National Patient Advocate Foundation
The Patient's Voice | since 1996

July 31, 2013

The Honorable Joseph Pitts
Chairman
Committee on Energy and Commerce
Health Subcommittee
House of Representatives
Congress of the United States
2125 Rayburn House Office Building
Washington, DC 20515-6115

cc: Sydne Harwick
Legislative Clerk

Re: **Response to Additional Questions for the Record Relating to the Hearing Entitled "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors"**

Additional Questions for the Record from the Honorable Cathy McMorris Rodgers

Question 1: In 1992, Congress created the 340B discount program to increase affordability and accessibility of pharmaceuticals for the nation's poor and unserved populations. It is my understanding that this is an important part of our medical safety net.

In your exchange with Congressman Cassidy during the hearing, you cite the 340B programs as having grown from 600 to 900 hospitals originally to about 6,000 hospitals today. Are you aware that there are only 2,000 hospitals in the program and 5,700 total in the United States?

Thank you for the opportunity to clarify the quoted statistics. According to Health Resources and Services Administration (HRSA) data cited in the September 2011 U.S. Government Accountability Office (GAO) Report "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," there were 1,233 hospitals participating in the 340B program in 2011.[1] Additionally, in 2011 there were 4,426 clinics and other sites affiliated with those hospitals, but physically separate from the hospitals themselves, that independently participated in the 340B program.[2] Together, they represent a total of 5,659 hospitals and their affiliated sites that participated in the 340B program in 2011, which is how I arrived at the 6,000 figure I stated during my testimony. Moreover, as of July 1, 2013, there were 22,641 covered entity sites (including all affiliated sites), up from 16,572 total covered entity sites in 2011, a 37% increase.[3]

[1] GAO, Drug Pricing: "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," (Washington, D.C.: Sep. 2011) at 28, *available at* http://www.gao.gov/products/GAO-11-836.
[2] Id.
[3] Modern Healthcare, "Who benefits from drug discounts?" pg. 8-9 (Jul. 15, 2013).

Congresswoman McMorris Rodgers is also correct: according to the American Hospital Association (AHA) there are 5,724 U.S. hospitals registered with the AHA.[4] Per a July 29, 2013 review of the HRSA 340B Covered Entity database, more than a third of those hospitals—2,015 hospitals to be precise—have currently enrolled one or more sites as a 340B Covered Entity.[5] Per the GAO in its September 2011 report entitled "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement" referenced above, hospital participation in the 340B program grew nearly three-fold from 2005 to 2011.[6] I surmise that the number of hospitals participating in the 340B program has only continued to grow given that the Affordable Care Act expanded the program to four new eligible entities—certain freestanding cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals.[7]

National Patient Advocate Foundation's (NPAF's) companion organization, Patient Advocate Foundation (PAF) is a national 501 (c)(3) non-profit organization which provides professional case management services to Americans with chronic, life threatening and debilitating illnesses. Through these coordination efforts, PAF case managers have assisted patients receiving care from hundreds of 340B Covered Entities, including hospitals, throughout the United States. I have attached a list of such 340B Covered Entities, including hospitals for your review and consideration. The interactions of PAF case managers with providers at such 340B Covered Entities, including hospitals, has influenced both my testimony and follow-up responses set forth herein.

Question 2(a): You indicated that you have data to show the 340B hospitals are using these drug discount savings to purchase community oncology practices. Can you provide me with that evidence?

As noted above, NPAF's companion organization, PAF, is a national 501 (c)(3) non-profit organization which provides professional case management services to Americans with chronic, life threatening and debilitating illnesses. PAF case managers serve as active liaisons between the patient and their insurer, employer and/or creditors to resolve insurance, job retention and/or debt crisis matters as they relate to their diagnosis. The PAF case managers collaborate with physicians and healthcare attorneys in achieving resolutions to specific cases when needed. As such PAF representatives regularly coordinate with oncologists in all fifty states caring for patients who have sought case management and cost-sharing assistance from PAF. Through these coordination activities and, as I highlighted in my original statement to the Committee on June 28, 2013, PAF has heard from patients identifying numerous oncologists throughout the United States who have either shifted Medicare patients (or all patients) to hospital outpatient departments for chemotherapy and/radiation services, or who have had their practices acquired or consolidated with hospitals due to decreases in reimbursement, most notably Medicare reimbursement, for oncology services provided in physicians' offices, including chemotherapy and radiation therapy services.[8] I have excerpted the examples of such site–of-service shifts from my June 28, 2013 testimony and attached them to this document for your consideration. In addition, I have also attached a communication from Zangmeister Cancer Center to its patients explaining its decision to shift Medicare patients to hospital outpatient departments for medication administration, including chemotherapy, for your review.

Industry associations and oncologists have indicated to various media outlets that hospital acquisition of oncology offices or the consolidation of hospitals and oncology practices have occurred, at least in part, due to the prevalence of hospital participation in the 340B program. In February 2012, the New York Times reported in an article entitled

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[4] See AHA Fast Facts on U.S. Hospitals, *available at* http://www.aha.org/research/rc/stat-studies/fast-facts.shtml last visited Jul. 29, *2013*.

[5] National Patient Advocate Foundation (NPAF) staff reviewed the HRSA 340B Covered Entity database (http://opanet.hrsa.gov/opa/CESearch.aspx) and accumulated the number of participating hospitals by consolidating all sites affiliated with each unique 340B identification number.

[6] GAO, Drug Pricing: "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," (Washington, D.C.: Sep. 2011) at 27, *available at* http://www.gao.gov/products/GAO-11-836.

[7] Section 7001 of the Affordable Care Act.

[8] *See* Statement of Nancy Davenport-Ennis, Founder and CEO, National Patient Advocate Foundation on "Examining Reforms to Improve the Medicare Part B Program for Seniors" before the United States house of Representatives Committee on Energy & Commerce Health Subcommittee on June 28, 2013.

"Dispute Develops over Discount Drug Plan," that "[s]ome oncologists say the 340B program is one reason that more than 400 practices have become part of hospitals in recent years."[9] Recently, MedPage Today quoted Ted Okon, Executive Director of the Community Oncology Alliance, in an article entitled "Oncology Clinics Caught in Financial Vase" published on July 27, 2013. In that article Mr. Okon states that in recent years "[w]e've seen almost an explosion in the number of nonprofit hospitals that have applied for and have been granted 340B status. As a result, with those deep discounts [on medicines under the 340B program], a lot of those hospitals have looked at increasing their inflow of drug revenue. The way to do that is to acquire an oncology practice, which has the largest flow of revenue attributed to chemotherapy."[10] In addition, just yesterday on July 30, 2013, The Wall Street Journal published an article by Dr. Scott Gottlieb entitled "How ObamaCare Hurts Patients" in which Dr. Gottlieb concludes that the 340B program is increasing the cost of cancer care and eroding its quality due to site of care shifts from physicians' offices to hospital outpatient departments. Dr. Gottlieb further states, as did Mr. Okon, Executive Director of the Community Oncology Alliance, in the MedPage Today article cited above, that "eligible [340B program] hospitals are buying private oncology practices so they can book more of the expensive cancer drug purchases at the discount rates. More than 400 oncology practices have been acquired by hospitals since ObamaCare passed. Acquiring a single oncologist and moving the doctor's drug prescriptions under a hospital's 340B program can generate an additional profit of more than $1 million for a hospital." I have attached the articles excerpted above and some additional articles from other news publications echoing the sentiment that many oncologists and industry associations have concluded that hospital acquisition of oncology offices or the consolidation of hospitals and oncology practices have occurred, at least in part, due to the prevalence of hospital participation in the 340B program.

In the absence of federal law or regulations dictating how 340B Covered Entities, including qualifying hospitals, may use revenues generated from the 340B program and oversight to monitor compliance with such restrictions, we can only rely on anecdotal evidence provided by physicians and other stakeholders as to how hospitals are funding their oncology practice acquisitions and why they are acquiring numerous oncology practices.

Question 2(b): Are 340B hospitals purchasing oncology practices at any greater rates than non-340B hospitals?

The acquisition of community oncology practices by 340B hospitals far exceeds the trend of consolidation of community practices into hospital systems generally. In fact, 70% of community oncology practices that were acquired over the 14 months ending in June 2013 were acquired by 340B hospitals, according to data from the Community Oncology Alliance. In addition, one group purchasing organization dedicated to specialty drug contracting and distribution to independent oncology practices and hospitals has stated that in 2012, of the independent oncology practices that were acquired by hospitals that were members of its organization, 75% of the practices were acquired by hospitals that participate in the 340B program. In 2013, of the independent oncology practices that were acquired by hospitals that were members of its organization, 61% of the practices were acquired by hospitals that participate in the 340B program.

Question 2(c): Is it plausible that 340B hospitals purchase these practices because the oncologists are seeking stable, reliable income in a difficult market for all independent physicians and they hope to ensure that their patients can still receive care despite their own economic uncertainty?

Yes, it is plausible. The Community Oncology Alliance (COA) has been tracking changes in the oncology treatment landscape for more than four years.[11] Its database quantifies the aggregate effects of all the factors contributing to the shift in cancer care services from community-based offices and treatment centers to hospital outpatient departments. COA's most recent Community Oncology Practice Impact report, released in June 2013, which we have

[9] New York Times, "Dispute Develops Over Discount Drug Plan." (Feb. 12, 2012).
[10] MedPage Today, "Oncology Clinics Caught in Financial Vase." (Jul. 27, 2013).
[11] Community Oncology Alliance, Community Oncology Practice Impact Report, "The Changing Landscape of Cancer Care" (June 25, 2013), *available at* http://www.communityoncology.org/site/blog/detail/2013/06/25/access-the-2013-community-oncology-practice-impact-report-showing-continued-cancer-care-consolidation.html.

attached hereto for your consideration, shows that 43 practices are referring all their patients elsewhere for treatment, 288 oncology office locations have closed, 131 practices have merged or been acquired by a corporate entity other than a hospital, and 469 oncology groups have entered into contractual relationships with a hospital, such as a professional services agreement, or been acquired outright by a hospital. Another 407 oncology practices report they are struggling financially. The latest COA report reflects substantial changes in the practice landscape from April of 2012. Specifically, it shows a year-over-year increase in clinic closings of 20% and an increase of 20% in practices with hospital arrangements. COA states affirmatively that "[t]he reasons for this consolidation are due to insufficient Medicare reimbursement to community oncology clinics and higher reimbursement and margins to hospital outpatient facilities, especially those eligible for 340B discounts."

Thus, oncologists are often forced to consolidate or enter into alternative arrangements with hospitals because their independent practices cannot financially compete with hospitals to provide chemotherapy, radiation therapy and other cancer treatments to patients because hospitals receive more favorable reimbursement from Medicare for many of the same treatments and procedures. (For example, 2013 payment rebates for common chemotherapy codes 96409 and 96413 in the hospital outpatient department are $146 and $231 compared with 2013 rates of ($109 and $132 in the physician office.) Those hospitals that participate in the 340B program also post significantly more favorable margins for separately reimbursable physician-administered drugs, such as chemotherapy, because they are able to acquire the drugs at substantial discounts—ranging generally from 20% to more than 50%--yet the Medicare reimbursement for the drugs---before sequestration, Average Sales Price (ASP) + 6%--is the same as that available to independent oncology practices that must purchase drugs at much higher commercial prices from wholesalers or distributors. Based on currently available data, media reports and the continued trend in declining Medicare reimbursement for chemotherapy and other services in physicians' offices,[12] one could surmise this trend will only continue.

<u>Question 2(d)</u>: Could this trend be part of a general broader trend toward integration of health care systems, and not directly and solely attributable, as you suggest, to 340B hospitals?

In my testimony I did not address any potentially broader, general trend toward health system integration in the United States, nor did I solely attribute any potential trend related to hospital acquisition of oncology practices or arrangements between hospitals and independent oncology practices directly to 340B hospitals. Rather, I merely highlighted that "the 340B hospital structure now allows [hospitals] to offer very attractive packages to oncologists, for them to leave their practices and associate, or to bring their entire practices to the hospital setting."

