Development of a metrics dashboard for monitoring involvement in the 340B Drug Pricing Program

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The 340B Drug Pricing Program is a federal program enacted by Congress in 1992 under Section 340B of the Public Health Service Act.1 Administered and overseen by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) within the Department of Health and Human Services (HHS), the 340B program requires participating drug manufacturers to provide discounted prices on covered outpatient drugs to safety net providers. According to the Institute of Medicine, “Safety net providers organize and deliver a significant level of health care and other related services to the uninsured, Medicaid, and other vulnerable patients.”

Seventeen categories of hospital providers and HRSA grantees are eligible for the 340B program, ranging from large freestanding children’s hospitals and cancer hospitals to small federally qualified health centers and hemophilia treatment centers. Some of these 340B-eligible safety net providers, known as covered entities, are in the disproportionate-share hospital (DSH) category; these hospitals qualify for the 340B program based on their Medicare DSH adjustment percentage. The common thread of these various covered entities is that they are nonprofit healthcare organizations that have certain federal designations or receive government funding and regulatory compliance efforts. A team of pharmacists led the development of an electronic dashboard tool to help monitor 340B program activities at the system’s 340B-eligible facilities. After soliciting input from an array of internal and external 340B program stakeholders, the team designed the dashboard and associated data-entry tools to facilitate the capture and analysis of 340B program-related data in four domains: cost savings and revenue, program maintenance costs, community benefits, and compliance.

Conclusion. A large health system enhanced its ability to evaluate and monitor 340B program-related activities through the use of a dashboard tool capturing key metrics on cost savings achieved, maintenance costs, and other aspects of program involvement.

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serve the country’s indigent and vulnerable patient populations.

Historically, the 340B program has lacked a metrics-driven reporting framework that captures the value of the program to the covered entity, how covered entities benefit underserved populations with their realized cost savings, and cost consequences associated with statutory compliance. This situation has arisen in part because there is no statutory requirement or standardized guidance on how to measure program integrity and effectiveness.

Today’s political environment has led to a surge of visibility for the 340B program in the face of congressional scrutiny and pressures for growth containment, increased program oversight and enforcement by OPA, and greater consistency in regulatory compliance. In response to this vigorous regulatory landscape, covered entities are increasingly held accountable for the manner in which they utilize the program. Further, there is a lack of defined and standardized metrics and accompanying tools to demonstrate an effective 340B program. This article describes the development of a metrics dashboard to support hospitals and health systems in evaluating the effectiveness and integrity of their 340B program–related activities.

Background

Memorial Hermann Health System (MHHS), composed of 12 hospitals located throughout the greater Houston area, is the largest not-for-profit health system in southeast Texas. The system contains 7 DSH-covered entities, including a 1000-bed academic medical center and community hospitals with bed counts ranging from 80 to 600. Through the development and deployment of a dashboard for the evaluation and monitoring of 340B program–related metrics, the MHHS pharmacy division and hospital executives sought to enhance their ability to evaluate the utilization and integrity of 340B activities at both the system and the facility level.

According to a 1992 committee report to the U.S. House of Representatives, the legislative intent of the 340B drug-discount program was to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” A drug manufacturer must enroll in the 340B program in order for its covered outpatient drugs to be reimbursable by Medicaid or the Medicare Part B program. By entering into a Pharmaceutical Pricing Agreement with the secretary of HHS, a manufacturer agrees to charge a price that is at or below the 340B price for covered outpatient drugs. According to the Congressional Budget Office, the maximum price that manufacturers can charge covered entities (i.e., the 340B ceiling price) is, on average, 51% of the average wholesale price (AWP) for brand name drugs and can be negotiated even lower by the covered entity and the 340B Prime Vendor Program.

In recent years the status quo of the 340B program has been disrupted due to five primary catalysts:

- Tremendous growth in the program driven by the enactment of the Patient Protection and Affordable Care Act (PPACA) by Congress in 2010;
- HRSA’s issuance of a final notice on 340B contract pharmacy services the same year;
- A 2011 report from the Government Accountability Office (GAO) calling for increased 340B program oversight;
- A 2014 report from the Office of Inspector General (OIG) of HHS citing an array of concerns about the program, and
- Recent changes to the OPA database intended to improve 340B program integrity and transparency.

