

The Impact of Growth in 340B Contract Pharmacy Arrangements

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EXECUTIVE SUMMARY

Congress established the 340B Drug Discount Program (340B) in 1992 to support access to prescription medicines for medically underserved populations. The program was designed to reduce outpatient drug costs for safety net providers and their patients by statutorily mandating deep discounts from drug manufacturers as a condition of Medicaid reimbursement.¹ For many years, the 340B program was relatively small and attracted little attention.

However, starting about a decade ago, the program changed dramatically and today bears little resemblance to the program established in 1992. Two trends at the heart of the 340B program's transformation are: (1) the surging numbers of participating health care facilities eligible for the program under the disproportionate share hospital (DSH) criteria and their satellite clinics; and (2) the contractual extension of 340B discounts to retail pharmacies.

This paper examines the rapid growth of so-called “contract pharmacies” in the 340B program. Such pharmacies are not owned by a 340B-participating health care facility, also known as a “covered entity.” Rather, covered entities contract with retail pharmacies—typically off-site, for-profit entities—to dispense drugs acquired at a discount through the 340B program. Entities gain revenue from these arrangements because it increases the number of prescriptions filled through the 340B program. The vast majority of contract pharmacies—and not coincidentally, 75 percent of 340B drug purchases²—are tied to DSH hospitals. In general, federal “grantees” that participate in the 340B program raise far fewer concerns and are therefore not the focus of this paper.

The 1992 law that created the 340B program does not give the government the authority to permit contract pharmacies.

Nonetheless, in 1996, the Health Resources and Services Administration (HRSA)—the federal agency charged with administering the 340B program—issued guidance allowing covered entities *without an on-site pharmacy* to contract with *one* off-site pharmacy. Subsequent guidance (2010) eliminated the limitation of one contract pharmacy and the limitation to 340B entities lacking an on-site pharmacy. As a result, the contract pharmacy program grew by over 1,200 percent in just three years.³ By 2014, there were almost 30,000 contract pharmacy arrangements.⁴

HRSA's 2007 proposed guidance⁵ indicates that the contract pharmacy program was intended to benefit vulnerable patients by helping them overcome barriers to obtaining prescriptions. Yet there is no assessment of whether vulnerable patients *actually* benefit from the addition to the 340B program of these tens of thousands of for-profit entities (many of which are no more accessible to vulnerable populations than the DSH hospitals themselves).⁶ Indeed, there is little evidence to suggest that many vulnerable patients see any direct benefit from the expanding 340B contract pharmacy program, particularly because data indicates that neither the pharmacy nor the patient know that the transaction is “340B” at the point of sale. As a result, the patient often does not benefit from the covered entity receiving the 340B discounts. A lack of adequate program integrity standards and resources, coupled with seemingly unchecked growth in the number of contract pharmacy arrangements, has yielded a high-risk program with low rewards for patients that is ripe for reform. Additionally, the 340B contract pharmacy program may create disproportionate benefits and incentives for the largest retail pharmacies—often in wealthier areas—without demonstrating any tangible improvement in access to prescriptions for medically underserved Americans who should benefit from the program.

EXECUTIVE SUMMARY (CONTINUED)

Needed improvements, including those summarized below, could help reduce many vulnerabilities in the 340B program resulting from the current contract pharmacy program, while helping to ensure that 340B as a whole remains true to its original objective. To do this, there must be:

- Requirements that 340B discounts reach clearly defined vulnerable patients of eligible entities;

- New standards regarding the locations of contract pharmacies to ensure they truly assist vulnerable patients in filling prescriptions;
- Restructured contract pharmacy program standards to require that these pharmacies operate as they did prior to the 2010 HRSA guidance; and
- Bolstered program integrity standards and enforcement.

BACKGROUND

Congress created the 340B program in 1992 to reinstate the deep discounts that manufacturers had voluntarily provided to many safety net facilities before the enactment of the Medicaid drug rebate statute in 1990. The Medicaid drug rebate statute established government price controls for drugs, requiring a nationwide drug rebate for Medicaid that took into account both the average manufacturer price and the “best price” a manufacturer gave to any customer. In crafting the rebate formula, Congress failed to exempt voluntary discounts to safety net providers from the Medicaid best price, which inadvertently penalized manufacturers that provided such discounts. Two years later, Congress responded by amending the Medicaid drug rebate statute to exempt these discounts from best price⁷ and created the 340B program to establish discounted prices for eligible safety net providers.⁸

Eligibility for the 340B program is defined in statute and extends to certain hospitals and non-hospital entities. Many hospitals qualify for 340B based in part on their DSH percentage, which was intended to be a proxy for identifying hospitals that serve a significant volume of needy patients.⁹ Non-hospitals may be eligible for 340B if they receive one

of 10 types of federal grants that typically offer resources for serving vulnerable, low-income, uninsured individuals – examples include Federally-Qualified Health Centers and Ryan White facilities.¹⁰ These entities are commonly referred to as “grantees,” and hospitals and other facilities eligible for 340B are collectively referred to as “covered entities.”

For much of its early history, the 340B program was relatively small and attracted little attention. However, over the past decade, the program has changed dramatically and today bears little resemblance to the program established in 1992.¹¹ Growth has been driven in part by the program’s DSH hospital eligibility criteria. Concerns with those criteria are explored in depth in the Alliance for Integrity and Reform of 340B’s (AIR 340B) paper from March 2014, *Unfulfilled Expectations: An analysis of charity care provided by 340B hospitals*.¹² In short, the DSH criteria have allowed many hospitals to qualify for 340B even though they may not serve significant numbers of vulnerable and uninsured patients, or provide significant amounts of charity care.¹³ This concern generally does not apply to non-hospital entities (grantees) that participate in the 340B program.

