

Fast Track to 340B

FEATURE: ROBERT F. GRICIUS AND DOUGLAS WONG

MANY HOSPITALS AND HEALTH SYSTEMS HAVE A PROFOUND NEW OPPORTUNITY TO OBTAIN SAVINGS ON OUTPATIENT PHARMACEUTICALS THROUGH THE 340B DRUG PRICING PROGRAM.

Medicaid expansion under the Affordable Care Act (ACA) has opened up eligibility for the 340B Drug Pricing Program to many hospitals. Thirty-one states, including the District of Columbia, have expanded Medicaid eligibility to 138 percent of the federal poverty level or are pursuing alternatives to traditional Medicaid expansion.^a As a result, by August 2015, the nation saw a nearly 22 percent increase in the population served by Medicaid, and the Children's Health Insurance Program (CHIP), already the single largest insured group in the country, grew by roughly 14 million people—compared with pre-ACA levels.^b

The 340B program is administered by the Office of Pharmacy Affairs of the Health Resources and Services Administration (OPA/HRSA), a part of the U.S. Department of Health and Human Services (HHS). It was established in 1992 to require drug manufacturers to provide certain eligible healthcare organizations—deemed “safety net” providers—with significantly reduced pricing for outpatient pharmaceuticals required to serve their patient populations. Cost savings under the program can amount to 25 percent of an organization's annual outpatient pharmaceutical cost in the initial year of participation, with savings being in perpetuity as long as the provider stays qualified for the program.

The key factor determining a hospital's eligibility to participate in the 340B program is the extent to which the hospital serves a large percentage of low-income patients defined as Medicaid-eligible (and not eligible for Medicare Part A) as well as Medicare Part A eligible patients who also qualify for federal Supplemental Security Income (SSI) payments, as is characteristic of hospitals qualifying for Medicare disproportionate share hospital (DSH) payments. In fact, the formula for qualifying on a quantitative basis for the 340B program is exactly the same as the pre-ACA Medicare DSH criteria (see the sidebar below). The difference is simply the threshold level: For Medicare DSH, it is 15 percent, whereas for 340B, a DSH hospital must meet a threshold of 27.32 percent. For rural referral centers and sole community hospitals, the threshold is 22.8 percent.

With Medicaid expansion, hospitals that have not previously qualified for the 340B program have an important new opportunity to gain eligibility. Moreover, that opportunity even extends to hospitals in states that have not expanded Medicaid, through out-of-state Medicaid services—i.e., services provided to Medicaid enrollees in expansion states who receive care in non-expansion states.

In addition, hospitals that had previously qualified for 340B but lost eligibility due to changes reflected in the recent 2013 published metric on SSI or to a Medicaid utilization decline now have an opportunity to requalify.^c

To illustrate key points in our discussion of the process required to both qualify for and succeed under the 340B program, we will highlight the experiences of a large academic medical center (AMC) on the East Coast that successfully navigated a fast-track process in early 2015 and went on to achieve a 25 percent savings on pharmaceutical expense in its first year in the program.

340B FastTrack Process

Hospitals seeking to participate in the 340B Drug Pricing Program must first understand the compressed time frames during which an organization can apply: OPA/HRSA will accept applications only during any of four 15-day windows occurring on the first 15 days of each calendar quarter (i.e., Jan. 1-15, April 1-15, July 1-15, and Oct. 1-15). If an applying organization is accepted into the program, its participation begins on the first day of the next calendar quarter. If a hospital misses these windows of opportunity, those savings are not retroactively obtainable and the start of the program is deferred another quarter.

The experience of our case study AMC underscores the importance of being aware of the application time frames. The organization has a December 31 fiscal year end, with a cost report due date of May 31. Once it became apparent that participation in the 340B program was a viable option, the AMC was proactive in preparing its application as quickly as possible to meet the April 1-15, 2015, window. Had the AMC delayed this effort until after it had filed its cost report on May 31, 2015, it would have had to wait until the July 1-15, 2015, window to apply for the 340B program. Then, even if the AMC were approved, it would have had to wait until October 1 to begin program participation, with the result that it would have missed out on substantial savings that it actually was able to achieve during the third quarter of 2015.

