

**Analysis of Patient Characteristics
among Medicare Recipients of
Separately Billable Part B Drugs from
340B DSH Hospitals and Non-340B
Hospitals and Physician Offices**

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Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices

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Executive Summary

Conclusions in Brief

A comparison of demographic characteristics of Medicare beneficiaries receiving separately billable outpatient drugs from Medicare Part B providers shows that, compared to non-340B hospitals and physician offices, 340B disproportionate share (DSH) hospitals treat significantly more Medicare beneficiaries that are dually eligible for Medicaid and Medicare, disabled, Black or African-American, Hispanic, or have end stage renal disease (ESRD). This analysis demonstrates that the 340B program eligibility criteria for DSH hospitals target hospitals that serve low-income and vulnerable patient populations, consistent with the intent of the 340B program.

Background

340B Health commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to examine the Medicare beneficiary population receiving separately billable Medicare Part B drugs from 340B DSH hospitals. The intent of the 340B legislation¹ is to assist hospitals that treat a high level of Medicaid and low-income Medicare patients or serve rural communities in providing services to their patient populations by giving these hospitals discounts on outpatient drugs. The focus of this analysis is on DSH hospitals, which qualify for 340B due to their high volume of low-income patients.

The purpose of this study is to examine the characteristics of three Medicare beneficiary populations receiving separately billable Part B drugs from the perspective of three distinct populations: 1) Medicare beneficiaries served exclusively by 340B DSH hospitals, 2) beneficiaries served by non-340B hospitals, and 3) those served by physician offices. Our hypothesis is that the patient population served by 340B DSH hospitals is significantly different than populations receiving care in non-340B hospitals and physician offices.

¹ Section 340B of the Veterans Health Care Act of 1992

Executive Summary

In a separate study that used 2014 Medicare cost reports, we determined the extent to which 340B DSH hospitals were targeting their services to low-income populations (defined as the sum of Medicaid patient days as a percent of total patient days and Medicare/Supplemental Security Income (SSI) patient days as a percent of total Medicare days, because that is the low-income patient metric used for 340B DSH hospital eligibility).² We found that 340B DSH hospitals had a significantly higher proportion of low-income patients days overall than non-340B hospitals (42.5% vs. 26.0%). We also found that 340B DSH hospitals provided a disproportionate amount of uncompensated care compared to non-340B hospitals (\$23.7 billion vs. \$16.1 billion). Although 340B DSH hospitals accounted for only 36% of all hospitals in the analysis, 340B DSH hospitals provided 59% of all uncompensated care.

These findings suggest that 340B DSH hospitals have significantly higher low income caseloads than non-340B hospitals, both overall and on a per hospital basis, and provide a disproportionately greater amount of uncompensated care than non-340B hospitals. Thus, the 340B eligibility criteria are and continue to be appropriate in that they target hospitals serving low income, vulnerable patient populations. Furthermore, the population served by 340B DSH hospitals is very different than that served by non-340B organizations.

Study Purpose

The purpose of this study is to compare the demographic characteristics of the beneficiary population receiving separately billable Part B drugs solely from 340B DSH hospitals, and compare them to the characteristics of the population being served by the rest of the providers in the Part B market (non-340B hospitals and physicians). Our study compared patients who **only** use 340B DSH hospitals to patients who received care from non-340B providers that provide Part B drugs, specifically non-340B hospitals and physician offices.

Findings

Our analysis of the characteristics of the populations receiving Part B drugs in 340B DSH hospitals alone found that 340B DSH hospitals treat more low income and vulnerable populations than non-340B providers. Pairwise comparisons between 340B DSH hospitals and non-340B hospitals, and between 340B hospitals and physician offices, were significant ($p < 0.0001$). As shown in Table ES-1 below, our analysis of the 2013 Medicare 5% SAF LDS claims found that:

- 517,420 beneficiaries received their separately billable Part B drugs in 340B DSH hospitals in 2013 (including DSH hospitals, rural referral centers and sole

² DaVanzo JE, Murray K, Haught R. *Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations, Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals*, Nov. 2016.

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community hospitals paid under the Medicare inpatient prospective payment system).

- 671,960 beneficiaries received their separately billable Part B drugs in non-340B hospitals.
- 2,959,450 beneficiaries received their separately billable Part B drugs in physician offices.