Furthermore, 2012 data collected and analyzed by Jackson Healthcare suggests that independent oncology practices are being acquired by hospitals at a disproportionately high rate when compared to primary care practice acquisitions. Per Jackson Healthcare in its publication Trend Watch: "Physician Practice Acquisitions- Tracking Which Physician Practices Hospitals are Acquiring," attached hereto for your reference, Jackson Healthcare notes that in 2012, 44% of hospitals acquired physician practices.[13] Of those physician practices acquired, between 6% and 8% were oncology practices. However, per an American Society of Clinical Oncology (ASCO) 2006 workforce study, there are only 3.3-4 oncologists per 100,000 people in the United States, while there are 240 total physicians per 100,000 people in the

[12] *See* the Center for Medicare & Medicaid Services' proposed "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 at 78 Fed. Reg. 43, 282 (Jul. 19, 2013) setting forth additional proposed cuts in Medicare reimbursement for oncology-related services in physicians' offices.

[13] Jackson Healthcare," Trend Watch: "Physician Practice Acquisitions- Tracking Which Physician Practices Hospitals are Acquiring." (2012).

United States.[14] As such, a 6%-8% acquisition rate seems disproportionately high given that oncologists represent less than 2% of physicians in the United States.

We at NPAF appreciate the Subcommittee's interest in improving the Medicare Part B program for beneficiaries. We specifically applaud the Subcommittee for exploring the impact of the 340B program on cancer care available to Medicare beneficiaries. Thank you for the opportunity to provide testimony during the June 28, 2013 hearing as well these additional, clarifying comments for the hearing record.

Respectfully submitted,

Nancy Davenport-Ennis
Founder and Chairman of the Board

Attachments

[14] *See* The Advisory Board Company, Oncology Rounds, "Estimating the Demand for Oncology Physicians," (Jun. 13, 2011), *available at* http://www.advisory.com/Research/Oncology-Roundtable/Oncology-Rounds/2011/06/Estimating-the-Demand-for-Oncology-Physicians (quoting the 2006 ASCO workforce study as to the number of oncologists in the United States); *see* The World Bank data for "physicians for 1,000 people" in the United States, *available at* http://search.worldbank.org/data?qterm=physicians+in+the+United+States (last visited Jul. 31, 2013) for the total number of physicians in the United States.

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Fast Facts on US Hospitals

The American Hospital Association conducts an annual survey of hospitals in the United States. The data below, from the 2011 annual survey, are a sample of what you will find in AHA Hospital Statistics, 2013 edition. The definitive source for aggregate hospital data and trend analysis, AHA Hospital Statistics includes current and historical data on utilization, personnel, revenue, expenses, managed care contracts, community health indicators, physician models, and much more.

AHA Hospital Statistics is published annually by Health Forum, an affiliate of the American Hospital Association. Additional details on AHA Hospital Statistics and other Health Forum data products are available at www.ahadataviewer.com. To order AHA Hospital Statistics, call (800) AHA-2626 or click on www.ahaonlinestore.com.

For further information or customized data and research, call the AHA Resource Center at (312) 422-2050 for one-stop service.

Total Number of All U.S. Registered * Hospitals	5,724
Number of U.S. **Community** ** Hospitals	4,973
Number of Nongovernment Not-for-Profit Community Hospitals	2,903
Number of Investor-Owned (For-Profit) Community Hospitals	1,025
Number of State and Local Government Community Hospitals	1,045
Number of Federal Government Hospitals	208
Number of Nonfederal Psychiatric Hospitals	421
Number of Nonfederal Long Term Care Hospitals	112
Number of Hospital Units of Institutions (Prison Hospitals, College Infirmaries, Etc.)	10
Total Staffed Beds in All U.S. Registered * Hospitals	924,333
Staffed Beds in Community** Hospitals	797,403
Total Admissions in All U.S. Registered * Hospitals	36,564,886
Admissions in Community** Hospitals	34,843,085
Total Expenses for All U.S. Registered * Hospitals	$773,546,800,000
Expenses for Community** Hospitals	$702,091,034,815
Number of Rural Community Hospitals**	1,984
Number of Urban Community Hospitals**	2,989
Number of Community Hospitals in a System ***	3,007
Number of Community Hospitals in a Network ******	1,535

*Registered hospitals are those hospitals that meet AHA's criteria for registration as a hospital facility. Registered hospitals include AHA member hospitals as well as nonmember hospitals. For a complete listing of the criteria used for registration, please see Registration Requirements for Hospitals.

**Community hospitals are defined as all nonfederal, short-term general, and other special hospitals. Other special hospitals include obstetrics and gynecology; eye, ear, nose, and throat; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

***System is defined by AHA as either a multihospital or a diversified single hospital system. A multihospital system is two or more hospitals owned, leased, sponsored, or contract managed by a central organization. Single, freestanding hospitals may be categorized as a system by bringing into membership three or more, and at least 25 percent, of their owned or leased non-hospital preacute or postacute health care organizations. System affiliation does not preclude network participation.

**** Network is a group of hospitals, physicians, other providers, insurers and/or community agencies that work together to coordinate and deliver a broad spectrum of services to their community. Network participation does not preclude system affiliation.

Updated January 3, 2013

Community Oncology Practice Impact Report

The Changing Landscape of Cancer Care

Issued June 25, 2013

Summary

- This is an update to the last Community Oncology Alliance (COA) *Practice Impact Report*, which was issued on 4/4/12. This report is derived from a tracking database on the changing oncology treatment landscape. The database is compiled from private and public sources. Included in this report are a table of numbers of impacted practices by state and a map depicting the impact.

- With this update, 1,338 clinics/practices during the past 6 years have been impacted as follows:
  - — **288 Clinics Closed** — Denotes individual clinic sites that have closed.
  - — **407 Practices Struggling Financially** — Denotes practices (possibly comprised of multiple clinic sites) that have financial difficulties.
  - — **43 Practices Sending Patients Elsewhere** — Denotes practices (possibly comprised of multiple clinic sites) that are sending *all of their patients* elsewhere for treatment.
  - — **469 Practices with a Hospital Agreement or Purchased** — Denotes practices (possibly comprised of multiple clinic sites) that have entered into contractual relationship with a hospital, such as a professional services agreement, or have been acquired by a hospital.
  - — **131 Practices Merged or Acquired** — Denotes practices (possibly comprised of multiple clinic sites) that have merged together or been acquired by a corporate entity, other than a hospital.

Points to Note

- Relative to the last report issued 15 months ago, the data documents the following:
  - — **20% Increase in Clinics Closed**
  - — **8% Decrease in Practices Struggling Financially**
  - — **9% Decrease in Practices Sending Patients Elsewhere**
  - — **20% Increase in Practices with a Hospital Agreement or Purchased**
  - — **1% Decrease in Practices Merged or Acquired**

  The decreases represent practices that have closed or have been acquired by hospitals.

- We continue to see consolidation in the cancer care delivery landscape, especially in terms of clinics being closed and practices being acquired by, or affiliating with, hospitals. A recent analysis by The Moran Group[1] confirmed this consolidation by reporting that physician-owned community oncology clinics administered 87% of the chemotherapy in 2005 (analyzing Medicare fee-for-service data). By the end of 2011, chemotherapy administration by community oncology clinics fell to 67%.

- The reasons for this consolidation are due to insufficient Medicare reimbursement to community oncology clinics and higher reimbursements and margins to hospital outpatient facilities, especially those eligible for 340B discounts. Studies by Avalere[2] and Milliman[3] have documented the higher cost of cancer care in the hospital outpatient setting. Medicare pays $6,500 more per patient (annualized) for chemotherapy administered in the hospital outpatient setting, and cancer patients on Medicare pay $650 more.

- This report does not reflect the adverse impact of the sequester cut to cancer drugs, which based on recent survey results[4], is expected to accelerate hospital acquisitions of community oncology clinics.

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[1] *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries*, The Moran Group, May, 2013.
[2] *Total Cost of Cancer Care by Site of Service: Physician Office vs. Outpatient Hospital.* Avalere Health, May, 2012.
[3] *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy.* Milliman, October, 2011.
[4] *National Medicare Sequestration Survey: Post: Follow-up*; Community Oncology Alliance, March 2013.

Community Oncology Practice Impact Report

Updated 6/20/13

State	*Total Sites/Practices*	*Clinics Closed*	*Practices Struggling Financially*	*Practices Sending Patients Elsewhere*	*Hosp. Agreement/ Purchase*	*Merged/Acquired by Another Entity*
Alabama	15	4	4	0	7	0
Alaska	2	0	2	0	0	0
Arizona	11	6	0	0	3	2
Arkansas	18	4	11	0	3	0
California	86	20	38	4	10	14
Colorado	42	7	15	1	19	0
Connecticut	10	1	0	0	9	0
DC	2	0	2	0	0	0
Delaware	4	4	0	0	0	0
Florida	122	32	26	0	27	37
Georgia	40	10	16	0	14	0
Hawaii	0	0	0	0	0	0
Idaho	2	0	0	0	2	0
Illinois	74	11	28	11	11	13
Indiana	37	10	5	2	19	1
Iowa	11	2	0	1	8	0
Kansas	4	3	0	0	1	0
Kentucky	34	15	2	0	17	0
Louisiana	18	3	4	0	11	0
Maine	12	3	4	0	3	2
Maryland	15	1	6	2	6	0
Massachusetts	0	0	0	0	0	0
Michigan	91	30	46	6	8	1
Minnesota	25	1	1	2	21	0
Mississippi	12	0	5	0	6	1
Missouri	39	8	9	2	19	1
Montana	7	0	3	0	4	0
Nebraska	9	2	0	0	7	0
Nevada	25	3	20	2	0	0
New Hampshire	1	0	0	0	1	0
New Jersey	39	4	12	0	13	10
New Mexico	7	1	4	0	2	0
New York	65	9	41	0	12	3
North Carolina	30	6	4	4	14	2
North Dakota	1	0	0	0	1	0
Ohio	51	11	9	0	29	2
Oklahoma	21	0	18	0	3	0
Oregon	19	1	3	1	14	0
Pennsylvania	62	6	9	0	44	3
Rhode Island	5	0	3	0	2	0
South Carolina	27	10	4	0	9	4
South Dakota	3	0	0	0	3	0
Tennessee	61	13	31	0	15	2
Texas	66	28	7	0	7	24
Utah	8	2	5	0	1	0
Vermont	1	1	0	0	0	0
Virginia	36	8	5	2	16	5
Washington	19	1	2	0	15	1
West Virginia	10	4	1	1	4	0
Wisconsin	33	2	0	2	28	1
Wyoming	6	1	2	0	1	2
Total	**1,338**	**288**	**407**	**43**	**469**	**131**

Clinics Closed denotes individual sites that have closed.

Practices Struggling Financially denotes practices (possibly comprised of multiple clinic sites) that have financial difficulties.

