

Alexander Mansour



healthcare financial management association hfma.org

## built for the road ahead

The 340B Drug Pricing Program is helping one health system meet the needs of patients who continue to require assistance with the costs of care despite the expansion of healthcare coverage under the Affordable Care Act.

Nationally, uncompensated care—the overall measure of hospital care for which no payment is received—reached an all-time high of \$46.4 billion in 2013, according to the American Hospital Association (AHA).<sup>a</sup> The AHA notes that since 2000, U.S. hospitals of all types have provided more than \$459 billion in uncompensated care, including bad debt and charity care.

Despite data that portray these costs on a national scale, the reality is that the costs are concentrated in certain rural and urban communities. The costs are directly related to the continuing access to care for low-income communities that cannot support the full cost of hospitals, physicians, and clinics without financial help, such as the savings associated with the 340B Drug Pricing Program.

### AT A GLANCE

Henry Ford Health System in Detroit is seeking new ways to lower and cover costs for the large, low-income population it serves in southeastern Michigan. Employing a strategy that couples the federal 340B Drug Pricing Program with a prescription assistance program of its own creation, Henry Ford has seen improvement in the following areas:

- > Increased medication adherence
- > Reduced readmissions
- > Cost savings that are sufficient to expand services where expansion otherwise would not have been feasible

High costs of uncompensated care persist for safety net hospitals despite expanded healthcare coverage under the Affordable Care Act (ACA). For some organizations, changes under the ACA may have brought about shifts in the distribution of uncompensated care costs among bad debt, charity care, and undercompensated care (via both Medicare and Medicaid).

An example is Henry Ford Health System (HFHS), a large integrated delivery system in southeastern Michigan. HFHS's uncompensated care costs for 2014 were \$317 million, including \$35 million in uncompensated drug costs, on total revenues of \$4.71 billion, with uncompensated care up slightly from \$314 million in 2013. Michigan's health insurance exchange began enrollment late 2013, and Medicaid expansion became effective in April 2014. Between 2013 and 2014, HFHS's charity care costs shrank by about \$14 million, while bad debt increased by about \$7 million and undercompensated care (primarily from Medicaid and Medicare) increased by approximately \$9 million. Henry Ford has significantly improved its margin during this time period, reporting an overall profit of \$35 million in 2014, compared with less than \$500,000 in 2013.

a. "Uncompensated Hospital Care Cost Fact Sheet," American Hospital Association, January 2015.

Patient financial responsibility in the form of high deductibles and copayments, as well as higher premiums in the southeastern Michigan private market and Michigan's health insurance exchange, contribute to the continued growth in uncompensated care and need to support patients who can't afford to pay.

By means of the Medicaid expansion and tax-subsidized coverage through the insurance exchanges, the ACA significantly fills in previous gaps in drug coverage. Medicaid does cover most drugs, but often fails to reimburse hospitals and physicians for basic acquisition costs. The Medicaid program also generates savings on drugs through rebates from the pharmaceutical companies, but providers serving the Medicaid population do not benefit financially from these rebates.

The ACA requires that individual and small group health plans sold in the health insurance exchanges cover prescription drugs as part of an essential health benefits package. However, the states and health plans have discretion in determining the design of the drug benefit, and limitations continue to exist. In addition, although 30 states and Washington, D.C., have chosen to expand Medicaid under the ACA, non-expansion in the remaining states leaves a sizeable population nationally without the benefit of coverage for the poorest patients. The challenge for hospitals in this environment is to identify opportunities to maintain positive margins and at the same time stretch and sustain programs to provide clinical and pharmacy services to the patients they serve.

### **Need for Charity Care Continues Despite the ACA**

HFHS serves both low-income urban and high-income suburban communities in the metropolitan Detroit area. The health system owns and operates five inpatient hospitals, including the 900-bed flagship Henry Ford Hospital in Detroit, which meets all requirements for the 340B program. About 30 HFHS clinics are outpatient departments of Henry Ford Hospital and participate in 340B. Fifteen additional HFHS

clinics do not qualify for 340B, and HFHS does not bill the 340B discount for patients at these clinics. HFHS clinics are a mix of primary care sites and large multispecialty facilities with full-service emergency departments (EDs) and the capability to deliver ambulatory surgery, cancer care, and nearly every service found in a hospital except inpatient beds.