BACKGROUND (CONTINUED)

Compounding the surge in DSH hospitals participating in 340B, such hospitals also have relied on program guidance and entered into contract pharmacy arrangements to dispense 340B prescriptions on their behalf. Hospitals can gain revenue from these arrangements because it can increase the number of prescriptions filled through the 340B program. For example, when more privately insured patients fill prescriptions eligible for 340B at contract pharmacies, the hospital and the pharmacy can split the difference between the lower 340B price and the higher price that the insurance company pays. Although the 1992 law creating the 340B program did not authorize contract pharmacies, two subsequent guidance documents issued by HRSA have yielded almost 30,000 unique contract pharmacy arrangements as of this writing.¹⁴ These arrangements lead to a range of program integrity concerns, including diversion, which takes place when covered entities resell or transfer discounted drugs to individuals or entities who are not their patients, and duplicate discounts, which occur when manufacturers provide a Medicaid rebate for drugs purchased through the 340B program. Both activities are prohibited under the 340B statute.

A. HRSA's 1996 Guidance Created Contract Pharmacies

HRSA first issued final guidelines authorizing 340B contract pharmacies in 1996, four years after the original 340B law was passed.¹⁵ This guidance “permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an individual contract pharmacy.”¹⁶ Three aspects of the 1996 guidance are particularly noteworthy:

1. The guidance *explicitly* rejected a proposal that 340B covered entities be permitted to contract with more than

one pharmacy site and contractor, noting that, “Covered entities are unlikely to select a contract pharmacy that is not convenient for their patients.”¹⁷

2. HRSA emphasized that covered entities that will use contract pharmacies “provide medical care for many individuals and families with incomes well below 200 percent of the federal poverty level and subsidize prescription drugs for many of their patients...”¹⁸

3. HRSA stated an understanding that:

While some [340B covered entities] may pass all or a significant part of the discount to their patients, others may set the price *slightly higher* than the actual acquisition cost plus a reasonable dispensing fee, using the savings to reach more eligible patients and provide more comprehensive services. The Department intends to examine the section 340B drug pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of the issue, the Department notes that a *modest* section 340B price markup, with savings realized from the discounts used by covered entities only for purposes of the federal program (including certain disproportionate share hospitals) which provides its section 340B eligibility does not appear inconsistent with the drug pricing program [emphasis added].¹⁹

In the 1996 guidance, HRSA committed to examining the 340B drug pricing practices of covered entities, but 18 years later, no study “to determine the various approaches” covered entities use in their 340B pricing activities or the “rationale for these approaches” has been issued.

BACKGROUND (CONTINUED)

B. HRSA's 2010 Guidance Expanded the Contract Pharmacy Program

By 2010, there were 2,362 unique contractual relationships between a pharmacy and a 340B covered entity.²⁰ That changed when, that same year, HRSA issued new guidance allowing covered entities to contract with an *unlimited number* of 340B contract pharmacies.²¹ The central justification for the change was a reference to comments (many of which were identified as being submitted by 340B entities) indicating that “some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements....”²²

HRSA offered no further information or data to define patient/pharmacy access problems in the 340B context, or what an effective, well-tailored solution to such problems might look like. Instead, the guidance provided an overly broad response—allowing for an unlimited number of contract pharmacies—without a single standard to assure that contract pharmacies alleviate obstacles that 340B patients face when filling prescriptions. Indeed, as the Government Accountability Office (GAO) has indicated, there are no 340B program policies on using revenues from 340B drugs to eliminate obstacles for vulnerable patients in need of prescriptions.²³ As the American Society of Clinical Oncology (ASCO) stated in its April 2014 *Policy Statement on the 340B Drug Pricing Program*, “concerns regarding whether and how the 340B program is achieving its goals are accentuated by the rapid growth of the program” and other factors.²⁴

HRSA's 2010 guidance was premised on the expectation that entities contracting with multiple pharmacies would not increase the risk of two illegal activities – diversion of 340B medicines to persons who are not eligible to receive them and permitting manufacturers to be charged duplicate Medicaid and 340B discounts for the same drug.²⁵ HRSA further assumed that entities contracting with multiple pharmacies would adhere to certain program integrity standards.²⁶ Independent reports by the GAO and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) call into question whether these expectations are being met.²⁷

PROGRAM INTEGRITY CONCERNS RISE WITH INCREASE IN CONTRACT PHARMACIES

As the 340B program has grown, so too have its program integrity risks, which have been recognized in recent years by increased congressional and press scrutiny.²⁸ The almost 30,000 contract pharmacy arrangements that existed in 2013 were nearly three times the number HRSA had projected just two years earlier.²⁹ The program's extraordinary growth is self-evident, if unexpected, but what has been accomplished by this growth from the perspective of patients may not be as obvious. There is no systematic evidence demonstrating that the three-year, 1,245 percent increase in contract pharmacy arrangements³⁰ improved vulnerable patients' access to medicines relative to the pre-2010 contract pharmacy program. Additionally, as GAO has recognized, the larger number of contract pharmacies increases program integrity risks and may distort pharmacy markets.³¹

A. Faulty Assumptions Underlie HRSA's 2010 Change in Guidance Permitting Unlimited Contract Pharmacies

The 340B program currently has limited guidance related to key program integrity issues. While the statute prohibits diversion of 340B drugs to individuals not eligible to receive them³² and prohibits duplicate 340B and Medicaid discounts on the same drug,³³ evidence suggests a significant lack of compliance with these requirements in the contract pharmacy context.³⁴ Currently, hospital covered entities are not subject to transparency or accountability procedures on how they spend the billions of dollars in revenue they generate by reselling the discounted drugs at marked-up prices.³⁵ These

oversight shortcomings are traceable to faulty assumptions that may stem from the 2010 contract pharmacy guidance.