We found that 340B DSH hospitals, compared to non-340B hospitals and physician offices were:

- More likely to treat beneficiaries dually eligible for Medicaid and Medicare (26.7% compared to 18.1% in non-340B hospitals and 15.1% in physician offices).
- More likely to treat beneficiaries eligible for Medicare on the basis of disability (23.8% compared to 18% in non-340B hospitals and 12.4% in physician offices).
- More likely to treat Black or African-American beneficiaries (14.8% compared to 7.4% in non-340B hospitals and 7.5% in physician offices).
- More likely to treat Hispanic beneficiaries (2.2% compared to 1.4% in non-340B hospitals and 1.9% in physician offices).
- More likely to treat beneficiaries with ESRD (3.5% compared to 2.8% in non-340B hospitals and 1.4% in physician offices).

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Table ES-1: Distribution of Beneficiaries receiving Part B Drugs by Demographic Characteristics - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
	517,420	100.0%	671,960	100.0%	2,367,560	100.0%
Age Category (Often a Proxy for Disability) (p < 0.0001)*						
Under 65	148,260	28.7%	146,480	21.8%	374,300	15.8%
65 and Over	369,160	71.4%	525,480	78.2%	1,989,200	84.0%
Unknown	-	0.0%	-	0.0%	4,060	0.2%
Gender						
Male	221,480	42.8%	292,420	43.5%	997,920	42.1%
Female	295,940	57.2%	379,540	56.5%	1,365,580	57.7%
Unknown	-	0.0%	-	0.0%	4,060	0.2%
Current Reason for Medicare Entitlement (p < 0.0001)*						
Old Age and Survivor's Insurance	383,080	74.0%	541,040	80.5%	2,052,440	86.7%
Disability Insurance Benefits	123,180	23.8%	120,740	18.0%	293,180	12.4%
ESRD	6,100	1.2%	5,440	0.8%	10,680	0.5%
DIB and ESRD	5,060	1.0%	4,740	0.7%	7,200	0.3%
Unknown	-	0.0%	-	0.0%	4,060	0.2%
ESRD (p < 0.0001)*						
Beneficiary has ESRD	18,240	3.5%	18,660	2.8%	33,640	1.4%
Beneficiary does not have ESRD	499,180	96.5%	653,300	97.2%	2,329,860	98.4%
Unknown	-	0.0%	-	0.0%	4,060	0.2%
Dual Eligibility (p < 0.0001)*						
Beneficiary is Dual Eligible	137,960	26.7%	121,640	18.1%	358,060	15.1%
Beneficiary is not Dual Eligible	379,460	73.3%	550,320	81.9%	2,005,440	84.7%
Unknown	-	0.0%	-	0.0%	4,060	0.2%
Race and Ethnicity (p < 0.0001)*						
White	408,100	78.9%	591,320	88.0%	2,046,560	86.4%
Black or African American	76,440	14.8%	49,460	7.4%	177,920	7.5%
Other	6,760	1.3%	7,640	1.1%	30,500	1.3%
Asian	8,460	1.6%	8,360	1.2%	44,200	1.9%
Hispanic	11,500	2.2%	9,300	1.4%	44,120	1.9%
North American Native	3,240	0.6%	2,680	0.4%	8,720	0.4%
Unknown	2,920	0.6%	3,200	0.5%	15,540	0.7%

¹ 340B hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

*p < 0.0001 for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Introduction and Study Purpose

340B Health commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to compare the Medicare patient populations receiving separately billable Part B drugs from 340B disproportionate share (DSH) hospitals to the population receiving these drugs from non-340B providers (specifically non-340B hospitals and physician offices). Our separate study of 340B DSH hospital services delivered to low income patients found that the beneficiary population served by 340B DSH hospitals is a different population than those served in non-340B settings.³ In this report, “340B DSH hospitals” refers to hospitals that are registered in 340B as a DSH, rural referral center (RRC), or sole community hospital (SCH) paid under the Medicare Inpatient Prospective Payment System (IPPS).

When Congress enacted the 340B program in 1992, it targeted DSH hospitals, which provide a disproportionate amount of care to Medicaid and low-income Medicare beneficiaries. Hospitals that treat high levels of low-income beneficiaries have often been referred to as “safety net” hospitals. The 340B program was established to provide safety-net hospitals (one of the categories of 340B “covered entities”) an avenue for purchasing separately billable outpatient Part B drugs at a reduced cost. Congress intended for the savings from these discounted prices to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”^{4, 5}

Drugs included in the 340B program generally comprise outpatient prescription drugs and drugs administered by physicians in an outpatient setting, excluding vaccines.