The PPACA amended the 340B statute through the addition of several types of organizations to the list of entities eligible to participate in the program, leading to the growth of the program and its registered covered entities; the number of covered entities doubled from about 8,600 to about 16,500 from 2001 to 2011 and continues to increase today. The statistic of registered covered entities has also increased due to the fact that HRSA has mandated that not only a covered entity but all of its outpatient facilities be registered in the OPA database as a requirement of participation in the 340B program. As of October 2013, there were 23,739 registered sites in the OPA database, 10,075 of which were hospital-registered sites.

Further, the growth of the program has expanded through contract pharmacy arrangements. Covered entities have the option to enter into multiple contract pharmacy arrangements in order to increase patient access to 340B-purchased drugs in the retail pharmacy setting. Through these agreements, contracted retail pharmacies dispense outpatient drugs to eligible patients served by the 340B-covered entity. Due to the financial outcomes of these agreements and expanded patient access to 340B-purchased medications, the percentage of all covered entities that use contract pharmacies increased from 10% to 22% from 2010 to 2013. Contract pharmacy arrangements present covered entities with opportunities for revenue generation—but also another layer of compliance challenges.

For these reasons, the program has received a surge of attention from various stakeholders and critics. The 2014 OIG report highlighted concerns about inconsistencies in Medicaid exclusion practices that ensure prevention of duplicate discounts. The 2011 GAO report evaluated the overall integrity of the program, particularly whether or not the program has been supporting its initial legislative intent, in response to a congres-
ional request associated with passage of the PPACA. The GAO study found that covered entities generally reported that the 340B program was used to support or expand access to services and that the resultant cost savings have been an integral component of the sustainability of covered entities’ operations. In another pertinent conclusion, the report cited insufficient HRSA oversight of the 340B program. The systematic examination of the program’s impact on covered entities was paramount in demonstrating potential consequences of program restriction.

Problem

Covered entities struggle to self-monitor 340B processes in a holistic manner, with attention to financial, community-benefit, and integrity components. The intricacy of the 340B program stems from its statutory genesis and its vagueness and openness to multiple interpretations. The lack of consistency in policy-to-practice interpretation has led to decades of shortcomings in compliance. Due to insufficient program oversight, covered entities have been self-policing and obtaining guidance and recommendations from multiple sources, including attorneys, consultants, and vendors. Further, it was not until after the OIG and GAO reports in 2014 and 2011, respectively, that all stakeholders were held accountable for the program’s integrity. Institutions can now be audited by both the federal government and participating manufacturers.

Amendments to guidance and policy statements regarding 340B program components have led to extreme operational and implementation challenges for affected institutions. As noted in the 2011 GAO report, “HRSA’s current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. 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.”

The 2014 Omnibus Spending Bill became Public Law 113-76 on January 17, 2015, and increased HRSA’s OPA budget from $4.4 million to $10.2 million to help support 340B program integrity efforts and strengthen program oversight through compliance audits of covered entities and manufacturers, mechanisms to validate 340B prices, and other initiatives.

Because the 340B program operated for many years without extensive oversight, most covered entities do not have systems to provide details about their internal programs. The extent of compliancy varied widely, and some of the covered entities did not have a clear view of how they utilized the 340B program, their level of regulatory compliance, and whether or not the original intent of the program was satisfied through their practices. Some covered entities did not monitor the financial consequences of the 340B program for their facilities, as the cost savings achieved were an assumed item in budgets and operations.

Another obstacle to optimal hospital involvement in the 340B program is the major gap in knowledge regarding the 340B program’s compliance requirements and financial impact among covered-entity stakeholders both within and outside pharmacy departments. One of the foremost misconceptions about the 340B program is that it is solely a pharmacy-driven program. Since the implications of the 340B program and its sustainability affect multiple accountable decision-makers within a facility, it is pertinent to ensure proper education. Awareness of the environment surrounding the program and program best practices is often lacking among pharmacy leadership, hospital executives, legal counsels, and internal audit departments.