It is clear that HRSA did not fully recognize the heightened program integrity risks of contract pharmacy arrangements

when developing the 2010 guidance. HRSA's view was that experience with multiple contract pharmacies in the Alternative Methods Demonstration Program (AMDP), which, prior to 2010, had allowed covered entities to apply to HRSA for permission to have multiple contract pharmacies, "provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity."³⁶ HRSA also stated a belief that "there are appropriate safeguards in place, based on the parameters of the program."³⁷

The AMDP experience relied on in HRSA's 2010 guidance was very limited. According to HRSA, "sites exceeded 50 and the number of contract pharmacies was over 170."³⁸ While HRSA identified some of the AMDP projects as including "a large number of health care sites and contract pharmacies,"³⁹ today there are individual covered entities that have contract pharmacy networks exceeding the number of all the contract pharmacies in the entire AMDP demonstration. For instance, at least three hospitals have contract pharmacy

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PROGRAM INTEGRITY CONCERNS (CONTINUED)

networks involving more than 200 pharmacies.⁴⁰ Given the small scale of the AMDP, it seems unlikely that it provided sufficient insight regarding the conditions present in today's contract pharmacy program that make it difficult to detect diversion, such as pharmacies contracting with multiple covered entities and sub-entities, which limits any ability to associate utilization with a specific covered entity.⁴¹ Additionally, the AMDP required annual audits, thereby increasing incentives for entities to comply with the requirements of the program. While those audits were not required under the 2010 guidance currently administered, it was HRSA's expectation that such audits would occur.⁴²

[T]oday's contract pharmacy program falls short of meeting critical assumptions at the heart of ensuring program integrity.

In 2010, HRSA also expected that covered entities would adhere to certain program integrity practices that had been developed to mitigate risks, stating that, "Covered entities will be permitted to use multiple pharmacy arrangements

as long as they comply with guidance developed to help ensure against diversion and duplicate discounts...."⁴³ A series of audits and reports detailed below make clear that today's contract pharmacy program falls short of meeting critical assumptions at the heart of ensuring program integrity. The contract pharmacy program's wildly unanticipated scale—with almost 30,000 unique contractual relationships⁴⁴—far exceeds the oversight resources and program integrity requirements HRSA has put in place to date. A mounting body of evidence highlights multiple causes for concern.

1. In 2011, a GAO report found that "increased use of the 340B program by contract pharmacies and hospitals may result in greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants self-policing to oversee the program. Operating the 340B program through contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."⁴⁵
2. The 2014 OIG report found that contract pharmacies create "complications" in preventing diversion and duplicate discounts.⁴⁶ The report provides strong indications that 340B covered entities often fail to adhere to the types of practices intended to assure that program integrity requirements are met in the contract pharmacy program. Furthermore, OIG notes that noncompliance does not seem to have resulted in termination of covered entities' permission to use multiple pharmacy arrangements.⁴⁷
3. Over the last few years, HRSA has begun auditing covered entities and has revealed frequent program integrity problems. HRSA's website provides summary information on audit results and the 2014 OIG report provides further detail. According to OIG, "[R]ecent HRSA audits of covered entities have found instances of diversion and duplicate discounts related to contract pharmacies. Of the 32 covered entities for which finalized HRSA audits resulted in adverse findings, 10 were cited for diversion and/or duplicate discounts through contract pharmacies."⁴⁸ Further inspection of the data reveals that 7 of the 10 facilities cited in the OIG report for diversion and/or duplicate discounts through contract pharmacies were DSH hospitals.

PROGRAM INTEGRITY CONCERNS (CONTINUED)

B. OIG Exposed Large Compliance Gaps with Contract Pharmacies

The OIG’s report provides the best available information about 340B covered entities’ program integrity practices in relation to HRSA’s 2010 expectations. When facilities’ self-reported practices are compared to the 2010 guidance, it becomes evident that there are large gaps in compliance, including limited monitoring of contract pharmacies by HRSA; a failure to enforce the statutory prohibition on duplicate discounts and diversion; and, ongoing health system changes that may further increase program integrity risks.

The recent OIG report notes limited monitoring of contract pharmacies by HRSA. The OIG report also notes that, “HRSA guidance states that while specific compliance methods are left up to the covered entity, annual independent audits are expected.” In particular, the 2010 HRSA guidance emphasized that, “Independent audits are particularly valuable where the covered entity utilizes multiple pharmacy options.”⁴⁹ However, 23 of 30 (77 percent) covered entities interviewed by OIG reported that they had not retained independent auditors for their contract pharmacy arrangements.⁵⁰

HRSA’s 2010 guidance also stated that if any internal compliance activity or audit performed by a covered entity indicates a violation of 340B program requirements, “it is HRSA’s expectation that such finding be disclosed to HRSA along with the covered entity’s plan to address the violation.”⁵¹ The OIG report states that 10—or one-third—of the covered entities interviewed reported discovering “instances that could be considered diversion or that could have resulted in duplicate discounts in their

contract pharmacy arrangements.” Of these 10 entities, none reported notifying HRSA.⁵²

Further, the OIG report found pervasive failure to conduct any monitoring of contract pharmacy arrangements.⁵³ In addition to the finding that 77 percent of entities interviewed had not retained independent auditors, the OIG report states that 4 of the 30 (13 percent) covered entities it interviewed “reported that they neither monitor their contract pharmacy arrangements nor retain independent auditors.”⁵⁴

The OIG also found a failure among covered entities to follow HRSA guidance to prevent duplicate discounts.

The law expressly prohibits duplicate Medicaid and 340B discounts on drugs dispensed to Medicaid beneficiaries.⁵⁵ In applying this requirement to the contract pharmacy program, HRSA’s 2010 guidance states:

Neither [the covered entity nor the contract pharmacy] will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA [Office of Pharmacy Affairs], HRSA, by the covered entity.⁵⁶

Covered entities are responsible for ensuring that the system of distribution chosen fully meets statutory obligations of ensuring against diversion or creating a situation that results in a State Medicaid Program seeking a rebate on a discounted drug.⁵⁷

However, a lack of enforcement of specific safeguards to ensure compliance by covered entities yields questions

PROGRAM INTEGRITY CONCERNS (CONTINUED)

about the extent of HRSA’s knowledge of and ability to detect diversion and duplicate discounts. A key provision of HRSA’s 2010 guidance allowing an unlimited number of contract pharmacies states that, “Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts...”⁵⁸

The OIG report suggests that this condition often has not been enforced.