³ DaVanzo JE, Murray K, Haught R. *Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations, Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals*, Nov. 2016.

⁴ H. Rep. No. 102-384(II), at 12 (1992)(Conf. Rep.).

⁵ “Health Policy Brief: The 340B Drug Discount Program,” *Health Affairs*, November 17, 2014.

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Covered entities generally save 25 to 50% on drug costs by participating in the program. Specific 340B prices are determined by statutory formulas based on manufacturers' rates.⁶

Study Purpose

The purpose of this study is to examine the demographic characteristics of the beneficiary population receiving separately billable Part B drugs from 340B DSH hospitals only, and compare them to the characteristics of the population being served by the rest of the providers in the Part B market (non-340B hospitals and physicians). Our study compared patients using **only** 340B DSH hospitals to patients who received care from non-340B covered entities that provide Part B drugs, specifically non-340B hospitals and physician offices.

⁶ "Medicaid Drug Rebate Program." <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>. Centers for Medicare and Medicaid Services, 16 June 2016. Web. 3 November 2016.

Background

340B Drug Pricing Program

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible health care organizations⁷ or covered entities at reduced prices. To participate in the 340B Program, eligible organizations or covered entities must register and be enrolled with the 340B program and comply with all 340B program requirements.

Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.⁸ Participating hospitals benefit from being able to purchase outpatient drugs at reduced prices and, in turn, are able to stretch their resources to serve uninsured, low income, and vulnerable patient populations.

In a separate Dobson | DaVanzo report,⁹ we used 2014 Medicare cost reports to compare DSH hospitals in the 340B program to comparable hospitals not participating in the 340B program on the following metrics: 1) relative number of low-income patients (defined as Medicaid patient days and Medicare/Supplemental Security Income (SSI) patient days as a percent of all days, because that is the low-income patient metric used for 340B DSH hospital eligibility), 2) uncompensated care, and 3) provision of specialized services. This study showed that DSH hospitals in the 340B program have significantly more low-

⁷ Eligible entities include federally qualified health centers, urban Indian organizations, family planning clinics, sexually transmitted disease grantees, Native Hawaiian Health Centers, state-operated Ryan White AIDS Drug Assistance Programs, other Ryan White grantees, hemophilia treatment centers, and black lung clinics. Eligible hospitals include certain DSH hospitals, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), freestanding cancer hospitals, and children's hospitals. Additionally, providers that meet all of the requirements for the federally qualified health centers program, but do not receive federal grants—referred to as federally qualified health center look-alikes—are eligible to participate in the 340B program.

⁸ Health Resources and Services Administration (2015). *340B Drug Pricing Program*.

⁹ DaVanzo JE, Murray K, Haught R. *Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations, Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals*, Nov. 2016.

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income patient days (42.5% vs. 26.0%) and more uncompensated care (\$23.7 billion vs. \$16.1 billion) than hospitals that are not in the 340B program. The study also showed 340B DSH hospitals were more likely to provide public health and/or specialized services, many of which are unprofitable but are essential to their communities, than hospitals not in the 340B program.

This current study is designed to further explore the premise that beneficiary populations who receive their care from 340B DSH hospitals are different from those receiving their care in non-340B hospitals and physician offices and whether the 340B program continues to benefit vulnerable patient populations.

Study Methodology

Identifying 340B DSH Hospitals and Non-340B Providers

In order to understand the demographics of Part B beneficiaries receiving drugs from 340B DSH hospitals and non-340B providers, we first identified DSH hospitals participating in the 340B program. In this report, “340B DSH hospitals” refers to hospitals enrolled in the 340B program as DSH, RRCs, or SCHs that are paid under the Inpatient Prospective Payment System (IPPS).

Three criteria were applied to identify 340B DSH hospitals: 1) active participation in the 340B program based on the July 2015 quarterly update of the HRSA Office of Pharmacy Affairs (OPA) Drug Pricing Program Database; 2) completed and filed Medicare Cost Report for FY 2013; and 3) inclusion in the IPPS Impact File for 2013.