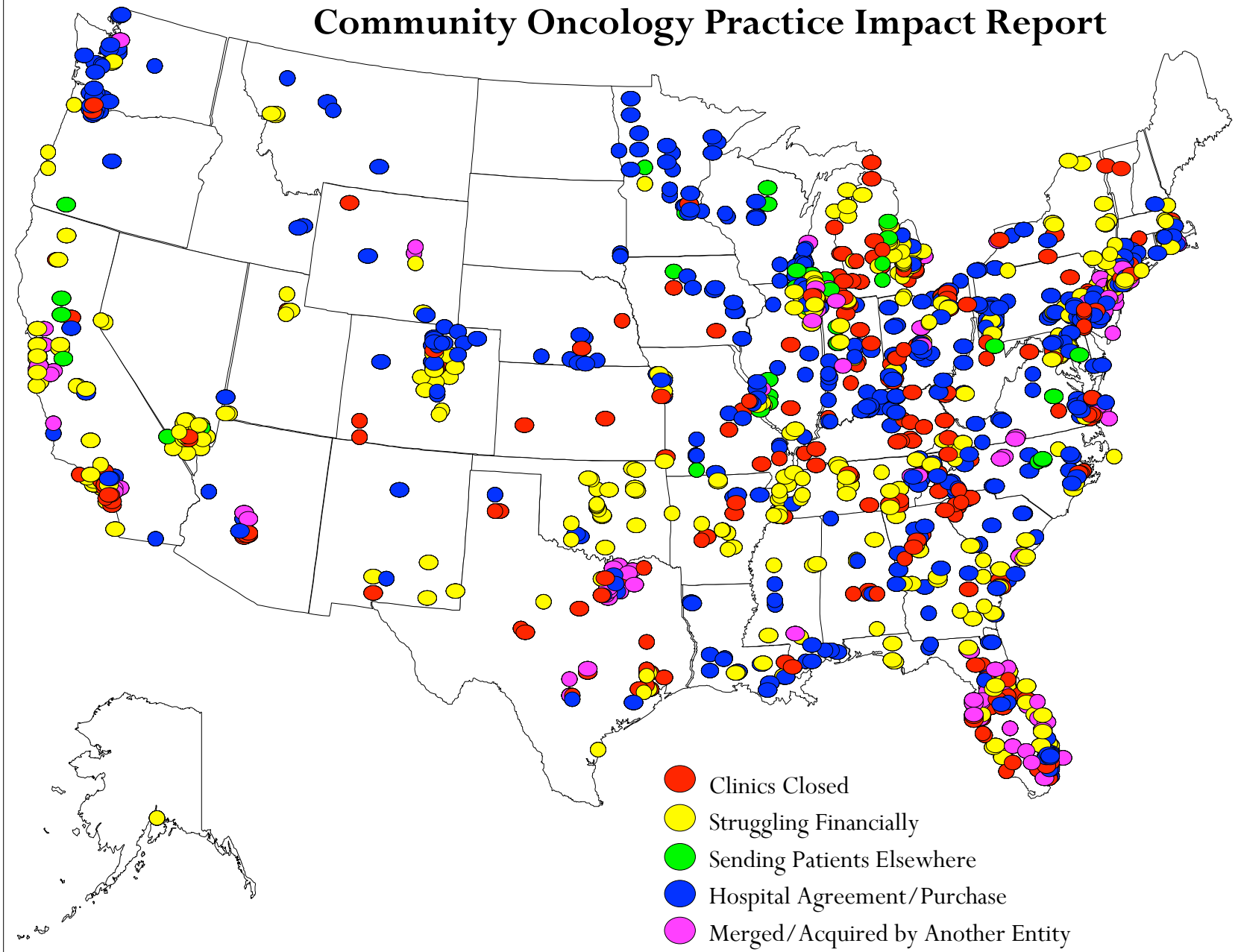
Practices Sending Patients Elsewhere denotes practices (possibly comprised of multiple clinic sites) that are sending all patients elsewhere for treatment.

Hosp. Agreement/Purchase denotes practices (possibly comprised of multiple clinic sites) that have a formal agreement/arrangement with a hospital or have been purchased by a hospital.

Merged/Acquired by Another Entity denotes practices (possibly comprised of multiple clinic sites) that have merged with other practices or have been acquired by a corporate entity, other than a hospital.

Source: Community Oncology Alliance practice impact database compiled and updated from data obtained from public and private sources.

Community Oncology Practice Impact Report



Dispute Develops Over Discount Drug Program

By ANDREW POLLACK
Published: February 12, 2013

When a private oncology practice in Memphis formed a partnership with a nearby hospital in late 2011, the organizations proclaimed that the deal would "transform cancer care" in the region.

Enlarge This Image

Robin Trimarchi for The New York Times

Burnis D. Breland, the pharmacy director of a Georgia health system, says the federal program is essential.

What they did not emphasize was that the deal would also create a windfall for them worth millions of dollars a year, courtesy of an obscure federally mandated drug discount program.

The program, known as 340B, requires most drug companies to provide hefty discounts — typically 20 to 50 percent — to hospitals and clinics that treat low-income and uninsured patients.

But despite the seemingly admirable goal, the program is now under siege, the focus of a fierce battle between powerful forces — the pharmaceutical industry, which wants to rein in the discounts, and the hospitals, which say they might have to cut services without them.

One issue is that the program allows hospitals to use discounted drugs to treat not only poor patients but those covered by Medicare or private insurance. In those cases, the hospital pockets the difference between the reduced price it pays for the drug and the amount it is reimbursed.

That is what happened in Memphis. When the West Clinic teamed with Methodist Healthcare, the huge volume of chemotherapy drugs used by the clinic suddenly qualified for the hospital's discount, while reimbursement remained the same.

In a report issued on Tuesday, pharmaceutical industry trade groups say that some hospitals have gone overboard in using the program to generate revenue, straying from the original intent of helping needy patients. The report, which was supported by groups representing pharmacies, pharmacy benefit managers and oncology practices, called for the discounts to be more narrowly focused.

FACEBOOK
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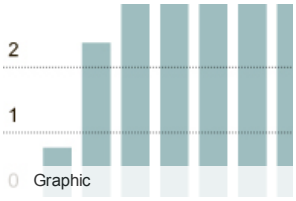
GOOGLE+
SAVE
E-MAIL
SHARE
PRINT
REPRINTS

Multimedia



A Popular Discount Drug Program Under Fire

DOCUMENT: White Paper on 340B Hospitals

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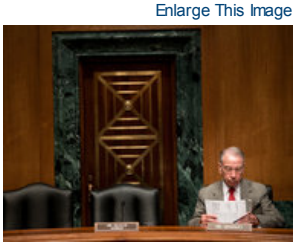

Brendan Smialowski/Getty Images

Some senior Republicans, like Senator Charles E. Grassley, are scrutinizing the 340B program.

What's Popular Now

Eileen Brennan, Who Played Flinty Captain in 'Private Benjamin,' Dies at 80

Manning Is Acquitted of Aiding the Enemy

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Over a Million Are Denied Bank Accounts for Past Errors

8. WELL

Some senior Republicans in the House and Senate are investigating the program, which they say has suffered from murky rules and lax enforcement.

"If 'nonprofit' hospitals are essentially profiting from the 340B program without passing those savings to its patients, then the 340B program is not functioning as intended," Senator Charles E. Grassley, Republican of Iowa, said in letters sent to three medical centers last October.

One reason for the scrutiny is that the program — named after the section in the law that created it in 1992 — now includes one-third of the nation's hospitals, triple the number in 2005. About $6.9 billion worth of drugs, or about 2 percent of the nation's total, are sold through the program annually, reducing revenue for the pharmaceutical companies by hundreds of millions of dollars a year.

The industry report says sales could grow to $12 billion by 2016. That is in part because the nation's new health care law will make more hospitals eligible for the discounts by increasing the number of Medicaid patients they treat, even as the need for the discounts should arguably diminish because fewer people will be uninsured.

Hospitals say 340B was never meant to merely provide cheap medicines to poor people. Rather, it was meant to help the hospitals that treat such patients, and to stretch federal resources. Making money from the spread helps keep the hospitals operating, which in turn helps needy patients, they say.

"If we didn't have our 340B program, I seriously doubt we could have our outpatient cancer center," said Burnis D. Breland, director of pharmacy at the Columbus Regional Healthcare System in western Georgia.

Nevertheless, with the program under scrutiny, the organization representing 340B hospitals, Safety Net Hospitals for Pharmaceutical Access, has warned companies that help those hospitals run their discount programs to avoid using terms like "increasing profits" and "revenue enhancement."

A 2011 report by the Government Accountability Office, the investigative arm of Congress, said that federal oversight of the program was insufficient to ensure that hospitals and drug companies were adhering to the rules.

In response, the Health Resources and Services Administration, which oversees the program using an annual budget of only $4.4 million, audited 51 hospitals last year, its first audits since the program began. It also made all hospitals recertify themselves as eligible for the program.

As a result, some 271 treatment sites belonging to 85 hospitals were ejected from the program, said Krista Pedley, the federal official in charge of the 340B program. She said that three hospitals acknowledged receiving discounts for which they were ineligible and were repaying manufacturers.

Some drug companies — Genentech is the only one that has publicly identified itself — are also auditing hospitals or considering doing so.

Previous studies have shown drug companies do not always offer the full discount, though no drug companies are being audited.

"Basically the pendulum has swung so aggressively toward oversight of the hospitals, with little concern about the drug companies," said Ted Slafsky, president of Safety Net Hospitals for Pharmaceutical Access.

With so much money at stake, the 340B program has given rise to a cottage industry of companies that help hospitals increase their savings, and two big conferences are held each year on the program. The most recent one, in San Francisco last month, drew 800 people and about 50 exhibiting companies.

Some oncologists say the 340B program is one reason that more than 400 oncology practices have become part of hospitals in the last several years. The 340B discounts apply to all drugs, but oncologists use a lot of costly ones, providing a potentially larger spread.

A single oncologist might use $2.5 million to $4 million in drugs a year, according to the Community Oncology Alliance. If those drugs can be acquired for a 25 percent discount, that is a potential profit of up to $1 million.

“It’s the loophole that’s made cancer drugs profitable again,” said Dr. Peter B. Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center and a former adviser to Medicare.

Dr. Lee S. Schwartzberg, medical director of the West Clinic in Memphis, said the 340B program “definitely was a factor” in the decision to form the partnership with Methodist Healthcare.

The hospital and clinic say they will donate $5 million a year from the 340B proceeds to the University of Tennessee, which is building a cancer center with which they are affiliated.

The money is also being used to help pay for nursing and genetic counseling, Dr. Schwartzberg said.

Some prison systems, meanwhile, save on drug costs by making a 340B hospital their official health care provider.

If inmates “become ‘patients’ of the hospital, a ‘win-win’ arrangement can be negotiated with the state, county or city,” said a slide from a 2010 presentation by Safety Net Hospitals for Pharmaceutical Access.

A big increase in the use of 340B occurred in 2010, when the government allowed hospitals to use an unlimited number of neighborhood pharmacies to fill 340B prescriptions. Before that, patients generally had to go to the hospital pharmacy, which can be inconvenient.

The University of California medical centers, which now have 240 pharmacies under contract, expect 35 percent of eligible prescriptions to go through the 340B program this year, up from only 10 percent in 2011, said Lynn Paulsen, director of pharmacy practice standards.

In these arrangements, needy patients typically get the drugs at little or no cost.

But if a patient is insured, the hospital keeps the difference between the reduced price it paid for the drug and the higher price reimbursed by the insurer, and pays the neighborhood pharmacy a dispensing fee.

There are already about 25,000 arrangements between a treatment site and a pharmacy, according to the Health Resources and Services Administration.

“It’s morphed into a big revenue-capture game — how can we get as many 340B prescriptions filled at a 340B price,” said Aaron Vandervelde of the Berkeley Research Group, a consulting firm to pharmaceutical companies.

It is too early to say what, if any, changes will be made by Congress.

Hospitals say that restricting the discounts to drugs actually consumed by poor patients would eviscerate the benefits of the program. The hospitals are hoping the program might be expanded to help balance the federal budget.

Ailing hospitals might garner more sympathy than profitable drug companies. It is perhaps telling that no Democrats have joined the investigation of the 340B program.

“It’s saving the government money, so they don’t have an incentive to change it,” said

Carlton Sedberry, senior director at Medical Marketing Economics, a pharmaceutical industry consulting firm.

“It’s making the hospitals money, so they don’t have an incentive to change it.” And patients, for the most part, are unaware of 340B.

“The only people this smacks are the manufacturers.”

This article has been revised to reflect the following correction:

Correction: February 22, 2013

An article on Feb. 13 about a drug discount program for hospitals known as 340B misstated the target of a warning from an organization representing hospitals that use the program. The organization, Safety Net Hospitals for Pharmaceutical Access, warned companies that help the hospitals run their discount programs to avoid using terms like “increasing profits” and “revenue enhancement.” It did not issue that warning to the hospitals themselves.

A version of this article appeared in print on February 13, 2013, on page B1 of the New York edition with the headline: Drug Industry Sees Abuse in Discount Program.

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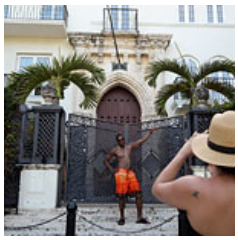
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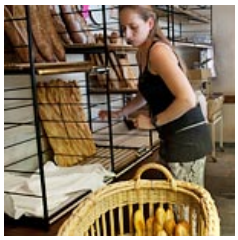
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United States Government Accountability Office

GAO

Report to Congressional Committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

GAO-11-836

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-11-836, a report to congressional committees

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.[1] The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),[2] requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.[3]

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

[1]Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

[2]42 U.S.C. § 256b.