Savings under the 340B program and disproportionate share hospital (DSH) payments help offset the continued burden of uncompensated care and allow HFHS to keep clinics open in parts of the southeastern Michigan service area that can't support private practice. (Currently, Detroit has no public hospital and very few private practice physicians.) The HFHS clinics operate at a 10 percent average loss, with higher losses at the Detroit-based clinics. The key to keeping these clinics open is a combination of 340B savings, DSH payments, and other special payments to ensure access for all patients throughout the region.

Medicaid and Medicare together constitute 60 percent of the overall HFHS payer mix, with Blue Cross and commercial plans at 21 percent and the Henry Ford Health Alliance Plan at 14 percent.

Along with many safety net hospitals nationally, HFHS is revising its corporate charity care policy to ensure patients in need receive care, while retaining incentives for patients to obtain the coverage for which they may be eligible under Michigan's Medicaid expansion and health insurance exchange. The goal is to ensure that patients receive treatment regardless of their ability to pay.

HFHS enrolled in the 340B program in 2003, implementing the program in a mature, community-based clinic network staffed by employed physicians. A prescription assistance program was initiated to specifically address two key concerns: providing assistance to patients with economic barriers and improving medication adherence.

In view of the continuing challenges patients face with the affordability of drugs in both the private

## About the 340B Program

When it was created by Congress in 1992, the 340B program enjoyed bipartisan support as part of the Public Health Services Act. Congress noted in a House report at the time (H.R. Rep. 102-384[II], at 12) that its purpose in creating the program was to help “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” by reducing the amount spent on outpatient drugs. Although guidelines have continued to evolve in the 20-plus years since the program’s inception, and eligibility has opened to more entity types, the program continues to function as it was intended, allowing hospitals to stretch their budgets to serve their communities. According to an analysis of 2012 Medicare cost reports published by 340B Health, hospitals participating in the 340B program carry a low-income patient load nearly twice that of non-340B hospitals.

To qualify, a hospital or other eligible covered entity must be a not-for-profit organization that meets specific requirements outlined by the Health Resources and Services Administration

(HRSA) on the Office of Pharmacy Affairs website.<sup>a</sup> To remain in the program, a hospital must adhere to strict compliance guidelines and be subject to random audits by both drug manufacturers and HRSA.

Entities that qualify, including hospitals, receive drug discounts on eligible medications dispensed to outpatients. According to the American Hospital Association, the program saves hospitals approximately \$3.8 billion each year on drug purchases.<sup>b</sup> Safety net facilities such as Henry Ford Health System in Detroit can leverage this additional operating margin to offset their unreimbursed costs of care, provide more comprehensive services, and help maintain financial viability. In addition, many hospitals leverage the 340B program to provide charity care and other programs to benefit their communities.

a. Health Resources and Services Administration, 340B Drug Pricing Program: Eligibility & Registration, [hrsa.gov/opa/eligibilityandregistration/index.html](http://hrsa.gov/opa/eligibilityandregistration/index.html).

b. American Hospital Association, “340B Drug Pricing Program,” infographic.

insurance market and government programs, HFHS plans to revise and expand its prescription assistance program to better meet its patients’ needs. This effort is in keeping with the trend toward value-based payment among both government and private payers, with hospitals, clinics, and physicians having financial incentives to perform to specific measures of quality and outcomes. HFHS has identified medication compliance as one factor that significantly affects outcomes, especially in low-income populations.

Due to the high cost of many medications, some patients don’t take their prescribed medication at all, or they take it at reduced intervals. Some patients may not even fill a new prescription. Others abandon refills and long-term therapies. This failure to adhere to prescribed therapies has been linked to a higher volume of admissions, readmissions, and ED visits, overall higher healthcare costs, and worsening of chronic

conditions.<sup>b</sup> HFHS leverages four-person teams at the clinic to track medication dosage, frequency, and adherence and to communicate with patient and providers in managing each patient’s clinical care.

Meanwhile, the health system relies on the 340B program to help offset financial barriers to medication adherence.

### The Program in Action

When a patient presents to a HFHS clinic and states that he or she is unable to pay for prescription drugs, the clinic team initiates an eligibility screening process to determine whether that patient qualifies for HFHS’s prescription drug assistance. To apply, patients must complete an application and provide one of the following: two most recent pay stubs, most recent federal tax return, or proof of disability or unemployment income.

b. Jha, A.K., Aubert, R.E., Yao, J., Teagarden, J.R., and Epstein, R.S., “Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly \$5 Billion Annually,” *Health Affairs*, August 2012.

