Data Collection and Analysis

Prior to calculating and aggregating average acquisition cost figures for each of the sampled drugs, we examined the national drug codes (NDC), which are 11-digit drug identifiers, reported by the hospitals for each Healthcare Common Procedure Coding System (HCPCS) code to determine whether they were valid and associated with the correct code. We used the Centers for Medicare & Medicaid Services' HCPCS crosswalk file (a file that links NDCs to their associated HCPCS codes) to make this determination. We excluded all NDCs (and the associated cost data) that were not associated with a HCPCS code under review. In calculating the average acquisition cost, we identified any outliers among the costs reported by hospitals and removed them from our analysis. We defined an outlier as an average acquisition cost reported by a facility that fell more than three standard deviations from the mean.

[30] As of July 2009, there were 2,541 340B hospitals listed in HRSA's Covered Entity Database. There are a total of 851 purchasing agents.

[31] This sampling method for the selection of purchasing agents for 340B entities has been used previously by the Office of Inspector General (OIG). See *Review of 340B Prices*, OEI-05-02-00073, July 2006.

APPENDIX C

Table C-1. Number of Hospitals Providing Data per Drug

HCPCS Code[1]		
J0152	37	22
J0256	7	6
J0881	44	20
J0885	69	35
J1459	8	3
J1561	14	8
J1566	18	10
J1568	6	2
J1569	25	8
J1572	12	9
J1745	64	28
J1785	8	3
J2323	25	8
J2353	33	14
J2357	26	6
J2505	60	25
J2778	3	2
J3487	54	22
J3488	44	24
J9001	36	11
J9035	54	18
J9041	39	13
J9055	48	12
J9170	59	14
J9201	56	17
J9206	50	14
J9217	41	11
J9263	55	19
J9264	28	4
J9305	42	11
J9310	62	22
J9355	51	17
Q4101[2]	1	1

Source: Office of Inspector General analysis of hospital responses.
[1] Healthcare Common Procedure Coding System.
[2] Denotes the HCPCS code excluded from the analysis.
Note: Outliers and other invalid data were excluded from these figures.

APPENDIX D

Table D-1. Comparison of Medicare Payment Amounts to Average Acquisition Costs for 340B Hospitals

HCPCS Code*			
J1566	$28.87	$31.21	-7.50%
J1572	$34.92	$36.34	-3.92%
J1568	$36.18	$36.52	-0.93%
J1459**	$34.16	$34.33	-0.49%
J1561	$34.86	$34.42	1.28%
J1569	$34.71	$32.75	5.97%
J9055	$48.80	$41.04	18.91%
J1745	$55.85	$46.95	18.95%
J9035	$56.30	$47.10	19.53%
J2778	$398.92	$330.09	20.85%
J2357	$17.88	$14.62	22.29%
J1785	$4.02	$3.25	23.57%
J9263	$9.39	$7.59	23.75%
J3487	$211.15	$170.62	23.75%
J3488**	$218.51	$175.01	24.86%
J9264	$8.90	$7.12	24.98%
J9305	$47.31	$36.97	27.95%
J2505	$2,135.09	$1,633.68	30.69%
J0885	$9.03	$6.86	31.54%
J0881	$3.00	$2.23	34.78%
J9355	$60.48	$43.79	38.12%
J9170	$330.59	$230.16	43.63%
J9041	$35.59	$24.63	44.52%
J9310	$525.21	$362.08	45.06%
J9217	$206.11	$136.96	50.49%
J9001	$432.93	$274.37	57.79%
J2323	$7.76	$4.90	58.32%
J0152	$69.09	$41.93	64.77%
J0256	$3.64	$2.06	76.41%
J2353	$103.83	$56.72	83.06%
J9201	$135.58	$53.06	155.52%
J9206	$21.31	$6.62	221.76%

Source: Office of Inspector General (OIG) analysis of first-quarter 2009 Medicare payment amounts and 340B acquisition cost data.
* Healthcare Common Procedure Coding System.
** Denotes HCPCS codes for pass-through drugs.

Table D-2. Comparison of Medicare Payment Amounts to Average Acquisition Costs for Non-340B Hospitals

HCPCS Code			
J2505	$2,135.09	$2,389.83	-10.66%
J1569	$34.71	$38.26	-9.28%
J1785	$4.02	$4.42	-9.13%
J9170	$330.59	$355.19	-6.92%
J1566	$28.87	$30.34	-4.86%
J1745	$55.85	$58.68	-4.82%
J1568	$36.18	$37.42	-3.32%
J1572	$34.92	$36.04	-3.10%
J2357	$17.88	$18.34	-2.52%
J2323	$7.76	$7.88	-1.55%
J1459*	$34.16	$34.67	-1.48%
J0152	$69.09	$70.00	-1.31%
J1561	$34.86	$35.20	-0.96%
J9041	$35.59	$35.79	-0.55%
J0256	$3.64	$3.63	0.25%
J9263	$9.39	$9.32	0.77%
J9305	$47.31	$46.78	1.14%
J9201	$135.58	$133.67	1.43%
J9264	$8.90	$8.76	1.56%
J9001	$432.93	$425.90	1.65%
J9055	$48.80	$47.96	1.75%
J3487	$211.15	$207.43	1.79%
J2778	$398.92	$390.00	2.29%
J9355	$60.48	$59.03	2.45%
J9310	$525.21	$510.47	2.89%
J2353	$103.83	$99.37	4.49%
J9035	$56.30	$53.39	5.45%
J3488*	$218.51	$206.27	5.93%
J0885	$9.03	$7.69	17.48%
J9217	$206.11	$160.27	28.60%
J0881	$3.00	$2.13	41.17%
J9206	$21.31	$9.27	129.80%

Source: OIG analysis of first-quarter 2009 Medicare payment amounts and non-340B acquisition cost data.
* Denotes HCPCS codes for pass-through drugs.