[3]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.[4] Covered entities' current spending on 340B drug purchases is estimated to be about $6 billion annually.

Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.[5] For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.[6] As of July 2011, there were more than 16,500 covered entity sites

[4]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

[5]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

[6]In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.[7] Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.[8] Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.[9] This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,[10] stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

[7]Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[8]42 U.S.C. § 256b(a)(5)(B).

[9]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[10]According to HRSA, while there are no 340B-specifc requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.[11] PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.[12] The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.[13] Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

[11]Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

[12]Pub. L. No, 111-148, § 7102(b).

[13]For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),[14] 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent[15]—in this report we refer to these hospitals as DSH hospitals.[16] These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA's health insurance reforms on the 340B program.[17] In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

[14]FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS).

[15]General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital's DSH adjustment percentage is generally based on its DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

[16]While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

[17]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.[18] Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

[18]We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.[19] We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[20] HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,[21] which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

[19]HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

[20]The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

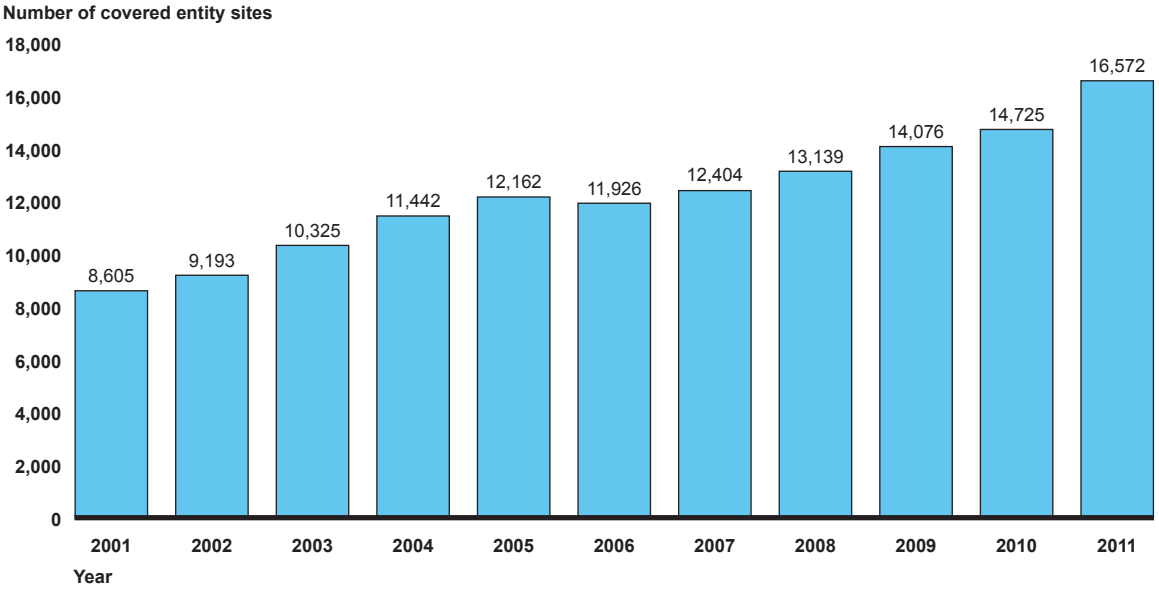
[21]The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.[22]

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

[22]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,[23] family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children's hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.[24]

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify; however, critical access hospitals are exempt from this requirement.[25] Additionally, all hospitals must be (1) owned or operated

[23]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[24]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

[25]To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children's, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children's and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,[26] or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.[27]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.[28] Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

[26]According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

[27]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

[28]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities;[29] however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.[30] As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.[31] In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient. This definition was issued in 1996 and outlines three criteria which generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services, from covered entities. (See table 1 for more information on HRSA's definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

[29]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

[30]42 U.S.C.§ 256b(a)(10).

[31]When a drug's average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug's unit rebate amount to be greater than the drug's average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA's Definition of a Patient Eligible for Discounted Drugs under the 340B Program

	Criteria for patient eligibility[a]
1.	The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
2.	The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.[b]
3.	The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance.

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207, 55156 (Oct. 24, 1996).

[a]These criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]DSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children's hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).[32] However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

[32]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same avenue that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.[33] Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:[34]

- **Third-party reimbursement rates**: Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.[35] However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

[33]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

[34]Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

[35]Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.[36] This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.[37] However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.[38] Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status**: Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

[36]A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

[37]State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

[38]These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices**: Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,[39] which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.[40] In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

[39]PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

[40]HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;[41] some services provided through this program included arranging

[41]Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.[42]

Manufacturers' Distribution of Drugs at 340B Prices Generally Did Not Affect Providers' Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities' or non-340B providers' access to drugs related to manufacturers' distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers' distribution of drugs at 340B prices affected providers' access to drugs primarily in two situations.[43] The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

[42]The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

[43]While stakeholders consistently reported two situations in which manufacturers' distribution of drugs at 340B prices affected providers' access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers' distribution of drugs at 340B prices.

of which is inherently limited;[44] and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.[45] Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,[46] or from GPOs.[47] Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

[44]IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

[45]Hospitals are the primary purchaser of IVIG in the United States.

[46]Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

[47]In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about $20,000 to $25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.[48] This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.[49] Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.[50]

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

[48]This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

[49]While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

[50]The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.[51] An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.[52] For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

[51]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

[52]In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.[53] Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.[54] Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

[53]We use the term hospitals that are not publicly owned or operated to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B program.

[54]HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.[55]

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

[55]In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02 -00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.[56] As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.[57] For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.[58]

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

[56]HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[57]HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

[58]HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.[59] Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.[60] Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

[59]For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

[60]In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

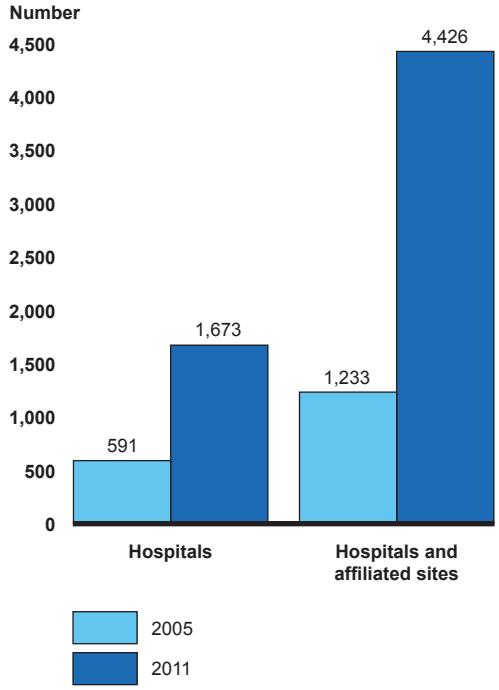
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[61] Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).[62] Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

[61]HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

[62]One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.[63]

[63]Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.[64] The number of hospitals eligible to participate may increase due to PPACA's Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals' eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.[65] The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

[64]According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

[65]See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.[66]

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

[66]See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified[a]	Developing implementation plan[b]
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified[a]	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified[a]	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: • requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; • if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and • referral to federal authorities.	Not specified[a]	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: • making a centralized list of HRSA-verified 340B prices available to covered entities, • conducting selective audits of manufacturers, and • establishing procedures by which manufacturers repay covered entities for overcharges.	Not specified[a]	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: • establishing procedures for covered entities to obtain information from manufacturers,[c] and • requiring manufactures to audit covered entities prior to submitting a request to initiate the dispute resolution process.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

[a]PPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

[b]HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[c]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.[67]

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

[67]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and

- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is available at no charge on the GAO web site at http://www.gao.gov.

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

Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details

Covered entities	29	27 were selected to take into account certain criteria:
		• Entity Type:
		  • We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.)
		  • We picked these types based on:
		  • variation in operational structure,
		  • variation in services and drugs provided,
		  • high levels of 340B participation,
		  • experience with the program, and
		  • potential difficulty accessing drugs at 340B prices.
		• Location:
		  • We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah.
		  • States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.[a]
		  • We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.[b]
		• We used information provided by trade organizations representing covered entities to help select individual covered entities to interview.
		2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.

Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager.[c]

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).[d]
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	**61**	

Source: GAO.

[a]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[b]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

[c]Distributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

[d]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC)[b,c]	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992[d]	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations[e]	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992[d]	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992[d]	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992[d]	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992[d]	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992[d]	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a "payer of last resort" to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992[d]	90[f]	HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992[d]	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992[d]	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992[d]	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75[g]	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992[d]	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75[g]	Primarily provide services to individuals under 18 years of age.	2006[h]	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement)[g]	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010[i]	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii))with a DSH adjustment percentage equal to or greater than 8[g]	Isolated from other hospitals by distance, weather, or travel conditions.	2010[i]	200	CMS and HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8[g]	Large rural hospitals that provide services for patients from a wide geographic area.	2010[i]	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886 (d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B(v))with a DSH adjustment percentage greater than 11.75[g]	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010[i]	5	CMS
Total				**16,572**	

Source: GAO analysis of federal laws and regulations.

[a]Data are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[b]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[c]This category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L.. No. 93-638) and administered by the Indian Health Service.

[d]Eligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

[e]Section 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

[f]According to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

[g]Facility must also be (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

[h]While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

[i]Became eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302,124 Stat.1029, 1082.

Appendix III: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 07 2011

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report:

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (*i.e.*, generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

> "HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

> 1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the hospital "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare-cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

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individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of $4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of $4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to deter potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

4

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

5

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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Oncology Clinics Caught in Financial Vise

Published: Jul 27, 2013

By Charles Bankhead, Staff Writer, MedPage Today

save | A A

Community oncology clinics continue to feel the squeeze of a changing reimbursement structure that has forced 288 clinics to close in the past 6 years.

If anything, the pace of closure, consolidation, and contraction has increased, with a 20% increase over the past year, which followed a 21% jump in closures between 2011 and 2012, according to the Community Oncology Alliance's (COA) Practice Impact Report.

Since the COA issued its first report in 2010, the number of community oncology clinic closures has increased by 67% (from 172).

An additional 43 oncology clinics have begun sending all of their patients elsewhere. All told, 1,338 community oncology clinics and practices have been adversely affected by changes in reimbursement practices, including 407 practices in financial straits, 469 that have entered into contractual arrangements with hospitals, and 131 that have merged or have been acquired by organizations other than hospitals.

"This is nothing new; it's been happening since 2005, when Medicare, which pays for roughly half of all cancer care, changed the way that they reimburse for cancer care," COA executive director Ted Okon told MedPage Today.

"You have two dynamics at work," he added. "Reimbursement was changed by Medicare, and over time, the private payers have followed suit. We've had reimbursement pressures that have put the pressure correspondingly on oncology practices. Those practices that have a large majority of patients who are Medicare beneficiaries simply have not been able to survive."

Rural Areas Hardest Hit

The pressures have disproportionately affected oncology clinics and practices in rural areas, which historically have been underserved.

However, other factors, some of them noneconomic, are at play, said Matt Farber, of the Association of Community Cancer Centers.

"The average age of physicians who are willing to be employees is declining," he said. "We are seeing more younger physicians coming into oncology who are happy to be an employee of a hospital or working within a system as opposed to being a partner or part owner or entrepreneur."

The current financial problems took root in 2003 with the Medicare Modernization Act, which introduced the Average Sales Price (ASP) to the reimbursement methodology associated with Medicare Part B drug coverage. According to the ASP formula, community oncology practices purchase the drugs, and Medicare reimburses the ASP plus a 6% service fee to cover the practices' acquisition and administration costs.

In congressional testimony in June, Barry Brooks, MD, of US Oncology, called the 6% add-on

"incredibly important because none of the work that must occur to prepare chemotherapy for administration to a patient is otherwise reimbursed by Medicare."

"Even in small clinics with one or two medical oncologists, the ancillary staff that do all of the above can be four to five highly trained professionals, and in larger clinics, the staffing is accordingly much larger," he added.

"Even if every drug were ready to be administered to a patient at the moment it arrived at the doorstep of the practice, paying exactly only acquisition for the drug would still be problematic and would not properly reflect the financial costs of inventory, as well as the significant infrastructure investment to manage and control this unique inventory."