The need for pharmacy assistance is great in the Detroit clinics. U.S. Census data for 2009-13 (the most recent period reported) show Detroit's median household income at \$26,325, which is close to the federal poverty level for a family of four. Nearly 50 percent of the population served by Henry Ford Hospital and its clinics qualifies for Medicaid, and 96 percent of those who apply for HFHS's prescription assistance program qualify for the program.

HFHS uses an algorithm to determine whether a patient will receive a 50 percent, 75 percent, or 100 percent subsidy toward the cost of the drug. Many patients qualify for 100 percent coverage based on need. Various stakeholders throughout the healthcare system—from case managers to patient account representatives, nurses, physicians, and pharmacists—provide education to patients about the prescription assistance program, including what it may cover and how to apply.

The application approval process takes 24 to 48 hours. To ensure that patients receive medications in a timely manner, Henry Ford gives patients a three- to seven-day supply of free medications while their application is being reviewed. This supply is available through pharmacies located throughout the HFHS hospital and clinic network.

Once a patient is deemed eligible for prescription assistance, he or she receives a discount savings card that can be presented at the hospital pharmacy to receive the prescription discount. The card expires one year from the date of the initial approval, at which point the patient must reapply to continue receiving benefits. With the exception of controlled substances, all drugs are eligible for a discount.

Recognizing that convenience is a key factor in whether patients fill or refill prescriptions, HFHS has established relationships with six different private pharmacy companies where patients using the prescription assistance program are able to fill and refill their Henry Ford prescriptions. These contract pharmacies, some of which

are open 24 hours, offer patients a variety of convenient options, making it easier for them to fill and refill their prescriptions close to home, even if they lack access to transportation—a common issue among eligible patients.

### Benefits of 340B

HFHS estimates that uncompensated drug costs for the patients served amount to about \$35 million per year, including costs for the pharmacy assistance program. Without participation in the 340B program, the health system's ability to keep clinics open and operate a comprehensive prescription assistance program would be limited, and the effects would be felt throughout the system in the form of preventable admissions, readmissions, an increase in ED visits, and a decline in clinical outcomes.

Using a number of strategies, including a systemwide pharmacy compliance program, HFHS reduced readmission rates by 11 percent in 2014 relative to 2013. Medication adherence among patients played a significant role.

### Challenges to the 340B Program

Opponents of the 340B program have become more vocal in questioning the need for the program, challenging the oversight of the program by the Health Resources and Service Administration (HRSA) and calling for changes—including limiting the scope of the benefit to only free or discounted drugs—that would severely impair hospitals' ability to generate savings.

Critics argue that 340B hospitals enjoy an unfair competitive advantage over organizations that do not qualify. Such opposition overlooks the costs 340B hospitals incur in providing low-income patients with access to care, and ignores the financial burdens these hospitals bear with Medicaid and Medicare constituting a large percentage of their payer mix.

Adding to the position of program critics, the Government Accountability Office (GAO) in August issued a report that found 340B hospitals provide more drugs and more expensive drugs

than non-340B hospitals. Sen. Charles Grassley (R-Iowa) has asked the Senate Finance Committee to investigate what the GAO describes as an “incentive” for 340B hospitals to provide more drugs and more expensive drugs, due to the savings 340B hospitals generate on drug discounts.

A careful review of these issues will come. In the meantime, it remains incumbent on program participants to demonstrate program integrity and compliance with all eligibility requirements and to be strong advocates for the program, highlighting the ways that 340B savings can be used to benefit patients.

### Evaluating Participation

The 340B program requires strict adherence to regulatory requirements for participation. To qualify, for example, a hospital must have a high DSH percentage and clear integration of its clinics within its organization through attestation on the hospital’s Medicare cost report, and/or demonstrated adherence to criteria defining such integration, as developed and administered by CMS.

Given the potential benefits of the 340B program, organizations that can qualify for participation and have not yet applied should carefully weigh the potential advantages to determine whether a

## 340B and Cancer Care

Critics of the 340B program have focused on the disparity in the cost of drugs for patients with cancer between private-practice physicians and hospital-based clinics participating in 340B. Some have said this difference in pricing of drugs creates a competitive edge for the 340B hospital and clinics.