Non-340B providers were defined as all other providers who delivered separately billable Part B drugs contained in either a non-340B hospital outpatient department or carrier (physician office) claims. This means that the hospitals were purposely not matched in any way. We wanted to determine if populations served were different in ways thought to influence health care use.

Identifying Mutually Exclusive Beneficiary Cohorts Treated by 340B DSH Hospitals and Non-340B Providers

Once the 340B DSH hospitals and non-340B providers were identified, a beneficiary-level working claims database was developed using the 2013 Medicare Standard Analytic File Limited Dataset (SAF LDS) for a 5% sample of Medicare beneficiaries using the hospital outpatient department and carrier (physician office) claims.

Separately billable Part B drugs were defined as Part B drugs with a status indicator of “G” (pass-through drugs and biologicals) or “K” (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals, brachytherapy, and blood and blood products) in the Hospital Outpatient Prospective Payment System (OPPS) Final Rule Addendum B for 2013. The drugs were ones for which we found

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claims in the Medicare files. Vaccines were excluded from this analysis, as these products cannot be purchased at a discounted rate by 340B hospitals.

In order to define the beneficiary cohorts of 340B DSH hospitals and non-340B hospitals and physician offices, we first identified all Medicare beneficiaries who received at least one separately billable Part B drug during the year. We then excluded beneficiaries who received at least one separately billable Part B drug from both 340B DSH hospitals and non-340B providers (either non-340B hospital or physician office) in 2013. These exclusion criteria were applied so we could assign beneficiaries exclusively to the 340B DSH hospital or the non-340B provider cohorts (without overlap).

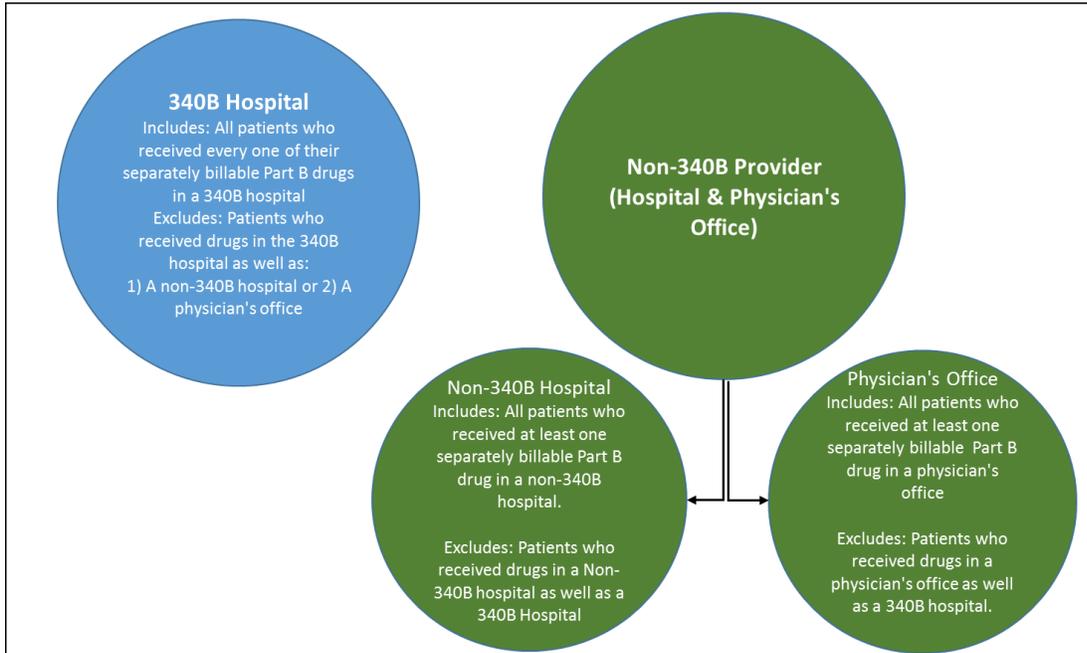
As a result of these criteria, our definition of the “340B DSH hospital” cohort included all beneficiaries who received their separately billable Part B drugs in a 340B DSH, RRC, or SCH hospital setting only. This excluded beneficiaries who received drugs in a non-340B hospital or physician office from our “340B hospital” cohort at any point during the year. Our definition of a “non-340B” beneficiary included all beneficiaries who received at least one separately billable Part B drug in a non-340B hospital and/or physician office. As noted above, we excluded beneficiaries who received at least one separately billable Part B drug in a 340B DSH hospital in 2013 from the non-340B provider group.