Even with the 6% service fee, Medicare reimbursement has not kept up with rising costs, Brooks continued. Since 2006 Medicare part B reimbursement for drugs and biologics has remained essentially flat, whereas the Consumer Price Index has gradually increased, eroding the effective rate of the service add-on.

Hospitals Get More of the Money

Community oncology practices also have come out on the short end of a reimbursement disparity versus hospitals. Medicare has a substantially higher reimbursement rate for cancer drugs administered in a hospital outpatient clinic versus a community-based clinic. Not surprisingly, the disparity has driven more of the drug administration volume to hospitals.

In his congressional testimony, Brooks noted that the 2013 Medicare Physician Fee Schedule for a 1-hour intravenous infusion of chemotherapy was $143.24, compared with $230.50 allowed by the Hospital Outpatient Prospective Payment Schedule, a 61% difference.

Okon traces the pricing disparity to the 340B Drug Pricing Program enacted in 1992 to give "select safety net providers" a price break on drugs distributed and administered in the outpatient setting. Over the years, hospitals have become adept at taking advantage of the 340B program, which allows them to acquire drugs at discounts ranging as high as 60%.

"We've seen almost an explosion in the number of nonprofit hospitals that have applied for and have been granted 340B status," said Okon. "As a result, with those deep discounts, a lot of those hospitals have looked at increasing their inflow of drug revenue. The way to do that is to acquire an oncology practice, which has the largest flow of revenue attributed to chemotherapy."

Brooks told members of the House Energy and Commerce Health Subcommittee that 340B-certified hospitals have a margin in excess of 30% for Medicare drugs, whereas margin for community clinics typically ranges from 0 to -2.0%.

In late May, the Moran Company issued findings from a study commissioned by US Oncology, the COA, and ION Solutions. According to the report, hospitals' share of fee-for-service chemotherapy administration lines increased from 13.5% in 2005 to 33% in 2011. During the same period, Medicare payments for chemotherapy administration in hospitals went from $98.3 million to $300.9 million, whereas payments for physician office administration decreased by almost 15%.

The study also showed that:

- Hospitals' share of Medicare fee-for-service payments for chemotherapy administration increased from 16.2% in 2005 to 41.0% in 2011
- Hospitals' reimbursement for chemotherapy drugs more than doubled from $904.5 million to $2.03 billion versus a 32% increase in payments to physician offices ($2.63 billion to $3.47 billion)
- Hospitals' share of Medicare reimbursement for chemotherapy drugs increased from 25.6% to 37%
- Despite the reimbursement disparity, two-thirds of all chemotherapy for Medicare beneficiaries is delivered in physician offices

The latest financial body blow to community oncology clinics has come from the budget cuts mandated by sequestration. The 2% across-the-board cuts will affect the 6% service fee plus the acquisition costs for drugs purchased and administered to Medicare beneficiaries.

Brooks concluded his testimony by asserting, "Oncologists should not be put in the untenable position of continuing to treat patients at a loss, which will result in clinic closings or sending

seniors fighting cancer to the hospital for treatment in order to keep the clinic doors open."

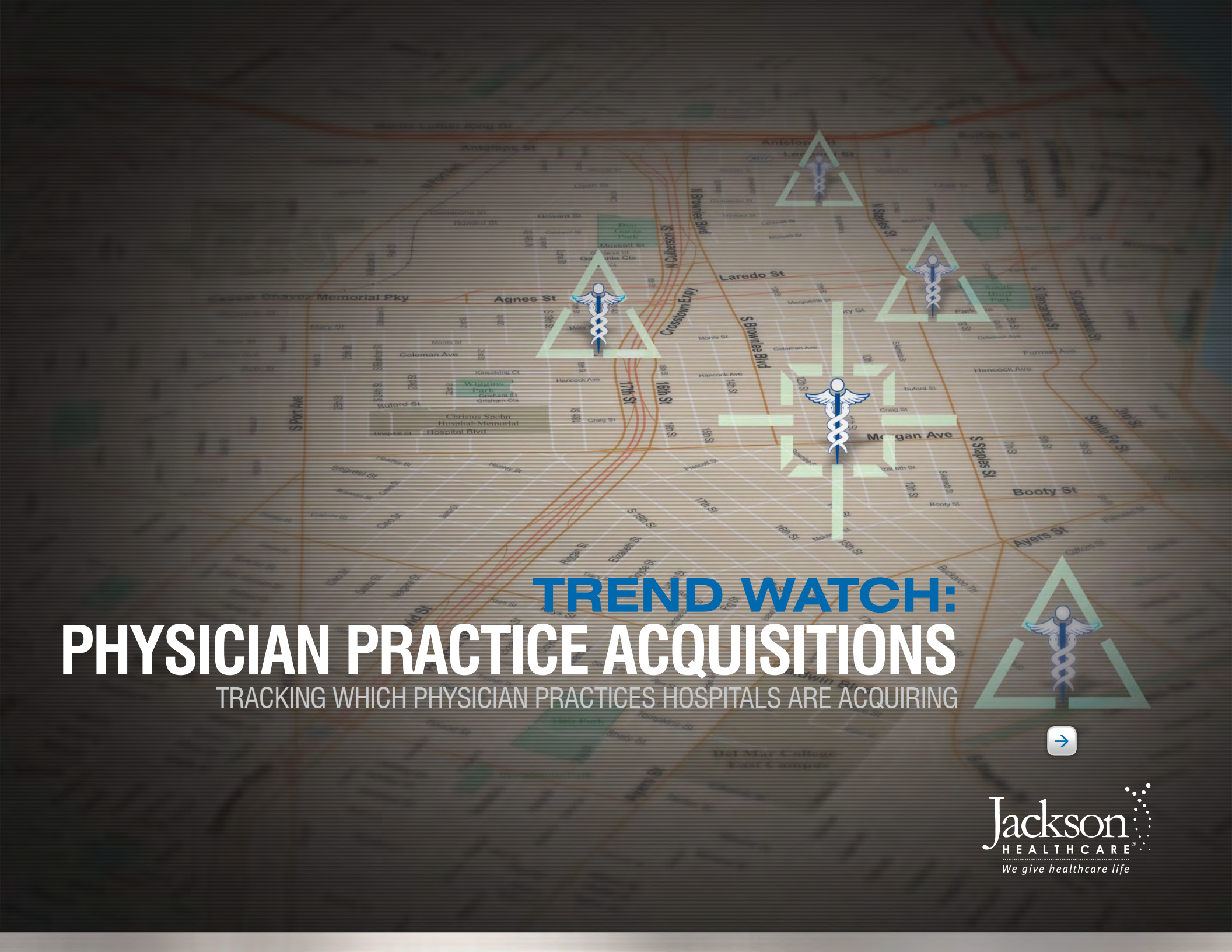
Will Congress Bring Relief?

The community oncology industry has hopes of getting some relief from Congress. At least two pieces of legislation have been proposed to eliminate cuts to the service fees associated with chemotherapy administration and to ensure that community oncology providers benefit from any pricing discounts between drug distributors and manufacturers.

Stanching the flow of oncology practice from the community has to be a priority because once the change has occurred, the situation is unlikely to reverse itself, said Matt Brow, of McKesson Specialty Health and US Oncology. Any change of direction would require capital investment and other expenses that would put a start-up community clinic out of the reach of physicians and small organizations.

"It would be in the best interest of the government, the patients, the taxpayers, and the private payers over time to pay the same amount for the same service, regardless of the setting where it's provided," said Brow, adding that he expects to see legislation to that effect introduced in Congress in the near future.

Ultimately, patients will pay the price for the loss of community oncology services, said Okon. As more practices leave community settings, patients will have to travel longer distances to get cancer treatment and will have to pay more for that treatment.



TREND WATCH:

PHYSICIAN PRACTICE ACQUISITIONS

TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING

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INTRODUCTION

Are hospitals actively acquiring physician practices? If so, which specialties?

In this report, we share the findings of Jackson Healthcare's first national study of hospital practice acquisitions.

Key takeaways:

- ***Nearly half the hospitals surveyed are actively involved in physician practice acquisitions***
- ***Family practice and internal medicine are the primary targets***
- ***Hospitals acquire practices primarily for competitive positioning or through physician inquiries***

METHODOLOGY

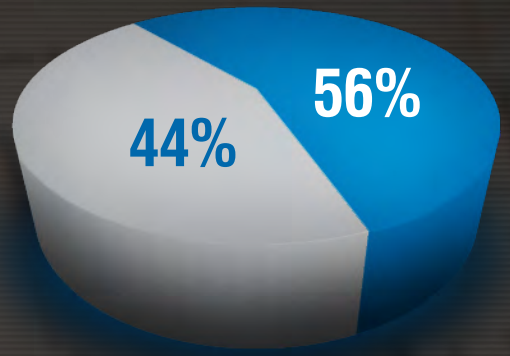
This survey was conducted via online and telephone surveys with hospital executives from November 1st through December 15th, 2012.

A total of 118 participants completed the survey. Online respondents were self-selected with 68 completing the survey. Fifty participants completed the telephone survey conducted by Survey Sampling International.

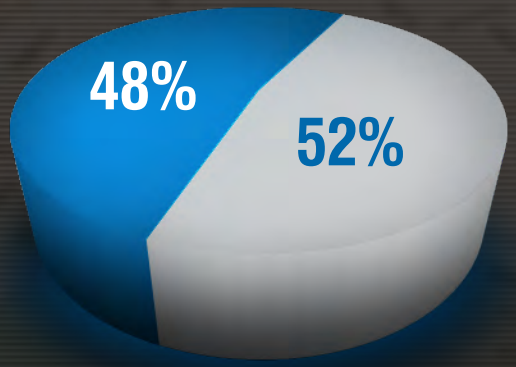
The error range for this survey at the 95th percent confidence level is nine percent.

ARE HOSPITALS ACQUIRING PHYSICIAN PRACTICES?

Actual Acquisitions in 2012 (n=118)



Planned Acquisitions in 2013 (n=119)



Yes

No

2012 ACQUISITIONS BY SPECIALTY (ACTUAL)

Specialty	(n=50)
Family Practice	54%
Internal Medicine, General	26%
Obstetrics/Gynecology	24%
Cardiology	18%
Primary Care	16%
General Surgery	12%
Urology	10%
Hospitalist & Rheumatology	8%*
Gastroenterology, Nurse Practitioner, Oncology, Orthopedic Surgery, Otolaryngology, Pediatrics, General	6%*
Emergency Medicine, Endocrinology, Diabetes & Metabolism, Neurology	4%*
Neurosurgery, Physical Medicine & Rehabilitation, Psychiatry (Adult), Pulmonary Medicine	4%*
Allergy & Immunology, Cardiothoracic Surgery, Infectious Diseases, Maternal & Fetal Medicine, Nephrology, Occupational Medicine, Pathology, Pediatrics, Subspecialty, Radiation Oncology, Radiology, Vascular Surgery	2%*

*The percentage represents each specialty individually, not as a group. For example, Gastroenterology=6%, Nurse Practitioner=6%, etc.

2013 ACQUISITIONS BY SPECIALTY (PLANNED)

Specialty	(n=119)
None/Not Planning to Acquire	48%
Family Practice	31%
Internal Medicine, General	22%*
Primary Care	13%
Cardiology, Orthopedic Surgery	10%*
Gastroenterology, General Surgery, Urology	8%*
Obstetrics/Gynecology, Oncology	7%*
Otolaryngology	6%
Neurology, Nurse Practitioner, Pulmonary Medicine	5%*
Ambulatory Care, Hospitalist, Infectious Disease, Pediatrics, General	4%*
Cardiothoracic Surgery, Neurosurgery, Rheumatology, Endocrinology, Diabetes and Metabolism, Geriatric Medicine, Orthopedic (non-surgical), Pain Medicine, Radiation Oncology, Trauma, Vascular Surgery	3%*
Anesthesiology, Bariatrics, Emergency Medicine, Ophthalmology, Plastic Surgery, Psychiatry (Adult)	2%*
Colon & Rectal Surgery, Critical Care Medicine, Dermatology, Hematology, Maternal and Fetal Medicine, Nephrology, Occupational Medicine, Podiatry, Radiology, Sleep Medicine, Sports Medicine	1%*

*The percentage represents each listed specialty individually, not as a group. For example, Cardiology=10% and Orthopedic Surgery=10%.