However, this perspective overlooks some noteworthy differences between the types of cancer patients treated by private-practice oncologists and the types typically seen in 340B hospitals and clinics. Compared with patients treated in physician offices, cancer patients receiving care in 340B clinics are more likely to be:

- > Self-pay, on Medicaid, or in need of charity care
- > From areas with low average household income, high rates of poverty, and low rates of college education
- > Burdened with more severe chronic conditions, with a more adverse effect on mortality

Hospitalized, inclined to visit an emergency department (ED), and associated with higher Medicare spending prior to receiving ambulatory care

The body of research points to a patient population at hospital-based clinics that is more expensive to treat and less likely to have access to a private practice physician for cancer care. Clinicians at Henry Ford Health System (HFHS) in Detroit report that private-practice physicians often will refer patients to HFHS clinics when the patients have Medicaid coverage or are not able to pay.

The 340B program makes it possible for the HFHS clinics to provide the care that community physicians cannot afford to

deliver, without incurring financial losses that undermine the health system’s solvency. Patients with cancer, in particular, may receive multiple drug therapies that can be highly targeted and expensive, and HFHS often covers the cost of these drugs entirely through its prescription assistance program.

The 340B program is a major factor supporting the viability of HFHS’s Josephine Ford Cancer Institute, the largest provider of adult cancer services in Michigan, which offers services at nine treatment facilities in southeastern Michigan and complex surgical care at a new cancer surgery center.

The intrinsic relevance of the 340B program to HFHS’s cancer institute is evident when one considers that medication adherence is a growing concern in cancer care, as a result of the increased toxicity of treatment medication and the shift toward patient self-administration of the drugs at home. HFHS’s oral chemotherapy management program was created to help patients manage at-home therapy. This program is important for all HFHS cancer patients, but has a significant impact on the success of care for low-income patients, many of whom are unable to read or understand written instructions. A team of registered nurses identifies cancer patients at the clinic who are self-administering oral cancer medication at home. Using a scripted template, a nurse contacts the patient at home throughout the treatment to determine adherence to the regimen and to detect any problems early on. Patients having problems are guided to an ED or to the cancer care specialist in charge of their care.

## CASE STUDY

340B strategy might be effective for their circumstances. To ensure they make the most of participating, such organizations also should undertake the following steps.

*Start with an understanding of the population you serve.* A community needs assessment can help identify the most pressing community needs to ensure that 340B savings are reinvested where they will have the greatest impact on the most patients.

*Highlight programs and services that leverage 340B savings to benefit patients.* Programs like HFHS's prescription assistance program and expanded oncology services help the public see 340B savings at work—and help them understand what's at stake if the program is altered.

*Continually measure outcomes and adjust your programs accordingly.* When hospitals can provide tangible data correlating with programs that help lower readmissions, reduce complications, and improve patients' overall health and well-being, it becomes clear why these programs are necessary in today's healthcare environment. They don't help just one patient at a time; they benefit the community and public health in general.

*Ensure that unreimbursed care and charity care figures are represented accurately and consistently.* Although the 340B program focuses on drug costs and access to care in low-income communities, the program is aimed at helping eligible hospitals offset the costs associated with unreimbursed care. Hospitals serving low-income communities have two strikes against them: They receive relatively low payment for a majority of their patients, and many of their patients lack sufficient insurance to cover all of the healthcare services they require. Uncompensated care

universally accounts for all costs and write-offs associated with services rendered to individuals unable to pay. According to the American Hospital Association and 340B Health Coalition, 340B DSH hospitals deliver nearly 60 percent of all uncompensated care provided by DSH hospitals in the United States.<sup>c</sup>

### Filling a Unique—and Important—Role

The 340B Drug Pricing Program requires drug manufacturers to sell most outpatient drugs at deeply discounted prices to hospitals and other entities that serve large safety net populations. In exchange, drug manufacturers are authorized to have their drugs covered by Medicaid—a greatly expanded market under the ACA. Currently, more than 1,000 hospitals and health systems throughout the United States serve their communities through participation in 340B.

Although each 340B hospital has its own story to tell, the program continues to fill a unique role with far-reaching significance. HFHS is among the majority of providers that welcome greater clarity and oversight for the program. The recent “Omnibus Guidance” released by HRSA addresses gray areas for patients, hospitals, and drug manufacturers.<sup>d</sup> HFHS believes the scrutiny from various quarters will serve to verify the continued need for 340B drug pricing and the role it plays in ensuring access to care for all patients. ■

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c. “340B DSH Hospitals,” May 2015 Update, 340B Health.

d. Health Resources and Services Administration, “340 Drug Pricing Program Omnibus Guidance,” *Federal Register*, Aug. 28, 2015.

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### About the author

#### Alexander Mansour

is director of finance and 340B compliance officer at Henry Ford Health System, Detroit.