Because we wanted to further examine non-340B hospitals separately from physician offices, the non-340B provider cohort was then separated into two sub-populations: those who received at least one separately billable Part B drug in a non-340B hospital and, separately, all beneficiaries who received at least one separately billable Part B drug in a physician office. There is slight overlap between these two populations. Our analysis could then compare 340B DSH hospital patients to non-340B hospital patients, and separately 340B DSH hospital patients to those served in physician offices. Because a small number of patients received their Part B drugs in both the non-340B hospital and the physician office, we do **not** compare non-340B hospital patients to patients receiving drugs in physician offices. See Figure 1 for our cohort selection criteria.

We obtained the distribution of patients for each care setting on the following demographic metrics: age category; gender; reason for Medicare eligibility; eligibility for both Medicare and Medicaid; the presence of end stage renal disease; and race and ethnicity. We tested distributions for significant differences. Significance tests were performed for 340B DSH hospitals versus non-340B hospitals and 340B DSH hospitals versus physician offices separately and adjustments were made for pairwise comparisons.

In the following chapter, we present the results of our analysis that compares the demographic characteristics of beneficiaries who receive separately billable Part B drugs from 340B DSH hospitals to the demographic characteristics of beneficiaries treated by non-340B hospitals, and separately, physician offices. We used the SAF LDS 5% sample for analysis, however, in these results, the number of beneficiaries has been extrapolated to the entire Medicare beneficiary population.

Figure 1: 340B DSH Hospital and Non-340B Provider Episode Design



Source: Dobson | DaVanzo analysis of 5% sample of 2013 SAF LDS Claims files, linked to the 340B DSH hospitals contained in the July 2015 quarterly update of the HRSA Office of Pharmacy Affairs (OPA) 340B Drug Pricing Program Database.

Study Results

In this chapter, we present the demographic characteristics for beneficiaries in each of the three cohorts who received separately billable Part B drugs: 1) beneficiaries treated only in 340B DSH hospitals, 2) beneficiaries treated by non-340B hospitals, and 3) beneficiaries treated in physician offices. We examined age, gender, current reason for Medicare entitlement, ESRD status, dual eligibility, and race and ethnicity within each care setting.

Our analysis extrapolated from the 2013 5% SAF LDS claims and found that 517,420 beneficiaries received their separately billable Part B drugs from only 340B DSH hospitals in 2013. We found that 671,960 beneficiaries received their separately billable Part B drugs in non-340B hospitals or physician offices (but not 340B DSH hospitals) and that 2,959,450 beneficiaries received their separately billable Part B drugs in physician offices.

Our analysis of these demographic characteristics of the beneficiaries served by the three provider groups found that compared to non-340B providers, 340B DSH hospitals are treating significantly more Medicare beneficiaries who are dually eligible for Medicaid and Medicare, disabled, Black or African-American, Hispanic, or who have ESRD, as described in the sections below.

Beneficiary Age Distribution

Patients treated in 340B DSH hospitals were significantly more likely to be under the age of 65 than were those treated by non-340B providers (28.7% compared to 21.8% in non-340B hospitals and 15.8% in physician offices). This age category is often used as a proxy for disability, since, by definition, the non-disabled population is not eligible for Medicare until age 65.

Table 1: Distribution of Beneficiaries receiving Part B Drugs by Age - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
Age Category (Often a Proxy for Disability) (p < 0.0001)*						
Under 65	148,260	28.7%	146,480	21.8%	374,300	15.8%
65 and Over	369,160	71.4%	525,480	78.2%	1,989,200	84.0%
Unknown	-	0.0%	-	0.0%	4,060	0.2%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

*p < 0.0001 for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

Beneficiary Gender Distribution

We found that slightly more females than males received pharmaceutical therapies in 340B DSH hospitals compared to the distribution of patients by gender in non-340B hospitals (57.2% vs. 56.5%). This difference was not significant.

Table 2: Distribution of Beneficiaries receiving Part B Drugs by Gender - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
Gender						
Male	221,480	42.8%	292,420	43.5%	997,920	42.1%
Female	295,940	57.2%	379,540	56.5%	1,365,580	57.7%
Unknown	-	0.0%	-	0.0%	4,060	0.2%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

Beneficiary Reason for Entitlement

Beneficiaries in 340B DSH hospitals were more likely to receive disability insurance benefits (23.8% compared to 18.0% in non-340B hospitals and 12.4% in physician offices). This difference was significant (p < 0.0001) for pairwise comparisons between 340B DSH hospitals and non-340B hospitals as well as between 340B DSH hospitals and physician offices.