Analysis and resolution

Analysis of stakeholder needs.

The primary goal of developing the 340B metrics dashboard described here was to provide MHHS with a view of its utilization of the 340B program. In order to ensure comprehensive measurement of program effectiveness, a stakeholder needs analysis was completed (Table 1). After a thorough literature review, the following stakeholders were identified: the covered entity’s pharmacy department and hospital leadership, 340B covered entity organizations, legislators, the 340B Prime Vendor Program, and HRSA. Most of these stakeholder groups were contacted directly through in-person or phone interviews in order to evaluate their priorities in defining program effectiveness.

It was determined that, as covered entities, MHHS facilities would benefit from determining metrics that would reveal the impact of the program on operations and the financial sustainability of pharmacy services. The pharmacy department leadership and hospital executives within various covered entities revealed that they did not calculate 340B-attributable cost savings but rather estimated those figures based on reported average discounts on 340B-covered drugs. They derived this estimation by calculating a discount of 25–50% of the AWP for covered outpatient drugs. In addition, there was an evident increase in the allocation of resources toward the 340B program, leading to direct and indirect costs associated with being a compliant covered entity.

Given the lack of literature on the cost consequences incurred by covered entities, quantifying program maintenance costs is essential in assessing a covered entity’s return on investment for participation in the 340B program. Although the 340B statute does not obligate a covered entity to demonstrate community benefits stemming from 340B pro-
program utilization, the political environment has made it a priority for organizations to demonstrate the investment of 340B-related cost savings into activities that fulfill the intent of the program. From a covered entity’s perspective, this correlation helps illustrate program integrity.

The results of the MHHS stakeholder analysis were compartmentalized into four domains: cost savings and revenue, program maintenance costs, community benefit, and compliance. The component of the program to which each stakeholder attached the highest priority was compliance. The metrics within each domain were determined by relevancy, utility, and availability.

Metric determination and assessment of data. Cost savings and revenue. The cost savings and revenue domain permits the covered entities to monitor cost savings monthly, quarterly, and annually. An analysis of the facility purchase data for the given time period is completed by comparing the 340B price, the group purchasing organization (GPO) price, and the wholesale acquisition cost (WAC) price corresponding to each National Drug Code (NDC). Metrics in this domain are used to adjust cost savings on the basis of projected drug costs at GPO prices. Further, financial implications of the HRSA guidance prohibiting GPO participation by certain covered entities are captured by incorporating drug costs into WAC accounts. The statutory prohibition on GPO participation is a program eligibility requirement that bars covered entities from "obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." To replenish needed inventory on the shelf without the 340B transactions already accumulated, the covered entity must purchase that drug at the WAC price. Since WAC pricing is substantially higher than GPO pricing, accounting for this additional drug cost in order to be compliant with this 340B eligibility requirement is crucial in accurately evaluating the financial impact of the 340B program.

This dashboard domain also evaluates the financial gain from contract pharmacy arrangements. Metrics within this domain capture the direct revenue stream, taking into account any expenses associated with the fee structure of the contract pharmacy agreements. According to the 2010 HRSA final notice regarding 340B contract pharmacy services, “the contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be made available to the covered entity.” With the accessibility of financial statement information through the contract pharmacies, information on revenue generation secondary to eligible prescriptions dispensed is readily available. The domain demonstrates the net revenue collected by the covered entity by accounting for administrative fees, dispensing fees, and inventory costs associated with transactions.

Program maintenance costs. As the 340B program becomes more complex and covered entities allocate more resources to program implementation and compliance, it is important that the entities continually monitor program maintenance costs. One of the most prevalent maintenance costs associated with compliance stems from the use of split-billing software to help address compliance with the prohibition of GPO pricing. Under a mixed-use model commonly seen in areas that serve both inpatients and outpatients, such as emergency departments and catheterization laboratories of DSH-covered entities, split-billing software electronically captures drug utilization to populate three transaction accumulators: GPO, non-GPO/WAC, and 340B.