The OIG report also raises the question of whether the gap between HRSA’s conditions for participation in the contract pharmacy program and covered entities’ practices is even larger than indicated. The central program integrity mechanism HRSA relied on in its 2010 guidance was voluntary, professionally conducted independent audits by auditors with expertise auditing pharmacies for diversion and duplicate discounts. With 77 percent of covered entities interviewed by OIG not having retained independent auditors, it is reasonable to ask whether the disclosures made by covered entities in interviews with OIG capture the full scope of contract pharmacy program integrity problems.

For instance, covered entities reported to OIG that administrators’ identification of 340B-eligible prescriptions after they are written “prevents diversion.”⁵⁹ But how can entities that have not conducted the expected independent audits know whether or not they are preventing diversion? By not conducting the independent audits expected by HRSA, covered entities may have made it impossible to determine the full extent of program integrity problems.

Further, 25 of the 30 covered entities reported to OIG that “they monitor their contract pharmacy arrangements internally to detect potential diversion of duplicate discounts.”⁶⁰ HRSA’s guidance recommends annual audits “performed by an independent outside auditor *with experience auditing pharmacies*” that “follow standard business practices for audits” [emphasis added].⁶¹ While the 340B contract pharmacy program is structured such that internal programs cannot be a substitute for independent audits, it is nonetheless important to assess the following in regards to these internal programs:

- What are the qualifications and capabilities of these internal programs’ personnel? Are covered entities’ monitoring programs staffed by personnel with expertise and experience in auditing pharmacies, which likely would be essential to detect duplicate discounts and diversion?
- Do these internal programs have the resources needed to monitor covered entities’ contract pharmacy networks, which may include over a hundred contract pharmacies across a large geographic region?
- How independent, accurate and effective are these internal programs?
- What is the frequency of in-depth assessments of diversion and duplicate discounts? Eight of the 25 covered entities informing HRSA that they monitor contract pharmacies through internal programs indicated they do so on an “ad hoc basis,” which was not further detailed in the report. HRSA’s expectation of independent audits–

PROGRAM INTEGRITY CONCERNS (CONTINUED)

which most of the covered entities interviewed for the OIG study do not conduct at all—is that they will be conducted.⁶²

- Do the covered entities follow standard business practices for audits?
- What incentives do these internal monitoring programs face, and what is their reporting structure within the covered entity?

Answers to these questions are needed to assess whether covered entities even had the information needed to accurately respond to OIG’s questions about diversion and duplicate discounts.

Finally, the OIG report underscores that increases in the use of Medicaid Managed Care may further increase program integrity risks. Failures described above to comply with requirements intended to prevent duplicate discounts take on added significance in light of OIG’s finding that, “Contract pharmacy arrangements also create complications in preventing duplicate discounts,”⁶³ and 340B administrators’ reporting that “it can be difficult to identify prescriptions for MCO [managed care organization] Medicaid beneficiaries in contract pharmacy arrangements.”⁶⁴

This difficulty applies on a vast scale – according to the Centers for Medicare and Medicaid Services (CMS), 42 million Medicaid beneficiaries were enrolled in Medicaid managed care plans on July 1, 2011.⁶⁵ Over this year and the next, Medicaid enrollment is projected to grow sharply, with nearly all new enrollments in Medicaid managed care plans.⁶⁶

HRSA’s 2010 contract pharmacy guidance was issued before the Medicaid rebate statute was extended to Medicaid managed care, and neither HRSA nor CMS has yet issued any further guidance to ensure that there is no duplicate discounting of Medicaid managed care claims. Drugs dispensed to Medicaid managed care enrollees were not subject to the Medicaid rebate until March 2010. Thus, the contract pharmacy program expanded dramatically at the same time that drugs sold to over 40 million additional people became, for the first time, capable of generating prohibited duplicate discounts, which are difficult to identify.

The expert services and consulting firm Berkeley Research Group (BRG) has estimated the volume of prescriptions for managed Medicaid beneficiaries that originate from 340B covered entities and are filled at a 340B contract pharmacy.⁶⁷ If not properly excluded from the 340B program, these prescriptions would likely result in duplicate discounts being paid by pharmaceutical manufacturers. The estimate uses conservative assumptions to project that up to 3.4 million prescriptions could be filled as 340B prescriptions at contract pharmacies by Medicaid managed care enrollees in 2014, increasing to over 3.8 million in 2016.⁶⁸ Under the 340B statute, no prescriptions from Medicaid managed care enrollees should be filled as 340B prescriptions.⁶⁹ BRG estimates that hospitals will generate about three-fourths of the prescriptions potentially subject to duplicate discounting.

Safety Net Hospitals for Pharmaceutical Access (SNHPA), the membership association for many 340B hospitals, has previously stated that the overwhelming majority of contract pharmacies “do not know at the time a claim is processed

PROGRAM INTEGRITY CONCERNS (CONTINUED)

Underlying all of these program integrity risks, moreover, is the concern that contract pharmacies have substantially altered the character of the 340B program.

whether or not it relates to a 340B drug.”⁷⁰ As a result, claims filed by a contract pharmacy for Medicaid beneficiaries may be included in the state Medicaid program’s rebate request.

If these claims are

later identified as 340B claims, then manufacturers could be billed for duplicate discounts. BRG estimates that if all 3.4-3.8 million Medicaid claims filled at contract pharmacies

were handled in this way, duplicate discounts could amount to \$424 million in 2014, and \$477 million in 2016.⁷¹

Underlying all of these program integrity risks, moreover, is the concern that contract pharmacies have substantially altered the character of the 340B program. Only not-for-profit hospitals may participate in the 340B program. Yet with the 2010 contract pharmacy changes, new business models were created to transfer 340B revenue to for-profit entities on a large scale. This appears to benefit the for-profit entities and is problematic in connection with DSH hospitals which, unlike grantees, do not necessarily have a charter that requires them to reinvest proceeds to advance grant purposes.⁷²

EXPLOSIVE GROWTH IN CONTRACT PHARMACIES HAS YIELDED QUESTIONABLE PATIENT BENEFITS

Between 2010 and 2013, the number of contract pharmacy arrangements exceeded HRSA’s projection by almost 20,000.⁷³ Hospitals eligible for 340B based on their DSH percentage account for most large contract pharmacy networks.⁷⁴ As of May 2014, of 114 facilities with contract pharmacy networks including 50 or more pharmacies, 64 percent were DSH hospitals.⁷⁵ And while entities that qualify for the 340B program as grantees often have missions that focus directly on needy or vulnerable populations, and are typically required to reinvest additional resources into serving those populations, this is generally not the case with DSH hospitals.