In addition, beneficiaries under age 65 that have a disability and also have end stage renal disease (ESRD) comprise a higher proportion of the population treated by 340B DSH hospitals than non-340B hospitals or physician offices (1.0% compared to 0.7% in non-340B hospitals and 0.3% in physician offices). The Medicare Payment Advisory

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Commission (MedPAC) found that these beneficiaries were less likely to have supplemental insurance (Medigap) than the overall Medicare population.¹⁰

Table 3: Distribution of Beneficiaries receiving Part B Drugs by Reason for Medicare Entitlement - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
Current Reason for Medicare Entitlement (p < 0.0001)*						
Old Age and Survivor's Insurance	383,080	74.0%	541,040	80.5%	2,052,440	86.7%
Disability Insurance Benefits	123,180	23.8%	120,740	18.0%	293,180	12.4%
ESRD	6,100	1.2%	5,440	0.8%	10,680	0.5%
DIB and ESRD	5,060	1.0%	4,740	0.7%	7,200	0.3%
Unknown	-	0.0%	-	0.0%	4,060	0.2%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

*p < 0.0001 for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

Beneficiaries with ESRD

Beneficiaries in 340B DSH hospitals were also more likely to have ESRD than beneficiaries served by non-340B providers (3.5% as compared to 2.8% in non-340B hospitals and 1.4% in physician offices). This difference was significant (p < 0.0001) for pairwise comparisons between 340B DSH hospitals and non-340B hospitals as well as between 340B DSH hospitals and physician offices. MedPAC also found that spending on beneficiaries with ESRD is six times greater than spending on non-ESRD beneficiaries over age 65.¹¹

Table 4: Distribution of Beneficiaries receiving Part B Drugs by ESRD Status - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
ESRD (p < 0.0001)*						
Beneficiary has ESRD	18,240	3.5%	18,660	2.8%	33,640	1.4%
Beneficiary does not have ESRD	499,180	96.5%	653,300	97.2%	2,329,860	98.4%
Unknown	-	0.0%	-	0.0%	4,060	0.2%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

*p < 0.0001 for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

¹⁰ Medicare Payment Advisory Commission (MedPAC). A Data Book: Health Care Spending and the Medicare Program. (June 2015), <http://medpac.gov/documents/data-book/june-2015-databook-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>.

¹¹ Medicare Payment Advisory Commission (MedPAC). A Data Book: Health Care Spending and the Medicare Program. (June 2015), <http://medpac.gov/documents/data-book/june-2015-databook-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>.

Beneficiary Dual Eligibility

340B DSH hospitals were more likely to treat dual eligible beneficiaries – those eligible for both Medicaid and Medicare – than were non-340B providers (26.7% compared to 18.1% in non-340B hospitals and 15.1% in physician offices). Dual eligible beneficiaries make up a disproportionate amount of overall Medicare spending and are more likely to have a poor health status compared to other beneficiaries, thereby adding to the vulnerable populations served by 340B DSH hospitals.¹² This difference was significant ($p < 0.0001$) for pairwise comparisons between 340B DSH hospitals and non-340B hospitals as well as between 340B DSH hospitals and physician offices.

Table 5: Distribution of Beneficiaries receiving Part B Drugs by Dual Eligibility Status - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
Dual Eligibility ($p < 0.0001$)*						
Beneficiary is Dual Eligible	137,960	26.7%	121,640	18.1%	358,060	15.1%
Beneficiary is not Dual Eligible	379,460	73.3%	550,320	81.9%	2,005,440	84.7%
Unknown	-	0.0%	-	0.0%	4,060	0.2%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

* $p < 0.0001$ for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

Beneficiary Race and Ethnicity Distribution

The racial and ethnic composition of patient populations served by 340B DSH hospitals differed from those served by non-340B hospitals and physician offices. We found that 340B DSH hospitals treated twice as many Black or African-American beneficiaries (14.8% compared to 7.4% of non-340B hospitals or 7.5% of physician offices). 340B DSH hospitals were more likely to treat Hispanic and North American Native beneficiaries than non-340B hospitals or physician offices.