The GPO prohibition guidance has also led to increased time spent by pharmaceutical buyers ensuring appropriate purchasing processes as well as a conservative WAC account spend. For example, a buyer must critically assess the need to replenish inventory on the shelf if transactions for dispensed product have not yet accumulated in the 340B account in order to avoid unnecessarily using the non-GPO/WAC account. This

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*aMHHS = Memorial Hermann Health System.*

*bStakeholders were asked to rate the need for improved methods of monitoring performance in the four listed areas.

*cSafety Net Hospitals for Pharmaceutical Access.*
The program maintenance costs domain also includes miscellaneous costs associated with program education and 340B association membership in order to equip the covered entities with the resources to maintain program integrity. By quantifying program maintenance costs, a covered entity is able to capture net 340B-related savings and, subsequently, a return on investment in program participation.

Community benefit. Because increased patient access is often difficult to quantify, the community-benefit domain is composed of both measurable metrics and anecdotal evidence. Information reported by hospital organizations on Internal Revenue Service schedule H (form 990) and results of the American Hospital Association (AHA) Annual Survey of Hospitals are two recognized sources of data to help hospitals define and develop a numerical representation of community benefit.

Hospital organizations use schedule H to provide information on community benefits and charity care provided by their facilities during the tax year; reported information includes financial assistance policies, specific community benefits provided, and the cost of financial assistance and other community-benefit activities and programs.  

The primary metric is the overall exposure risk, which is calculated by summing the point values assigned to each covered-entity facility within the system. Uncompensated care is defined as “an overall measure of unreimbursed hospital care provided to medically indigent and underinsured patients . . . it is the sum of a hospital’s ‘bad debt’ and the charity care it provides.” This value includes the costs of services for which the hospital anticipates collecting payment as well as those for which the hospital does not expect to receive payment.

Quantifiable metrics of community benefit can be supplemented with accounts of ways the covered entity has been able to expand access to indigent populations through its realized cost savings. Covered entities have reported various approaches to reinvestment of savings to benefit the community, including the implementation of medication therapy management programs, patient assistance programs, and school-based clinics. Through the anecdotal benefit inclusion within the dashboard, the covered entity is able to tell its individual story of 340B program participation and impact to its patients.

Compliance. The compliance domain of the 340B dashboard is intended to serve as a framework for evaluating compliance standards. The domain includes an internal auditing tool that allows the covered entity to assess the current state of program integrity as well as adverse findings and action plans. The components of the auditing tool were defined using policy guidelines and tools provided by HRSA and the 340B Prime Vendor Program, respectively. Within the dashboard, each standard is designated as either a quarterly or an annual requirement. Quarterly evaluations include transactional tracers and confirmation of appropriate site registration and conformance to eligibility requirements. A much more thorough evaluation is featured in the annual audit tool, which also assesses policies and procedures, contracts with government entities and contract pharmacies, and procedures to ensure appropriate Medicaid billing and prevention of duplicate discounts. As such, this domain can help support quarterly and annual internal audit program requirements. Each component of the audit tool is assigned a risk-level rating by the covered entity’s auditor; low-, moderate-, and high-risk components are designated by one, two, and three points, respectively. The primary metric is the overall exposure risk, which is calculated by summing the point values assigned using various components of the audit tool. Because of its subjectivity, the quantification of risk is merely intended to provide stakeholders within the covered entity with insights on perceived areas of program risk and the need for improvements.

Dashboard implementation. One of the challenges encountered during the design of the 340B metrics dashboard was that the data to be tracked resided in various sources. It was important to validate the metrics themselves as well as the data collection approach for each of the metric fields. This was done through a pilot test conducted at one of MHHS’s DS8-eligible hospitals. The process of populating metrics within each domain revealed lag times in collecting data, and it was
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determined that certain metrics should be collected at different time periods and at different frequencies. For example, the AHA survey information incorporated into the community-benefit domain is submitted at varying times throughout the year by each respondent facility; as such, the actual survey results are made available with a variable one-year lag. Metrics affected by extensive lag times in data availability, such as AHA survey data, must be reported retrospectively within the dashboard. At MHHS it was determined that two domains (cost savings and revenue and program maintenance costs) would be reported quarterly, with the other two (community benefit and compliance) reported annually. Once the dashboard data collection tool was pilot tested at one facility, the findings were presented to the director of pharmacy, the pharmacy operations manager, the chief operations officer, the chief finance officer, and the system director of operations responsible for the 340B program to elicit their feedback regarding the relevance and use of the dashboard components.