REASONS FOR PHYSICIAN PRACTICE ACQUISITION

Reason	(n=69)
Physicians approach hospital/seek to sell their practices	70%
Build a competitive advantage	58%
Part of a physician recruitment strategy	57%
Maintain a competitive advantage	55%
Accountable Care Organization formation	30%
Improve patient safety	28%

GEOGRAPHIC DISTRIBUTION OF RESPONDENTS

Region	(n=108)
Midwest	28%
Southeast	28%
Middle Atlantic	14%
Southwest	9%
Mountain	8%
Pacific	8%
New England	5%

Area	(n=110)
Rural	58%
Suburban	26%
Urban	16%

RESPONDENT STATISTICS

Bed Size	(n=110)
25 or less	9%
26-150	52%
150-300	16%
300+	23%

Respondent Title	(n=110)
CEO	25%
Administrator	17%
Physician Recruiter / Recruitment Manager	9%
COO	8%
Director	5%
President	3%
VP	3%
Director Medical Affairs / Provider Relations	3%
Business Development	2%
Other (Coordinator, HR, Associate Dean)	3%

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WSJ.com

OPINION | July 30, 2013, 7:16 p.m. ET

Scott Gottlieb: How ObamaCare Hurts Patients

The 340B program was meant to help about 90 hospitals buy drugs to treat the poor. Now 1,675 hospitals qualify.

By SCOTT GOTTLIEB

President Obama promised to mend the failings in the American health-care system, and yet for cancer treatment, ObamaCare is taking a rotten feature of the old system and making it worse.

The Affordable Care Act expands a program called 340B, which siphons money from drug makers and insurers to subsidize certain hospitals. The program has been expanded as a way to offset some of the cuts that the law imposes on hospitals. One significant side effect: 340B is increasing the cost of cancer care—and harming its quality.

When the program began in 1992, its aim was to support hospitals that cared for many uninsured, indigent patients. Over the years, the program was radically broadened, gradually morphing into a government cash cow that hospitals of every description have learned to exploit.

Under 340B, eligible hospitals are allowed to buy drugs from drug companies at forced discounts of 25% to 50%. The hospitals can then bill government and private insurers for the full cost of the drugs, pocketing the spread. The arrangement gives 340B-qualified hospitals a big incentive to search for patients and prescribe lots of drugs. The costlier the drugs, the bigger the spread. So expensive cancer drugs are especially appealing.

Getty Images/Imagezoo

The original legislation creating 340B envisioned that only about 90 hospitals that care for a "disproportionate share" of indigent patients would qualify. But remember, this is a well-intentioned government program handing out money, with the usual result: By 2011, 1,675 hospitals, or a third of all hospitals in the country, were 340B-qualified.

Even flourishing hospitals like the Hospital of the University of Pennsylvania and Duke University Health System feed off the subsidies. In 2011, Duke bought $54.8 million in drugs from the discount program and sold them to patients for $131.8 million, for a profit of $76.9 million—a substantial portion of the health system's 2011 operating profit of $190 million. Only one in 20 patients served by Duke's 340B pharmacy is uninsured. The rest have their prescription costs covered by Medicare,

Medicaid or commercial insurers.

Now ObamaCare is encouraging even wider 340B abuses. The new health-care law expands 340B to cover cancer centers, new categories of hospitals and rural health centers. Since one of the ways that hospitals qualify for 340B turns on how many Medicaid patients they serve, ObamaCare's Medicaid expansion will also increase the number of 340B-eligible entities.

To goose the windfall, eligible hospitals are buying private oncology practices so they can book more of the expensive cancer drug purchases at the discount rates. More than 400 oncology practices have been acquired by hospitals since ObamaCare passed. Acquiring a single oncologist and moving the doctor's drug prescriptions under a hospital's 340B program can generate an additional profit of more than $1 million for a hospital. In the process, treatment of the doctor's patients is moved from an office setting to a hospital outpatient department.

As a result, between 2005 and 2011 the amount of chemotherapy infused in doctors' offices fell to 67%, from 87%, according to a new analysis of Medicare billing data done for community oncology groups. The share of Medicare payments for chemotherapy administered in hospitals (as opposed to outpatient oncology practices) increased to 41% in 2011, from 16.2% in 2005.

If these trends continue, the majority of cancer care will soon be delivered by hospitals. When the practice of oncology shifts to outpatient hospital clinics, the care is often less comfortable and convenient for cancer patients—and more costly.

Because the overhead for a hospital is higher than for a doctor's office, a patient treated in a hospital clinic incurs $6,500 more in costs than the same person treated in a private medical office, according to data from the Community Oncology Alliance. Patients who get chemotherapy at a hospital also face an additional $650 in co-pays and other out-of-pocket expenses. The price for infusing the drugs alone rises by 55%, according to an analysis of Medicare data. These inflated prices for cancer treatment inevitably drive up the cost of health insurance.

The Obama team has used informal "subregulatory guidance" to expand the 340B program still further. One big change came in March 2010 "guidance" that allows hospitals to contract with an unlimited number of neighborhood pharmacies to dispense drugs through them. There is no requirement that these "satellite" pharmacies have any geographic tie to the hospital.

This has created an industry of middlemen who build vast networks of pharmacies, all to expand the number of 340B prescriptions that a hospital can capture. There are now more than 25,000 arrangements between such satellite pharmacies and 340B-qualified treatment sites, according to the Health Resources and Services Administration.

The definition of a "covered patient" for 340B purposes is so murky under other guidance that hospitals are able to buy and bill discounted drugs for patients when the hospital merely serves as a conduit and doesn't give direct patient care.

The regulatory loosening has led to a proliferation of abuse. The Health Resources and Services Administration, the federal agency that (nominally) oversees the program, recently audited 340B-

eligible hospitals. The agency found "adverse findings" (like discounted drugs diverted or dispensed to ineligible patients) with almost half of the 34 institutions the agency examined.

A separate report by the General Accountability Office shows that the money isn't being targeted for indigent patients, as required. As profits from the program rose, and oversight remained lax, more of the money has instead become a general revenue source for 340B-eligible hospitals.

To combat this sort of gaming, drug makers are tightening how they distribute cancer drugs, to make improper diversion more difficult. This drug-company strategy may stem some of the most rampant abuses, but it adds to the cost and complexity of the pharmaceutical supply chain. It's another way that 340B increases costs.

The 340B program doesn't print free money. The cost of the discounts are foisted onto patients and insurers, who are forced to pay higher prices that drug makers establish to offset the cost of the forced discounts.

One of the rationales behind the Affordable Care Act was that the law would end the gimmicks that distort incentives and drive up costs. In the case of the 340B program and its effect on cancer treatment, the law has only further distorted an already expensive gimmick.

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Oncology Rounds

Estimating the Demand for Oncology Physicians

on June 13, 2011 | **Permalink**

As frequent readers of this blog know, we often use it as a vehicle to share the answers to questions we receive frequently from our members. One question that has been coming across my inbox a lot recently, in various permutations, relates to the demand for key oncology physicians, particularly medical oncologists. Sometimes the questions is around estimating the true demand for physicians based on population and utilization, other times it's more specific to the volumes seen at a particular institution. While there is no perfect answer I thought I'd share a few numbers for those working through this issue.

Supply of physicians as a function of population

The most straightforward way to tackle this question is to take a supply side approach - the underlying assumption being that supply equals demand. I think we can all agree that this is flawed, but it's a helpful place to start. As most of you know, ASCO recently did a large workforce study, and they found there are approximately 10,000 medical oncologists and hematologists oncologistsin the US. If you add in pediatric oncologists and gyn oncs, the number is closer to 12,500. As a function of US population, this gets you to about 3.3-4.0 medical oncologists per 100,000 (assuming a US population of 308 million).

For radiation oncologists, the most comprehensive work I've seen completed is a study recently done at MD Anderson.They cite about 3,943 radiation oncologists nationally, equivalent to 1.28 per 100,000 US Population.

Supply does not equal demand

The challenge with this approach is that we all know that supply is not the same as demand. So the better question to look at is how many physicians do we actually NEED? This is a harder question to answer. The ASCO workforce study goes into detail on this at a population level, so I won't repeat their work here. But do look at the study if you haven't already. The MD Anderson study does not go into the same level of detail, but they do state that if the supply of radiation oncologists doesn't increase we will likely have a shortage given the fact that volumes are expected to rise based on demographics alone, and treatments are only getting more complex.

Translating to hospital specific demand

In terms of translating this to a specific hospital and how many they might need, here are a few thoughts. First, starting with medical oncologists. The most definitive data I have seen to date on patient load continues to be from Oncology Metrics recently published in the *Journal of Oncology Practice*. Their survey data indicates, that on average, a medical oncologist will see about 350 new patients annually (counted as new patients and consulations both in the office and the hospital). It's important to note that their survey focuses primarily on private practice physicians who may be more productive than those employed by a hospital. Some hospital administrators have told me they find that benchmark aggressive - in which case you may want to dial it back to 250 or 300. I think that one of the reasons this is high is the way they define new patients - it counts all new patient visits and consultations, both in the office and in the hospital.

For radiation oncology, we can take a similar approach. The average number of patients per radiation oncologist is about 250 (usually equal to one radiation oncologist per LINAC). This benchmark comes from a survey the Oncology Roundtable did of our membership 2-3 years ago.

Again, keep in mind these are estimates and will vary by practice structure, case mix etc. For instance, data in the ASCO study demonstrates that academic hem oncs spend only 47% of their time on patient care, while private practice physicians spend 76%. And men between the ages of 45 and 64 in private practice average over 100 visits per week, while women in that age group average only 90.

Why all the interest? Accountable care perhaps...

As I was pulling the data for the post I began thinking about why we've seen a huge surge in volumes of requests of this kind and I think it has to do with two major trends. First, the general uptick in interest in employment - more physicians are interested in employment and hospitals are trying to determine if they should take the plunge and employ and so they'll want to know if they have enough patients to support these physicians. A second, and related driver is accountable care. For those organizations setting up an ACO and striving to manage a population of patients, they'll want to know how many of each specialist they'll need to meet the demand of their specific patient population.

Learn more at our National Meeting

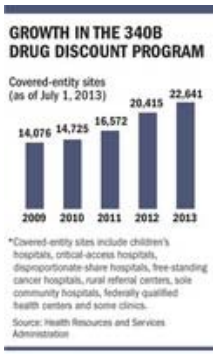
We'll be tackling both of these issues (amongst many others) at our 2011-2012 National Meeting series. The agenda and dates can be found here. Register now to save your seat!

Older Entries **Newer Entries**

Modern Healthcare

Article published July 13, 2013

Who benefits from drug discounts?



Drugmakers, hospitals battle over indigent-care program

By Jaimy Lee
Posted: July 13, 2013 - 12:01 am ET
Tags: Healthcare Reform, Hospitals, Medicare, Outpatient Care, Patient Care, Pharmaceuticals, Physicians, Purchasing, Suppliers, Supply Chain, The Week in Healthcare

Aspirus Ontonagon Hospital, a small not-for-profit hospital in Ontonagon, Mich., last year generated about $1 million in revenue from a federal program that allows safety-net providers to purchase deeply discounted drugs.

With improved margins due to savings from the 340B drug discount program since 2011, the 18-bed hospital prevented closures of its emergency department, family practice clinic and skilled-nursing facility. It also filled new positions and expanded services to offer oncology treatment for the first time.

“We would not have been able to start oncology without 340B,” said William Wood, a board trustee for Aspirus Ontonagon Hospital, who called 340B participation a “major contributing factor” in the broader turnaround.

The hospital's turnaround is the kind of success story that makes the case for the 340B program, which was established by Congress in the early 1990s to help clinics and hospitals serving the poor and uninsured by allowing them to purchase certain outpatient drugs at up to a 50% discount and has since been expanded several times.

However, the 340B program has become controversial because of alleged misuse by some hospitals.

Critics say some hospitals may not be using the 340B savings and revenue they generate to improve care for the uninsured and indigent patients for whom the program was designed. Other providers have raised questions about whether physicians will alter prescribing patterns toward more expensive drugs to boost profit margins.