BRG analyzed the 2014 contract pharmacy networks of 10 hospitals in 10 different cities that participate in 340B, based on their DSH percentage and their having 50 or more contract pharmacies.⁷⁶ BRG classified the location of each contract pharmacy by the median income of the zip code tabulation area in which the pharmacy was located,⁷⁷ and the analysis was conducted based on contract pharmacy networks as reported to HRSA in May of 2014.

The analysis identified 1,050 pharmacies in these 10 hospitals’ contract pharmacy networks, and found that

EXPLOSIVE GROWTH (CONTINUED)

there are many more contract pharmacies in areas with median incomes above 400 percent of the poverty level than at or below 200 percent of the poverty level. Of the 1,050 contract pharmacies, 16 percent were located in areas with a median income at or below 200 percent of the poverty level for a family of three. In contrast, 25 percent of contract pharmacies were located in areas with median incomes above 400 percent of the poverty level. The remaining 60 percent were in areas with median incomes between 200 percent and 400 percent of the poverty level. Thus, this analysis calls into question whether contract pharmacies are located in areas with high levels of unmet medical need.

The BRG analysis also found that the highest income areas that were 10 or more miles from the hospital had more than twice as many contract pharmacies (164) as the lowest income areas within five miles of the hospital (77). This is not due to a lack of available pharmacies in lower income areas – the 10 contract pharmacy networks examined contracted with about eight percent of all pharmacies in the low-income areas (and 11 percent in low-income areas

within five miles of the hospital).⁷⁸ These findings echo an observation about the 340B hospital outpatient setting made in ASCO’s 2014 policy statement: “Hospitals may expand their funding under the 340B Drug Pricing Program by expanding outpatient services in high-income areas rather than pursuing underserved markets.”⁷⁹

The information about where contract pharmacies are located, combined with indications from the OIG report that many 340B entities are not providing discounts to uninsured patients, adds to the evidence that the contract pharmacy program has, in practice, been structured by many covered entities to emphasize the generation of profits by buying drugs at a government-controlled price, and reselling them at a higher price rather than improving access for vulnerable patients facing barriers to obtaining medicines.

LOOKING AHEAD: RECOMMENDATIONS FOR “RIGHT-SIZING” THE CONTRACT PHARMACY PROGRAM

The unexpectedly and disproportionately large size of the contract pharmacy program is itself a reason to reconsider HRSA’s 2010 guidance. Certainly, HRSA’s predictions did not appear to account for the economic motivations that have pro-

pelled the explosive growth of contract pharmacies. As previously mentioned, in April 2011, HRSA projected there would be approximately 11,600 contract pharmacy relationships in 2013 (the actual number in 2013 was almost 30,000).⁸⁰

LOOKING AHEAD (CONTINUED)

This suggests that the program's incentives and how it would operate were not fully understood when the guidance was issued authorizing a change from one to unlimited contract pharmacies per covered entity.

Clearly, the contract pharmacy program must now be reconsidered, given its unanticipated growth and the program's lack of standards, accountability and transparency, coupled with evidence demonstrating the shortfall between the contract pharmacy program's goals and performance. There are no program data demonstrating that the 1,245 percent expansion in the number of contract pharmacy arrangements has improved access to medicines for vulnerable patients, as compared to the contract pharmacy program as it operated prior to the 2010 guidance. The ability to assure program integrity standards are met may also be affected by the program's size.

The large contract pharmacy program also holds the potential to distort the pharmacy market.⁸¹ Contract pharmacy guidelines require 340B entities to inform patients of their freedom to fill their prescriptions at any pharmacy.⁸² However, because covered entities benefit financially only when patients use that entity's contract pharmacies, there is at least an incentive to encourage use of contract pharmacies over other pharmacies.

The growth of 340B and the contract pharmacy program can have a significant impact on community pharmacies by reducing their patient base. Most 340B contract pharmacies are large, for-profit retail outlets and supermarket chains⁸³ with one chain dominating the contract pharmacy market,⁸⁴ which potentially harms community pharmacies, creating rather than resolving pharmacy access issues for many

patients. As of October 2011, 21 percent of 340B contract pharmacies were located in rural zip codes,⁸⁵ potentially putting rural community pharmacies at a disadvantage as they struggle to remain in business.

The effects of 340B on community pharmacies can also include the loss of business from covered entities' employees, who may be encouraged to seek care at the facility and use its on-site or contract pharmacy.

Some of the changes to 340B's character can be illustrated by the role in the program of the large, for-profit pharmacy chain, Walgreens. As of mid-2014, the chain accounted for 38 percent of all contract pharmacy arrangements in the 340B program.⁸⁶ Almost three-quarters (72.4 percent) of the chain's pharmacies participate in at least one contract pharmacy network, though less than 15 percent of the chain's pharmacies are in zip codes with an average income below 200 percent of the poverty level.⁸⁷

The chain has publicly discussed ways to "generate revenue from [its] 340B patients."⁸⁸ A chain employee with the title of Senior 340B Inventory and Reconciliation Analyst stated on his LinkedIn webpage that 340B "is projected to add a minimum of \$250 million in incremental revenue over the next five years" to the chain's revenue, and the program is described as helping make 340B clients "more profitable"⁸⁹ to Walgreens. In conducting oversight of Walgreens' role in 340B, one United States Senator has noted, "The intent and design of the program is to help lower outpatient drug prices for the uninsured. It is not intended to subsidize pharmacies that teamed up with covered entities to turn a profit."⁹⁰

LOOKING AHEAD (CONTINUED)