Quick acceptance into the program was possible because the AMC's state had expanded Medicaid early in the process, and because the AMC had previously been within 15 to 20 percent of qualifying for the 340B program before Medicaid expansion. These circumstances allowed the AMC to undertake a "fast track" 340B process to speed its entry into the program and help ensure its continued participation moving forward. At this point, a fast-track process may be available to any currently nonparticipating organization in a Medicare expansion state.

Such a fast-track process requires three broad steps:

- Use data analytics to assess both current and future percentages of Medicaid utilization and eligibility for federal SSI cash benefits.
- Determine the feasibility of early cost report filing.
- Prepare appropriate documentation and undertake the initial enrollment process.

Use of Data Analytics for Medicaid and SSI Visibility and Projections

To qualify for the 340B program on a fast-track basis and maintain compliance, a hospital must make a fundamental switch from verifying and tracking patient eligibility on an episodic basis to doing so on a continuous basis for all recipients of government-subsidized or government-paid health care. This population constitutes more than 60 percent of the insured lives in this country, including Medicaid, Medicare, CHIP, and all manner of government-based payers at the not only federal but also the state and local levels.

This ongoing tracking and reporting of patient eligibility can affect both the Medicaid and SSI metrics of the Medicare DSH calculation. HRSA uses the pre-ACA Medicare DSH formula to determine whether a hospital will qualify for the 340B program. Continuous data exchange between a hospital and both federal and state eligibility authorities provides the necessary visibility for assessment of the hospital's experience during the year, rather than at year end. As a result, the hospital avoids a year-end surprise in discovering that it has fallen below the threshold of 340B-eligible beneficiaries, which would force the hospital to scramble to find additional retroactive Title XIX allowable days to prevent an irrevocable interruption in cash flow.

In a Medicaid expansion state, it is important that the hospital understand three key points:

- How the state's expanded Medicaid population will differ from its pre-ACA Medicaid enrollment
- Where the state intends to place the expanded Medicaid population (for example, some patients might be funneled to a Medicaid ACO)
- How the state will "code" the expanded population in its eligibility response data files

Regarding the third point, states have three options for coding the expanded Medicaid population:

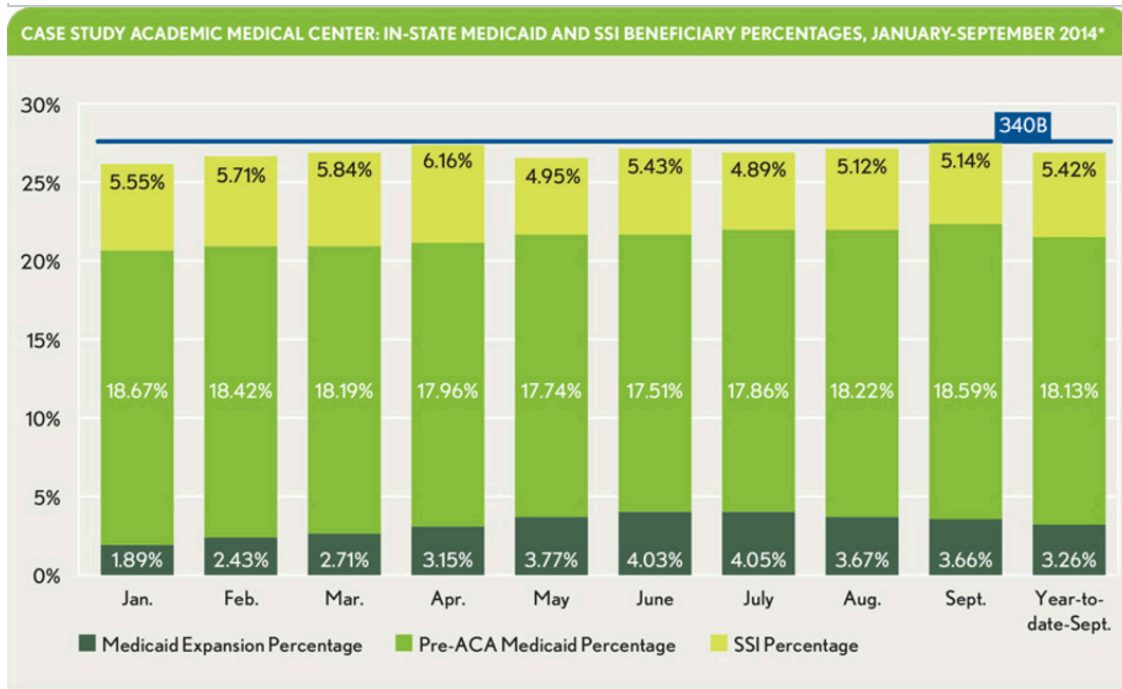
- Use an existing aid category/program code that already falls under the Medicaid classification.
- Convert an existing non-Medicaid aid category/program code to a Medicaid category.
- Develop a new series of aid categories/program codes to apply to all or some portion of the newly enrolled Medicaid members.