Hospitals in the 340B program purchase discounted drugs for any patient receiving medical care, not only those who are poor or uninsured, although Medicaid beneficiaries are excluded. The providers can then use savings or revenue generated from purchasing the discounted medications to enhance patient

care and services for all eligible patients. It's up to the providers to decide how to use the savings.

The number of providers participating in the 340B program has significantly increased in recent years, and roughly one-third of the nation's hospitals now participate in the program.

There were 22,641 covered-entity sites participating in the 340B program as of July 1, nearly 37% more than the 16,572 covered-entity sites in 2011, according to the Health Resources and Services Administration, which oversees the program.

That growth has fueled questions among 340B critics, notably drugmakers, who have said they don't want to see the 340B program expanded to include inpatient drugs.

But groups representing 340B-eligible hospitals say the program is operating as lawmakers intended and that the growth is tied to an expanded eligibility provision included in the 2010 healthcare reform law. The provision expanded 340B eligibility to critical-access hospitals, free-standing cancer hospitals, rural referral centers and sole community hospitals.

“There are a lot more rural hospitals in the program,” said Ted Slafsky, president and CEO of Safety Net Hospitals for Pharmaceutical Access, a trade group that represents more than half of the participating 340B hospitals. “The evidence is that the hospitals are investing whatever savings they have from the program to help patients and to meet their indigent care needs.”

As eligibility has widened in recent years, both the pharmaceutical industry and hospitals have said that some changes may be needed to reform the decades-old program and prevent abuse by providers, drug manufacturers and contract pharmacies.

“There's obviously a lot of potential for abuse, and that's not what anyone wants,” said Lisa Swirsky, a senior policy analyst for Consumers Union.

The Government Accountability Office in 2011 recommended that HRSA tighten its oversight. That would allow the providers that need 340B savings to continue to operate, as well as prevent vulnerable patient populations from being negatively affected, she said.

But legislative changes such as requiring covered entities to use the drug savings directly on care for indigent patients “could hurt the folks they're trying to help,” Swirsky added.

The drug industry, however, believes that the 340B statute requires the discount to be passed on directly to uninsured, indigent patients. The program, they say, should provide these patients with access to prescription drugs.

“While there remains a need for this safety net program, there are rising concerns about the program in its current form,” said Matt Bennett, PhRMA's senior vice president of communications, in an e-mailed statement.

SNHPA and an alliance of trade groups representing drug manufacturers and others have recently published dueling websites addressing separate concerns about the 340B program.

The Alliance for Integrity and Reform—composed of drug companies and organizations, oncology groups and a pharmacy benefit manager—in May established

340Breform.org, which argues 340B savings should be used to directly boost access to medications for indigent and uninsured patients. SNHPA's Slafsky said the launch of that website contributed to SNHPA's decision to put together a report and publish its own website, 340Bfacts.com.

The organization issued its own recommendations for reforming the program. The recommendations included increased transparency of 340B prices and how hospitals use 340B savings, audits of drug

manufacturers and more scrutiny of contract pharmacies that participate in the program.

U.S. Sen. Charles Grassley (R-Iowa) has joined in the criticism of the 340B program. Over the past year, he has requested information from stakeholders ranging from pharmaceutical trade groups to hospitals that were reportedly charging a mark-up on drugs purchased through the 340B program.

“Even if the 340B program allows this kind of upselling, that doesn't make it right,” Grassley said in a July 9 statement. “It also isn't right that we don't know how hospitals are reinvesting 340B revenue … They could use the money for uninsured patients or they could use the money toward building a new wing.

Follow Jaimy Lee on Twitter: @MHjlee

(This article has been updated to correct that the 340B drug discount program excludes Medicaid beneficiaries, not Medicare beneficiaries.

Today's Headlines

Community Health Systems to pay $3.9 billion to buy HMA OIG wants skilled-nursing access for all Medicare beneficiaries Healthcare Reform Update: Public health organizations work to prepare providers for Medicaid expansion Northwestern to pay nearly $3 million to settle claims against cancer researcher
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Share your opinion. Send a letter to the Editor or Post a comment below.

Post a comment

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340B Covered Entities that have provided services to PAF patients

11th St Clinic Drexel University
Advocate Trinity Hospital
Albany Medical Center
All Children's Hospital
Arrowhead Regional Medical Facility
Asante Three Rivers Community Hospital
Athens Regional
Aurora Sinai Medical Center
Aurora St. Lukes, Milwaukee
Avera Medical
Azeala Health
Bakersfield Hospital
Ball Memorial Hospital
Banner Desert Medical Center
Banner Estrella Medical Center
Banner Gateway Medical Center
Banner Good Samaritan Medical Center
Banner Health
Banner MD Anderson Cancer Center
Banner Thunderbird
Baptist Bartlett Clinic
Baptist Health
Baptist Health Care West Florida Hospital
Baptist Health Medical Group
Baptist Hospital
Baptist Hospital Nashville
Baptist Hospital Nassau
Baptist Hospitals of Southeast Texas dba Memorial Hermann Baptist Beaumont Hospital
Baptist Medical Center
Baptist Memorial Hospital
Baptist South
Barnes-Jewish Hospital. St. Louis MO
Baton Rouge General Medical Center
Baxter Hospital
Bay Medical Hospital
Bayhealth Medical Center
Baylor Medical Center
Baylor Plano Hospital
Baylor University Medical Center
Baylor University Medical Center Dallas, TX
Baystate
Berlin Memorial
Beth Israel Deaconess Medical Center Boston, MA
Beth Israel Medical Center

Beth Isreal Hospital, NJ
Beverly Hospital
Binghamton General Hospital/UHS
Birhmingham Clinic
Bluestone Health Center
Bon Secours Hospitals - St. Francis Medical Center
Bon Secours Mary Immaculate
Bon Secours Maryview Medical Center
Bon Secours St Francis Health System
Brackenridge Hospital
Breast Cancer Specialist...as parnter of TX Oncology
Bridgeport Hospital
Brigham and Women's Hospital
Bringham Hospital in Boston
Bronx Lebanon
Brooklyn Hospital
Broward General Hospital
Brunswick Hospital Southeast Georgia Regional Medical Center
Bucyrus Community Hospital
California Hospital Medical Center
California Pacific Medical Center
Came Care
Cancer Center of Oxford
Cancer Therapy & Research Center at The University of Texas
Candler Hospital
Cape Cod Hospital TB02601
Cardinal Glennon Children's Medical Center
Carilion Roanoke Memorial Hospital
Carolina Coastal
Carolinas Medical Center
Cedar Sinai Hospital, Los Angeles, CA
Cedars-Sinai Medical Center
Central Baptist Hospital
Centura Health-Avista Adventist Hospital
Charleston Area Medical Center
Children's Hospital
Children's Hospital of King Daughter
Children's Hospital of Oakland
Children's Hospital of Pittsburgh
Children's Medical Center
Children's National Medical Center
Chippewa County War Memorial Hospital
CHOP
Christ Hospital
Christiana Care Health System
Christus Schumbert It is a 340B entity
Christus Spohn Hospital Corpus Christy South

Citizen's Baptist Medical Center
City of Hope Hospital
City of Hope National Medical Center
Claiborne County Hospital
Clara Maass Medical Center
Cleveland Clinic Florida
Cleveland Clinic Foundation
Cleveland Metro Health
CMC-Pineville
Community Care
Community Health Center of Greater Dayton
Community Health Center of Yavapai
Community Hospital
Community Hospital of San Bernadino
Community Regional Medical Center
Conemaugh Memorial Medical Center
Contra Costa Regional Medical Center
Conway Medical Center
Cook County Bureau of Health Services
Cookeville Regional Medical Center
Cooper Green Mercy Hospital
Cooper Hospital
Covenant Michigan Avenue Clinic
Cox Medical Center
Cox Medical Center (Branson)
Cox Monett Hospital, Inc.
Crossroads Infusion Center Spectrum Health Grand Rapids
Crouse Hospital Syracuse
Crozer Medical Center
Crozer-Chester Medical Center
CTCA
CTCA, WV
CTCA-MidWestern
Cullman Regional Medical Center
Dallas County Hospital District, Parkland Health and Hospital System
Dana Farber Cancer Center
Dartmouth-Hitchcock Hemophilia Center
Dartmouth-Hitchcock Medical Center
DCH Regional Medical Center
Dekalb Memorial
Dell Children Hospital-Cancer Center
Doctor's Community Hospital
Doctor's Renaissance Hospital
Dorminy Medical Center
Douglasville HealthCenter Hospital
Driscoll Children's Hospital
DSH Grady Memorial Hospital

DSH University Medical Center
Duke University
Duke University Hospital
Duke University Medical Center
E Alabama Cancer Center
E.A. Conway Medical Center
East Texas Medical Center
Edwards Cancer Center
Einstine Medical Center
El Rio Community Health Center
Ellis Fischel Cancer Center
Emory Clinic
Emory University Hospital Midtown
Erlanger Health System University of Tennessee College of Medicine
Erlanger Medical Center
Essentia Health
Family Cancer Center
Family Health Centers of Baltimore
Feather River Hospital Cancer Center
Florida Hospital Altamonte Springs
Florida Hospital South
Florida Medical Center
Forrest General Hospital
Forsyth Medical Center
Fort Sanders, TN
Fox Chase Temple Univ Hospital
Franklin Memorial Hospital
Fremont Rideout Hospital
Froedhert Hospital Milwaukee WI
GA Cancer Specialist
Gaston Memorial
Geisinger Medical Center
Genesis Good Samaritan Medical Center Zanesville
Georgetown Lombardi
Georgetown Memorial Hospital
Georgetown University Medical Center Lombardi Cancer Center
Glennwood Hospital
Good Samaritan Hospital
Good Shepherd Medical Center
Grady Hospital-Atlanta Georgia
Grant Medical Center
Greene Memorial Hospital Miami Valley South Sloan Kettering
Greenville Memorial Hospital
Guadalupe Regional Medical Center
Gwinnett Medical Center
Halifax Hospital
Harbor Hospital

Harbor UCLA
Harris County Hospital District
Hartford Hospital
Health Partnership Clinic
HealthPark Medical Center (Lee Memorial Hospital System)
Hennepin Medical Center
Henry Ford
Hermann Memorial
Hernando County Health Dept
Hershey Medical Center
Highland General Hospital
Highlands Medical Center
Hillcrest Baptist Medical Center
Hillman Cancer Center
Hillsbourough County Department
Hollings Cancer Center
Holy Cross Medical Center
Holy Redeemer Hospital
Homestead Hospital, Inc.
Hope Cancer Center
Huntsman Cancer Institute
Huntsville Hospital
Iberia Medical Center
Illini Hospital
Indiana health Center, South Bend
Indiana University
Inova Fairfax Hospital
Intermountain
Jackson General Hospital
Jackson Hospital
Jackson Memorial Hospital
Jackson Memorial, Miami
Jackson-Madison County Hospital
Jacobi Medical Center
James Care East Ohio East Hospital
James Factor Program of the Ohio State University
Jasper Memorial Hospital
Jefferson Hospital
Jefferson University
Jewish Hospital
John H. Stroger, Jr. Hospital of Cook County
John Muir Cancer Center
John Peter Smith Hospital
Johns Hopkins
Johns Hopkins Hospital
Johns Hopkins Hospital Mercy Hospital
Johnson City Medical Center

JPS Health Systems
Kaiser Permanente Hospital
Kaiser Permanente Medical Office
Kalispell Regional Medical Center
Karmanos Cancer Center
Kelsey-Seybold Clinic
Kern Medical Center
Kernersville Medical Center
Kevin Kellogg Mercy Health Partners-Hackley Campus
Kingman Cancer Center
Kings Brook Jewish Mediacl Center
Kings County Hospital
Kings Daughter and Univ of KY Lexington
L.A. Country Department of Health Services Antelope Valley Health Center
LA General
Lafayette General Medical Center
Lake Health
Lakeland Regional Med Center
Lancaster General Hospital
Lasalle County Health Department
Laughlin Memorial Hospital, Inc.
Leconte Medical Center
Lee Memorial Hospital
Lehigh Valley
Leo Jenkins Cancer Center (affiliated with Vidant Cancer Center)
Lexington Medical Center
Lincoln Medical Center
Loma Linda Cancer Center
Long Beach Medical Center
Long Beach Memorial
Long Island Jewish Hospital
Loyola University Medical Center
LSCC OB/GYN of Roundrock Texas
LSU Health Services Center, Shreveport
LSU Medical Center
Lynchburg General
Lyndon B Johnson Hospital
Magee Women's Hospital
Maimonides Medical Center
Maricopa Integrated Health Center Hospital
Maricopa Medical Center
Marivel Hospital-Maricopa Integrated Health Systems
Markey Cancer Center
Marshfield Clinic Medical Center
Martin Luther King Jr.
Mass General
Maury Regional Hospital