One pharmaceutical supply chain expert suggests that 340B may be an especially good business for contract pharmacies: “Rather than earning traditional dispensing spreads, participating pharmacies earn per-prescription fees paid by the 340B entity. Given the spreads, hospitals can pay pharmacies fees that exceed traditional third-party prescription profits.”⁹¹

The OIG report provides evidence that the contract pharmacy program may often fail to provide assistance to vulnerable patients facing barriers in filling their

prescriptions. As noted, hospitals eligible for 340B based on their DSH percentage account for about 75 percent of all 340B drug purchases.⁹² Of the 15 DSH hospitals interviewed for its 2014 report, only one-third reported to OIG that they offer the 340B-discounted price to uninsured patients in at least one of their contract pharmacy arrangements.⁹³ As OIG states in their report, if covered entities do not offer the 340B price to uninsured patients, “their uninsured patients pay the full non-340B price for prescriptions filled at contract pharmacies.”⁹⁴

REFORMS TO 340B CONTRACT PHARMACY PROGRAM ARE NEEDED

Improvements in access to medicines outside of the 340B program raise questions about the contract pharmacy program’s blunt design for achieving its stated goal, which is to help vulnerable patients overcome obstacles limiting their ability to fill prescriptions (as noted, there are no standards requiring that contract pharmacies be targeted to or provide assistance to vulnerable patients). The 1,245 percent growth in the number of contract pharmacy arrangements came after access to medicines had improved for many Americans and as many more were about to gain coverage through the Affordable Care Act, thereby reducing obstacles to filling prescriptions. For instance:

- Between 1996, when one contract pharmacy per 340B provider was first permitted, and 2010, when an

unlimited number of contract pharmacies was permitted, the share of elderly persons without prescription drug coverage dropped by more than half.⁹⁵

- The overall share of the cost of medicines paid for out-of-pocket by consumers dropped by about a third between 1998 (31 percent) and 2010 (18 percent).⁹⁶
- Between 2010 and 2016, the share of the non-elderly population without prescription drug coverage is projected to drop by almost half, but purchases through 340B are projected to nearly double.⁹⁷

Vulnerable patients facing barriers to obtaining prescriptions need help, however the contract pharmacy program is poorly designed to provide it. The program

REFORMS TO 340B (CONTINUED)

should be reformed to do a better job of providing assistance, and reforms should center on a return to the pre-2010 guidance and include:

- *Require that assistance reach clearly defined vulnerable patients.* Requiring the provision of deep discounts to facilities that do not pass on the discount to vulnerable patients makes no sense. HRSA's 1996 guidance creating the contract pharmacy program suggests this was not HRSA's expectation about how the program would operate.
- *Set standards to assure that contract pharmacies are situated to truly assist vulnerable patients in filling prescriptions.* Contract pharmacies should be located where vulnerable patients qualifying for assistance live, rather than in distant communities selected on the basis of how many people have insurance that can be billed at the largest margin above 340B-acquisition cost.
- *Restructure the contract pharmacy program to operate as it did prior to the 2010 guidance.* The lack of a clear basis for the 2010 guidance authorizing a shift to an

unlimited number of contract pharmacies, the large gaps between HRSA's expectations about how the contract pharmacy program would operate and how it operates today, and the fact that the program rapidly mushroomed to a size nearly three times what HRSA predicted, all support returning to the pre-2010 parameters.

- *Improve program integrity standards and enforcement.* Program integrity standards should be comprehensively reviewed and updated based on what is now known about covered entities' practices and risks in the contract pharmacy setting. Compliance with program integrity standards must be the rule, not discretionary. Independent verification of compliance with meaningful standards should be required and submitted to HRSA annually. HRSA has been working hard to improve enforcement, and it is important that these initial steps continue and expand.

These reforms would help turn today's 340B program into an endeavor providing real assistance to the people who need its help.

¹Such discounts previously had been provided voluntarily by manufacturers, but federal legislation to control pricing of prescription drugs in Medicaid inadvertently discouraged" these voluntary discounts.

²Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011), 29.

³Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, Feb. 4, 2014, 1, 2 (hereafter referred to as OIG Report).

⁴Berkeley Research Group analysis for the Alliance for Integrity and Reform of 340B. Analysis excludes contract pharmacy arrangements between a child site and a contract pharmacy if the parent site also has an arrangement with that same pharmacy.

⁵72 Fed. Reg. 1540 (Jan. 12, 2007).

⁶A. Vandervelde, "Contract Pharmacy Mapping Analysis," Berkeley Research Group, June 17, 2014.

⁷42 U.S.C.A 1396r-8(C)(1)(c).

⁸The 340B program was enacted under the Veterans Health Care Act of 1992 (Public Law 102-585), codified as Section 340B of the Public Health Services Act (42 U.S.C. § 256b)."

⁹42 U.S.C. §256b(a)(4)(L)(ii).

¹⁰42 U.S.C. §256b(a)(4)(A)-(K).

¹¹According to a Government Accountability Office (GAO) report, in 2005—fully thirteen years after the 340B program was enacted—there were 591 participating hospitals. Government Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, (Washington, DC:" GAO, September 2011), 28, fig. 2 (hereafter referred to as GAO 340B report). By 2014, nine years later, almost four times as many hospitals were participating (2,048) according to a report of the Alliance for Integrity and Reform of 340B (AIR 340B). Alliance for Integrity and Reform of 340B, Unfulfilled Expectations: An analysis of charity care provided" by 340B hospitals, Spring 2014, 3 (hereafter referred to as AIR 340B Spring 2014 report).

¹²AIR 340B Spring 2014 report.

¹³Hospitals qualifying for 340B based on their DSH adjustment percentage account for about 75 percent of drugs purchased through 340B. The DSH percentage is not based on" measures of uncompensated or charity care provided by the hospitals.

¹⁴Berkeley Research Group analysis for the Alliance for Integrity and Reform of 340B. Analysis excludes contract pharmacy arrangements between a child site and a contract pharmacy if the parent site also has an arrangement with that same pharmacy.