The next stage was collecting all metrics for one quarter for the seven DSH-covered entities within MHHS, using the same data collection tool used in the pilot test. In the infancy of the dashboard, the metrics serve an informational purpose, without current benchmarks in place for some of the domains. As data are collected in future quarters, the dashboard will serve as a tool to track trends and establish benchmarks.

In regard to the structure of the dashboard, the surface of the tool consists of four gauges representing the designated primary metrics of the four domains. For example, for the cost savings domain, the primary metric of net cost savings is denoted on the display. Each domain and the corresponding dashboard gauge provide a user interface that allows the user to view a graphical representation of each of the metrics that reside within that domain. This allows for trending of each of the various metrics that make up a particular domain. With the compliance domain, the primary metric is an overall risk-level evaluation. The user interface allows the viewing of quarterly and annual internal audit tools and results.

Dashboard education. Once the dashboard was completed for the quarter, it was presented to the MHHS pharmacy coordinating council, which is composed of the pharmacy leadership throughout the system. For the dashboard to serve its purpose with sustainability, it was vital that pharmacy leadership define the dashboard’s value in the context of their 340B program’s framework. This dashboard can support collaboration with the system's legal team, internal auditing department, government reporting group, and hospital executive communication regarding 340B program utilization.

Discussion

Given the political landscape surrounding the 340B Drug Pricing Program, covered entities like MHHS are faced with a heightened need to demonstrate their appropriate utilization of the program. Unfortunately, standardized and established metrics that define an effective program are lacking. The definition of an effective program often varies among different stakeholder groups. A dashboard that supports a macroevaluation of these various values will allow for a comprehensive definition of 340B program integrity and success.

One of the limitations of the dashboard is the need for manual entry of data. In identifying relevant metrics for each domain, it was evident that data would be derived from multiple sources. These sources include Medicare cost reports, annual AHA surveys, facility drug purchasing data, and split-billing software, among others. For the dashboard to be effective and useful, a global evaluation of 340B program participation and its implications for the covered entity is necessary. The effect of 340B program involvement on the pharmacy departments, the hospital’s financial sustainability, and the community benefit must be captured. Metrics used to measure that impact are multifaceted and reside in varying sources. The user will have to manually collect data from the various sources and input them into the dashboard data-entry interface. Further, there is a notable lag time in the availability of certain data (e.g., community-benefit data derived from the AHA survey are published with at least a one-year delay); this limits the dashboard’s utility to retrospective assessment of that particular domain.

Critics of the 340B program often express concerns over the lack of quantitative data associated with 340B program integrity. From a program sustainability perspective, the metrics within the dashboard can be useful in advocating for the 340B program, as covered entities continuously monitor and ensure its effective application. This project highlights the importance of establishing robust and standardized metrics for the 340B program.

There is an opportunity to encourage covered entities to utilize the dashboard described in this article to measure their utilization of the 340B program in each of the four domains. Metrics could be aggregated to provide HRSA and stakeholders with national indicators of 340B program utilization. Such national indicators could subsequently be used to identify areas of opportunity and strength in 340B policy-to-practice interpretation. Future steps for such a project might include a feasibility assessment of the implementation of this dashboard at other health systems, once data collection viability is evaluated at hospitals with varying organizational structures and resources. Due to the varying
program requirements for other (i.e., non-DSH-eligible) categories of covered entities, this dashboard concept can serve as a starting point for program measurement at those types of providers, although metric adjustments, particularly in the compliance domain, would be required.

Conclusion

A large health system enhanced its ability to evaluate and monitor 340B program–related activities by developing a dashboard tool capturing key metrics on cost savings achieved, maintenance costs, and other aspects of program involvement.

References