Mayo Clinic
Mayo Clinic Rochester, MN
McCleod Reginal Medical Center
McGee Women's Hospital. at UPMC
MCV Hospital
MD Anderson
MD Anderson, FL
MD Anderson, TX
Meadville Medical Center
Medical Center of Central GA
Medical Center of New Orleans
Medical College of Georgia
Medical University of SC
Memorial Cancer Institute
Memorial Health
Memorial Hermann Southeast Hospital
Memorial Hospital
Memorial Hospital at Gulfport
Memorial Hospital in Paolo Springs
Memorial Medical Center
Memorial Regional Hospital Cancer Instittute Hollywood, FL
Memorial Sloan Kettering
Mercer County Health Department
Mercy Cancer Center
Mercy Health Partners
Mercy Hospital
Mercy Hospital Breast Center
Mercy Hospital, Springfied
Mercy Medical Center
Mercy Medical Clinic
Mercy San Juan Hospital
Mercy Sleep Clinic (part of Mercy Medical Springfield)
Methodist Hospital
Methodist Hospital Brooklyn, NY
Methodist Hospital Indianapolis, IN
Methodist Methodist Center
Metrohealth Medical Center
Metropolitan Hospital
Miami Baptist
Miami Valley Hospital
Middleton Clinic/Meritor Hospital
Milton Hershey Medical Center
Mission Hospital - Saint Joseph's
Mission Memorial Hospital
Missouri Baptist Hospital
Moffitt
Montefiore Medical Center

Montefiore Wakefield Hem Onc Cancer Ctr.
Monter Cancer Center
Moses Taylor Scranton
Mother Frances Hospital
Mount Sinai Hospital
Mount Sinai Medical Center
Mount Vernon Hospital
Nash General Hospital
Nassau University Medical Center
Nebraska Medical Center
Neuroscience Institute of SHNDS
New Hanover Regional Medical Center
New River Health
New River Medical Center
New York Hospital
New York Presbytarian Hospital
New York Presbyterian
Newark Beth Israel Medical Center
North Broward Hospital
North Florida Regional Medical Center
North Mississippi Medical Center
Northside Hospital
Northwestern Memorial Hospital
Northwestern University
Northwestern University, Rehibilitation Institute of
Norton Cancer Institute
Novant Forsythe Medical Center
NYU
Oakwood Hospital
Ochsner Medical Center
Ohio County Hospital
Ohio State University
Okaloosa County Health Department
Oklahoma University
Olive View Medical Center
Onslow Memorial Hospital
Oregon Health and Science University
Oregon Health Science Center OHSU Center for Health and Healing
Orlando Health
Orlando Regional Medical Center
OSU James Cancer Center
Our Lady of the Lake Regional Medical Center
Ozarks Medical Center, West Plains, MO
Palmetto Baptist Health
Palo Pinto General Hospital
Palomar Hospital
Parkland Medical Center

Parkview
Peacehealth Southwest Medical Center
Peggy and Charles Stephenson Cancer Center
Pennsylvania Hospital
Phoebe Sumter Medical Center
Phoenix Children's Hospital
Piedmont West
Pinnacle Health
Planned Parenthood of Fairfield/Shasta
Presbyterian Hospital
Presbyterian Intercommunity Hospital
Provena United Samaritans Medical Center
Providence Alaska Medical Center

Providence Health System Southern California dba Providence Holy Cross Medical Center
Providence Holy Cross Medical Center, CA
Providence Hospital
Providence Regional Medical Center
Providence Sacred Heart
Queens Hospital
Rady Childrens Hospital
Rapid City Regional Hospital
Reading Hospital
Regional Cancer Center
Renown Regional Medical Center
Rhode Island Hospital
Rideout Memorial Hospital
Riley Hospital, Indiana University Health
Riverside County Medical Center
Riverside County Regional Hospital
Riverside Hospital
Riverside Shore Memorial
Rochester General, NY
Rocky Mountain CARES
Rogue Valley Medical Center
Ronald Reagan UCLA Medical Center
Roper St Francis Healthcare
Rush University
Sacred Heart Hospital & Lehigh Valley Hospital
Sacred Heart Hospital and Cancer Center
Sacred Heart Hospital of Pensacola
Sacred Heart Medical Center
Sacred Heart Riverbend Hospital
Saint Francis Hospital
Saint Helena Hospital
Saint Joseph Hospital, Orange
Salem Hospital

Salinas Valley Hospital
Samaritan Medical Center
Samaritin Pacific
San Francisco General Hospital
San Joaquin General Hospital
San Ysidro Health Center
Sanford Medical Center
Sanford USD Medical Center
Santa Clara Valley Medical Center
Scott and White Memorial Hospital
Scripps Memorial Hospital.
Scripps Mercy, CA
Seminole County Community Assistance
Sentara
Sentra Care Plex
Sequoia
Seton Medical
Shands Hospital, Gainesville, FL
Shands Hospital, Jacksonville
Shands Sleep Center
Shands Teaching Hopital and Clinics
Shands, University of Florida
Sharp Grossmont Cancer Center
Sharp Medical Center
Sharp Memorial Hospital
Shelby Baptist Memorial
Shivers/Brackenridge
Sinai Hospital
Singing River Hospital
Siteman CA Cente Barnes Jewish
Skagit Valley Hospital (Skagit Regional Clinic Mount Vernon)
Sleepy Hollow Open door
Smith Clinic
South Broward Hospital District dba Memorial Hospital
South Florida Baptist Hospital
South Georgia Regional Medical Center
South Jersey Hospital
South Seminole Hospital Orlando Health
Southeast Alabama Medical Center
Southern Regional Medical Center
Sparks Regional Medical Center
Sparrow Hospital
Spectrum Health/Butterworth Medical Center
spring hill regional
Springfield Regional Hospital
SSM DePaul
St. Anothony's Hospital

St. Anthony Hospital
St. Catherine Hospital
St. Christopher's Philadelphia
St. David's Medical Center
St. Dominic-Jackson Memorial Hospital
St. Elizabeth Hospital
St. Francis and University of St. Louis
St. Francis Hospital
St. Francis Medical Center
St. Francis Medical Center Peoria
St. John Hospital and Medical Center
St. John's Mercy Medical Center
St. John's Riverside
St. Joseph's Hospital
St. Jospeh Medical Center
St. Jude's Hospital
St. Louis University Hospital
St. Luke's Cedar Rapids, IA
St. Luke's Hospital
St. Luke's Hospital of Kansas City
St. Luke's Hospital, NY
St. Luke's Regional Medical Center Mountain State Tumor Institute
St. Mary´s Pulmonary Care/Sleep
St. Mary's Health Care System, Inc.
St. Mary's Hospital
St. Vincent Charity Medical Center
St. Vincent Healthcare
St. Vincent Indianapolis
Stansbury Health Center/University of Utah
Staten Island University
Steward Health Care System
Stony Brook Hospital
Stormont-Vail Cancer Center
Strong Memorial Hospital, University of Rochester
SUNY Downstate
SUNY Upstate
Susquehanna Health Hospital
Sutter Hospital
Sutter Medical Center
Swedish American Hospital
Swedish Covenant Hospital
Swedish Medical Center
Tallahassee Memorial Healthcare, Inc.
Tampa Bay General
Tanner Medical Hospital Carrollton
Temple University Hospital
Tennova Healthcare

Terry Reilly Health Center
Texas Harris Methodist Hospital
Texas Medical Center
The Children's Hospital Association
The Gebhart Cancer Center at Fort Hamilton Hospital
The Medical Center of Bowling Green
Thomas Jefferson University Hospital
Tift Regional Medical Center
Tracy FAmily Clinic
Tri-City Medical Center
Trinitas Regional Medical Center
Trinity Hospital
Trintas Comprehensive Cancer Center
Truman Medical Center
Tuomey Healthcare System
Tuscon Medical Center
UAMS University of Arkansas Hospital
UMC of El Paso
UMPC McKeesport
Uniontown Hospital
United Regional Health Care System
Univeristy of Texas Medical Branch
University Health Center
University Health System
University Hospital
University Hospital Cleveland
University Hospital of Newark
University Hospital/Health System, San Antonio, TX
University Hospitals and Clinics
University Hospitals Case Medical Center
University Medical Association - University of Virginia Health System
University Medical Center in El Paso
University Medical Center of Southern Nevada
University of Alabama
University of Alabama at Birmingham
University of Arizona Health System
University of Arkansas for Medical Sciences Medical Center
University of California Irvine Medical Center
University of California Los Angeles Ronald Regan Medical Center
University of California San Diego
University of California San Diego Medical Center
University of California San Diego, La Joya
University of California San Francisco Hospital in San Francisco
University of California, Davis Medical Center
University of Chicago Medical Center
University of Cincinatti
University of Cinncinatti Hospital

University of Colorado
University of Florida
University of Illinois Hospital
University of Indiana Hospital
University of Iowa Hospital
University of Kansas
University of Kansas Medical Center
University of Kentucky Lexington
University of Loiusville James Graham Brown Cancer Center
University of Louisville
University of Maryland
University of Maryland Medical Center
University of Massachusetts Memorial
University of Medicine and Dentitry Hospital of New Jersey.
University of Miami
University of Miami Sylvester Cancer Center
University of Michigan
University of Michigan Health Systems
University of Minnesota
University of Mississippi Medical Center
University of Missouri Health System
University of New Mexico Hospital
University of North Carolina Chapel Hill
University of Pennsylvannia
University of Pennsylvannia Medical Center
University of Pittsbugh Medical Center Shadyside Family Health Center

University of Rochester Medical Center Strong Memorial Hospital Willmont Cancer Center
University of South Alabama Medical Center
University of South Carolina
University of Southern California
University of Tennessee Medical Center
University of Texas El Paso
University of Texas Galveston
University of Texas Health Center at Tyler
University of Toledo Medical Center
University of Utah Huntsman Cancer Hospital
University of Utah Medical Center
University of Virginia
University of Washington
University of Wisconsin Hospitals
UPMC
UPMC - West
UPMC Cancer Center
UPMC Greenville
UPMC Mercy
UPMC Shadyside

UPMC St. Margaret
Upstate University Hospital
USA Mitchell Center (Part of USA Medical Center)
USC Medical Center
USC-Kek Cancer Center
UT HealthScience Center
UT Southwestern Medical Cancer
VA Brooklyn
VA Hospital
Valley Baptist Medical Center
Valley Medical Center
Vanderbilt University
Vanderbilt University Hospital
VCU Medical Center
Ventura County Medical Center
Ventura Memorial Hospital
Veterans Administration
Veterans Administration Hospital in West Haven, CT
Via Christi Hospital Pittsburg
Villa Ricker
Virginia Commonwealth University
Virginia Commonwealth University Hospital, VA
Wade Family Medical Center
Wake Forest University Baptist Medical Center
Wake Medical Center
Waldo County General Hospital
War Memorial Hospital
Warren Hospital
Wellmont Health Systems
Wellstar Cobb
Wellstar Cobb (Kennestone)
West Clinic, Knoxville, TN
West Georgia Medical Center
West Jefferson Medical Center
Westchester Medical Center, NY
Western Maryland Health System
Western Pennsylvania Hospital
White County Medical Center
White Memorial Medical Center
Willis Knighton CC
Wilson Medical Center
Winston Salem Health Care
Winter Haven Hospital
Woodland Memorial Hospital
Wyckoff Hospital Brooklyn
Yale Medical Center
Yale New Haven Hospital

York Hospital
Zufall Health Center