¹⁵61 Fed. Reg. 43549, 43555 (Aug. 23, 1996).

¹⁶61 Fed. Reg. 43549 (Aug. 23, 1996).

¹⁷61 Fed. Reg. 43549, 43551 (Aug. 23, 1996).

¹⁸61 Fed. Reg. 43549 (Aug. 23, 1996).

¹⁹61 Fed. Reg. 43549, 43551 (Aug. 23, 1996).

²⁰Berkeley Research Group analysis for the Alliance for Integrity and Reform of 340B. Analysis excludes contract pharmacy arrangements between a child site and a contract pharmacy if the parent site also has an arrangement with that same pharmacy.

²¹75 Fed. Reg. 10272 (March 5, 2010).

²²" 75 Fed. Reg. 10272, 10273 (March 5, 2010).

²²75 Fed. Reg. 10272, 10273 (March 5, 2010).

²³GAO 340B report, p.3 states "[T]he 340B program has no requirements on how 340B revenue can be used..."

²⁴American Society of Clinical Oncology, Policy Statement on the 340B Drug Pricing Program, Journal of Oncology Practice, published online ahead of print at jop.ascopubs.org" on April 15, 2014.

²⁵75 Fed. Reg. 10272, "10273 (March 5, 2010).

²⁶75 Fed. Reg. 10272, "10274 (March 5, 2010).

²⁷Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011); Office of Inspector General, "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program," OEI-05-13-00431, Feb. 4, 2014.

²⁸Letter from Ranking Member Grassley, Senate Committee on the Judiciary, to Mr. Gregory Wasson, President and CEO, Walgreens, July 31, 2013; Letter from Ranking" Member Grassley, Senate Committee on the Judiciary, and Rep. Bill Cassidy, M.D. to Charles A. Stark FACHE, President and CEO, Columbus Regional Healthcare System, April 18, 2013; Letter from Ranking Member Grassley, Senate Committee on the Judiciary, to HRSA Administrator Mary K. Wakefield, March 27, 2013; Letter" from Ranking Member Grassley, Senate Committee on the Judiciary, to Mr. Michael C. Tarwater, CEO, Carolinas Medical Center, September 28, 2012; Letter from" Ranking Member Grassley, Senate Committee on the Judiciary, to Dr. Victor Dzau, President and CEO, Duke University Health System, September 28, 2012; Letter from" Ranking Member Grassley, Senate Committee on the Judiciary, to William L. Roper, CEO, University of North Carolina Health Care System, September 28, 2012; Letter" from Chairman Pitts, House Energy and Commerce Committee, Subcommittee on Health, and Rep. Bill Cassidy, M.D. to HRSA Administrator Mary K. Wakefield, July" 18, 2012; Letter from Ranking Member Grassley, Senate Committee on the Judiciary, to Dr. Carol Garrison, President, University of Alabama Hospital, May 10, 2012; See" Prognosis: Profits, a five-part investigation by The News & Observer and Charlotte Observer, www.newsobserver.com/prognosisprofits/, April 2013; B. Toland, "UPMC" 'moves' Hillman for chemotherapy savings," *Pittsburgh Post-Gazette*, June 9, 2014.

- ²⁹Berkeley Research Group, PowerPoint Presentation given at the 340B Coalition Annual Conference, Washington, D.C., July 16, 2013, 5.
- ³⁰OIG Report.
- ³¹Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011), 29.
- ³²42 U.S.C. Sec. 256(b).
- ³³42 U.S.C. Sec. 256(a)(5)(A)(i).
- ³⁴Government Accountability Office, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (Sept. 23, 2011); Office of Inspector General, "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program," OEI-05-13-00431, Feb. 4, 2014.
- ³⁵No data is collected about how providers use revenue gained from 340B sales. Hospitals sometimes point to 340B as the source of funding for health-related programs they offer, but there is no way to know whether 340B funds pay for these activities or are used for entirely different purposes, or whether the activities cited as funded by 340B are paid for by not-for-profit hospitals' favorable tax status, one of the other revenue streams hospitals receive, or hospital profits. See, e.g., Rosenthal, "Benefits Questioned in Tax Breaks for Nonprofit Hospitals," *The New York Times*, December 17, 2013, p. A18; Alexander et al., "NC hospitals reap profits from discount drugs," *The News Observer*, April 2, 2013, available at <http://www.newsobserver.com/2013/04/02/2797292/nc-hospitals-reap-profits-from.html>.
- ³⁶75 Fed. Reg. 10272, 10273 (March 5, 2010).
- ³⁷75 Fed. Reg. 10272, 10274 (March 5, 2010).
- ³⁸*Ibid.* Overall, the AMDP included about 0.2 percent of the sites and 0.5 percent of the contract pharmacy arrangements in the 340B program today.
- ³⁹*Ibid.*
- ⁴⁰HRSA, Office of Pharmacy Affairs Contract Pharmacy Database, analyzed June 18, 2014.
- ⁴¹Berkeley Research Group, PowerPoint presentation, 10th Annual Oncology Economics Summit, San Diego, CA, Feb. 26, 2014, 7.
- ⁴²75 Fed. Reg. 10272, 10274 (March 5, 2010).
- ⁴³75 Fed. Reg. 10272, 10273 (March 5, 2010).
- ⁴⁴Berkeley Research Group analysis for the Alliance for Integrity and Reform of 340B.
- ⁴⁵GAO 340B report, 28.
- ⁴⁶OIG Report.
- ⁴⁷75 Fed. Reg. 10272, 10278 (March 5, 2010).
- ⁴⁸OIG report, 2.
- ⁴⁹75 Fed. Reg. 10272, 10274 (March 5, 2010).
- ⁵⁰OIG Report, 15.
- ⁵¹75 Fed. Reg. 10272, 10273 (March 5, 2010).
- ⁵²OIG Report, 15.
- ⁵³75 Fed. Reg. 10272, 10273 (March 5, 2010).
- ⁵⁴OIG Report, 15.
- ⁵⁵42 U.S.C. Sec. 256(a)(5)(A)(i).
- ⁵⁶75 Fed. Reg. 10272, 10278 (March 5, 2010).
- ⁵⁷*Ibid.*
- ⁵⁸75 Fed. Reg. 10272, 10273 (March 5, 2010).
- ⁵⁹OIG Report, 9.
- ⁶⁰OIG Report, 14.
- ⁶¹75 Fed. Reg. 10272, 10278 (March 5, 2010).
- ⁶²OIG Report, 15; 75 Fed. Reg. 10272, 10278 (March 5, 2010).
- ⁶³OIG Report, 16.
- ⁶⁴OIG Report, 13.
- ⁶⁵Centers for Medicare & Medicaid Services (CMS), Medicaid Managed Care Enrollment Report: Summary Statistics as of July 1, 2011, 1.
- ⁶⁶Teresa Coughlin, Brigitte Courtot and Rebecca Peters, "Are State Medicaid Managed Care Programs Ready for 2014?" Robert Wood Johnson Foundation. May 2013. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf406305
- ⁶⁷Berkeley Research Group, *Estimate of the Managed Medicaid Prescription Volume in 340B Contract Pharmacies*, available at <http://www.brg-expert.com/engagements-109.html> (accessed May 5, 2014).
- ⁶⁸The Berkeley Research Group estimates are based on the following assumptions: 2.0 prescriptions per outpatient discharge and Community Health Center visit, a 5 percent growth rate for the number of contract pharmacies, that just 5 percent of prescriptions would be filled at contract pharmacies in 2014 and that that "capture rate" would grow at an annual rate of 5 percent per year.
- ⁶⁹42 U.S.C. § 256(a)(5)(A); 42 U.S.C. § 1396r-8(j).