The state in which our case study AMC is located elected to use a series of existing program codes with different implementation dates, to capture all the ACA-qualified Medicaid members, but, unfortunately, the state did not inform its hospitals of this decision in a timely manner.

To obtain such information, a hospital should check with its state Medicaid department.

With an understanding of how the state will code Medicaid-expansion beneficiaries, the hospital can assess its potential for qualifying for the 340B program. To illustrate such an assessment, the exhibit below shows the concurrent utilization pattern for the case-study AMC for the first nine months of its 2014 calendar year, compared with the 340B program's 27.32 percent utilization threshold that hospitals must exceed to qualify for the program.

Case Study Academic Medical Center: In-State Medicaid and SSI Beneficiary Percentages, January-September 2014



* These metrics represent only the organization's in-state Medicaid members; the AMC also participates with 28 states' Medicaid programs.

The yellow-green bars (on top) indicate the calculated monthly Supplemental Security Income (SSI) percentages based on aid category information provided by the state via 270/271 EDI data exchange. This metric illustrates those Medicare Part A/C inpatient days where the member is eligible for federal SSI cash benefits and is not institutionalized; it tracks closely to the CMS published annual SSI value most recently released for the case-study academic medical center described in this article.

The light green bars (middle) indicate the Medicaid percentage for those members who were already in a Medicaid fee-for-service or HMO plan before the Medicaid expansion under the Affordable Care Act (ACA) and retained their membership in the months shown.

The dark green (bottom) bars indicate Medicaid members who enrolled as a result of the ACA Medicaid expansion and required inpatient care.

The blue line on the top of the chart shows the 340B eligibility threshold for urban hospitals.

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The data shown in the exhibit indicate that the AMC would fall short of qualifying for the 340B program. However, based on its prior utilization experience and nationally recognized status as a regional referral center capable of taking out-of-state Medicaid-eligible (but not Medicaid-paid) admissions, the AMC also was able to project an increase of 4 to 5 percent in its total allowable Title XIX (Medicaid) days as a result of the Medicaid expansion. This projection effectively moved the AMC's September 2014 year-to-date utilization metric for 340B program eligibility to 27.71 percent, or 0.39 percent above the program's threshold.

It should be noted that although relatively few institutions would be able to count out-of-state Medicaid beneficiaries toward meeting the threshold for 340B program participation, for many organizations, the Medicaid expansion within the home state may be large enough for the organization to qualify without the need to count additional out-of-state beneficiaries.

The Advantage of Early Cost Report Filing

Ultimately, it became clear from the data through the first three quarters of the AMC's fiscal year combined with projections for the fourth quarter based on historical trends for national Medicaid payers that the AMC was a strong candidate for participation in the 340B program. At this point, the AMC further learned that it could accelerate its application for the program by moving the filing date for its cost report up to April 14, thereby allowing submission of an "as-filed" Medicare cost report with the 340B application within the April 1-15 window, and avoiding the need to wait until the July 1-15 application window. If approved, this change would qualify the AMC for program participation one quarter earlier (July 1 as opposed to October 1) than would have been possible had it filed its cost report on May 31. This accelerated filing ultimately translated into direct cost savings of roughly \$1.8 million for the additional quarter of 340B participation.

The AMC's initially determined eligibility status was corroborated at the end of January 2015 when analysis of data for the final quarter revealed that its final DSH percentage was 27.92 percent.

Initial 340B Enrollment Process and Implementation

The initial step required to prepare for an online enrollment application on the OPA/HRSA website is to gather the requisite documentation. To qualify for the program, a healthcare organization must present documents establishing that it meets three requirements.