¹² Medicare Payment Advisory Commission (MedPAC). A Data Book: Health Care Spending and the Medicare Program. (June 2015), <http://medpac.gov/documents/data-book/june-2015-databook-health-care-spending-and-the-medicare-program.pdf?sfvrsn=0>.

Study Results

Table 6: Distribution of Beneficiaries receiving Part B Drugs by Race and Ethnicity - FY 2013

	340B DSH Hospital ¹		Non-340B Hospital ²		Physician Office ³	
	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total	Number of Beneficiaries	Percent of Total
Race and Ethnicity (p < 0.0001)*						
White	408,100	78.9%	591,320	88.0%	2,046,560	86.4%
Black or African American	76,440	14.8%	49,460	7.4%	177,920	7.5%
Other	6,760	1.3%	7,640	1.1%	30,500	1.3%
Asian	8,460	1.6%	8,360	1.2%	44,200	1.9%
Hispanic	11,500	2.2%	9,300	1.4%	44,120	1.9%
North American Native	3,240	0.6%	2,680	0.4%	8,720	0.4%
Unknown	2,920	0.6%	3,200	0.5%	15,540	0.7%

¹ 340B DSH hospitals include all patients who received all of their Part B drugs in a 340B hospital.

² Non-340B hospitals include all patients who received at least one Part B drug in the non-340B hospital setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Physician Office category, as these two populations are not mutually exclusive.

³ Physician's Office Entities include all patients who received at least one Part B drug in the physician's office setting and no Part B drugs in a 340B hospital. This patient may also be represented in the Non-340B hospital category, as these two populations are not mutually exclusive.

*p < 0.0001 for pairwise comparisons between 340B Hospitals and non-340B hospitals, and between 340B hospitals and physician offices

Source: Dobson | DaVanzo analysis of the 2013 5% Standard Analytic File Limited Dataset (LDS)

Discussion

The Institute of Medicine (IOM) report, *America's Health Care Safety Net*, adopted a definition of vulnerable populations that includes the “uninsured, Medicaid, and other vulnerable patients.” The IOM report defines “core safety net providers” as having a “legal mandate or explicitly adopted mission, they maintain an ‘open door’ [policy], offering patients access to services regardless of their ability to pay.”¹³ As demonstrated by the distribution of beneficiaries by race and ethnicity, age, disability, and dual eligibility, 340B DSH hospitals have most often embraced that mission to treat vulnerable and underserved populations.

The purpose of this study was to examine the demographic characteristics of Medicare beneficiaries who receive separately billable Part B drugs only in 340B DSH hospitals as compared to the characteristics of beneficiaries treated by non-340B providers (includes non-340B hospitals and physician offices) to determine if 340B DSH hospitals treat different patient populations than non-340B providers. We found that beneficiaries who obtain their care at 340B DSH hospitals were significantly different from those who obtained care from non-340B hospitals as well as those who access physician private practices. Part B beneficiaries receiving drugs in 340B DSH hospitals were more likely to be dually eligible for Medicaid and Medicare, disabled, Black or African-American, Hispanic, or to have ESRD. These results demonstrate that the 340B DSH hospital eligibility criteria are targeting hospitals that treat vulnerable, low-income patient populations.

When Congress enacted the 340B program in 1992, it targeted DSH hospitals, which provide a disproportionate amount of care to Medicaid and low-income Medicare beneficiaries. Hospitals that treat high levels of low-income beneficiaries have often been referred to as “safety net” hospitals. The 340B program was established to provide safety-net hospitals (one of the categories of 340B “covered entities”) an avenue for purchasing

¹³ Lewin ME, Altman S., eds. *America's Health Care Safety Net: Intact but Endangered*. (Washington DC: National Academies Press. 2000.

separately billable outpatient Part B drugs at a reduced cost. Congress intended for the savings from these discounted prices to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”^{14, 15} The results of this analysis demonstrate that the eligibility criteria for 340B DSH hospitals are properly targeting hospitals that treat low-income, vulnerable patients and the 340B program continues to benefit these patient populations.

¹⁴ H.R. Rep. No. 102-384(II), at 12 (1992)(Conf. Rep.).

¹⁵ "Health Policy Brief: The 340B Drug Discount Program," *Health Affairs*, November 17, 2014.