⁷⁰Letter from Safety Net Hospitals for Pharmaceutical Access to Jason A. Helgerson, Medicaid Director & Deputy Commissioner, Office of Health Insurance Programs, New York State Department of Health, Dec. 19, 2011.

⁷¹Berkeley Research Group, *Estimate of the Managed Medicaid Prescription Volume in 340B Contract Pharmacies*, available at <http://www.brg-expert.com/engagements-109.html> (accessed May 5, 2014).

⁷²HRSA's central justification for its 2010 guidance changing the contract pharmacy program to permit an unlimited number of contract pharmacies ("[S]ome patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities" which would "create wider patient access by having more inclusive arrangements in their communities") includes a statement that this "would benefit ... pharmacies...." 75 Fed. Reg. 10,272,10273. This statement is remarkably out of place as a consideration included in the justification for the 2010 guidance. The 340B statute contemplates vulnerable patients, not pharmacies, as beneficiaries of the program. There is no suggestion in the 340B statute or its legislative history that a purpose of the program was to confer benefits on pharmacies or that HRSA's mandate in any way involved conferring such benefits on pharmacies.

⁷³Berkeley Research Group, PowerPoint Presentation given at the 340B Coalition Annual Conference, Washington, D.C., July 16, 2013, 5.

⁷⁴Berkeley Research Group analysis of HRSA OPA database for AIR 340B.

⁷⁵Berkeley Research Group analysis of HRSA OPA database for AIR 340B.

⁷⁶A. Vandervelde, "Contract Pharmacy Mapping Analysis," Berkeley Research Group, June 17, 2014.

⁷⁷Median income was classified based on the federal poverty level for a family of three.

⁷⁸*Ibid.*

⁷⁹American Society of Clinical Oncology, Policy Statement on the 340B Drug Pricing Program, *Journal of Oncology Practice*, published online ahead of print at ascopubs.org on April 15, 2014.

⁸⁰Berkeley Research Group, PowerPoint Presentation, given at the 340B Coalition Annual Conference, Washington, D.C., July 16, 2013, 5. HRSA projections previously posted on HRSA website, no longer available.

⁸¹See, Alliance for Integrity and Reform of 340B, *The 340B Drug Discount Program: A Review and Analysis of the 340B Program*, Winter 2013, 16-17.

⁸²75 Fed. Reg. 10272, 10278 (March 5, 2010).

⁸³Avalere Health analysis of HRSA files on 340B contract pharmacy arrangements.

⁸⁴Avalere Health analysis of the daily report of pharmacy contract arrangements, accessed on the HRSA website on October 10, 2011.

⁸⁵*Ibid.*

⁸⁶Berkeley Research Group, Study of Walgreen's Participation in the 340B Program, June 6, 2014, 4, http://www.brg-expert.com/media/publication/452_Analysis%20of%20Walgreens%20Participation%20in%20the%20340B%20Contract%20Pharmacy%20Progra....pdf.

⁸⁷*Ibid.*

⁸⁸Walgreen's, PowerPoint presentation given at Population Health and Care Coordination Colloquium, Philadelphia, PA, Feb. 28, 2012.

⁸⁹<http://www.linkedin.com/pub/timothy-hong/28/651/511>.

⁹⁰http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf, accessed May 6, 2014.

⁹¹Drug Channels, "Walgreens Still Dominates Booming 340B Contract Pharmacy Market, with CVS and Rite Aid Right Behind," February 5, 2014.

⁹²GAO, 2011 at p. 29.

⁹³OIG, 2014 at p. 14. For two DSH hospitals, whether their contract pharmacies offered the discounted 340B price to uninsured patients was, for unexplained reasons, "unclear."

⁹⁴OIG, 2014 at p. 14.

⁹⁵Avalere analysis of the Medical Expenditure Panel Survey. Data for 2012 is a projection and is based on Avalere analysis of CBO, Census and Medicare Trustees report data. Projections were calculated in October 2012 and account for the Supreme Court's ruling on the Affordable Care Act.

⁹⁶National Health Expenditure Accounts, National Health Expenditures by type of service and source of funds, CY 1960-2012 (accessed June 18, 2014).

⁹⁷Avalere analysis of the Medical Expenditure Panel Survey. Data for 2012 is a projection and is based on Avalere analysis of CBO, Census and Medicare Trustees report data. Projections were calculated in October 2012 and account for the Supreme Court's ruling on the Affordable Care Act.

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