The hospital must be government-owned or government-controlled. HRSA has stated that to be eligible for the 340B program, a hospital must be "owned or operated by a state or local government; be a public or private non-profit corporation which is formally granted governmental powers by a unit of state or local government; or be a private non-profit hospital with a contract with a state or local government to provide health care services to low-income individuals who are not entitled to benefits under Medicare or Medicaid."^d

The hospital must have a sufficient Medicare DSH adjustment percentage. Urban acute care DSH hospitals must have an adjustment percentage greater than 11.75 percent for the most recent cost reporting period ending before the calendar quarter in which the hospital is submitting its application.

The hospital must not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. Hospitals are required to sign a written certification to this effect.

The requisite documents include a recently filed Medicare Cost Report Worksheet A and Worksheet C and the associated working trial balance. A private not-for-profit hospital also is required to identify a contract with a state or local government to provide healthcare services to low-income individuals who are not entitled to benefits under Medicare or Medicaid.

Working with the state Medicaid office, the case-study AMC was able to identify a contract that would meet the first requirement. As part of the OPA/HRSA approval process, a newly enrolled entity must provide the name, title, organization, and contact information, including a valid email address, for a government official who could certify the entity's public ownership and operation and/or an appropriate contractual relationship (e.g., a state director who oversees the Medicaid program and can verify the organization's public ownership). That individual is contacted by email and requested to verify the registrant's status by following the link provided in the email within the next five calendar days, or by the end of the registration period, whichever comes first.

As part of the enrollment process, because the AMC is not only a large, complex teaching institution but also a health system with numerous facilities, it was necessary to review the Medicare cost report and trial balance to identify which specific hospital locations and departments potentially could participate and be enrolled in the 340B program. In addition to the main hospital location, all outpatient clinics and services not located within the AMC's main campus that intend to use or purchase 340B drugs for their patients needed to be identified so they could be registered with the 340B program as "child sites." Any service site that can receive payment as a provider-based facility and is not at the address of the main entity has the option to participate. If the main entity desires to provide the site with the 340B discounted price drugs, the site also must be registered. Generally the determination to register a child site is based on the potential volume of drug usage.

It also was necessary to review the AMC's methodology for providing drugs to outpatients and establish and implement a standard best practice in all locations to ensure the organization would be fully compliant with the 340B program. In addition, tracking methods were provided so that the AMC also had to establish methods for tracking pharmaceutical-prescribing performance so it would be prepared to address any audit requirement. Policies and procedures were established to provide hospital staff with processes for maintaining operational compliance, and ongoing self-audits were performed to test staff adherence to these processes.

During the April 1-15 open enrollment, the AMC undertook the online process of completing the registration form after having gathered all the requisite information and documentation needed to complete the registration process in a timely manner. Once approved, an email confirming successful enrollment in the 340B program was sent to the authorizing official designated in the registration. This email included the date on which the AMC was authorized to begin purchasing 340B discounted drugs and the AMC's 340B identification number. At this point, the AMC was ready to begin the ongoing process of maintaining compliance with the 340B program requirements.

The Financial Imperative of 340B Participation

The 340B program is a critical program for many hospitals in the United States that struggle with the financial challenges of delivering health care, including outpatient pharmaceuticals, to populations with large numbers of uninsured and underinsured individuals. Healthcare organizations that might qualify for participation in this program are well-advised to devote the requisite resources not only to qualify for the program but also to maintain coverage and compliance once accepted.

A critical prerequisite for any organization seeking to participate in the 340B program—whether it be a large AMC like our case study organization or a small community hospital—is to obtain visibility into utilization trends that will determine the extent to which it meets the criteria for qualification. The organizations that qualify for the short- and long-term substantive cost reductions available through the 340B program are, by definition, those that serve large populations of under-insured patients whose costs for treatments far outweigh the payments the organizations receive for delivering those treatments.

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Footnotes

- a. State Refor(u)m, "[Map: Where States Stand on Medicaid Expansion Decision](#)," Nov. 13, 2015, accessed Nov. 28, 2015.
- b. Kaiser Family Foundation, "[Total Monthly Medicaid and CHIP Enrollment](#)," August 2015.
- c. [The SSI metric](#) is published by CMS annually and is equal to the Medicare fraction in the formula for 340B and Medicare DSH.
- d. See "[Clarification of Eligibility for Hospitals that Are Not Publicly Owned or Operated](#)," 340B Drug Pricing Program Notice, HRSA, March 7, 2013.
- e. All organizations participating in the 340B program receive a unique identification number to be used by manufacturers, wholesalers, and others to verify an entity's participation in the program.

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