

# Establishing 340B Eligibility

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*A Step-by-Step Guide for Determining the Eligibility of Your Organization and Initiating 340B Contracts*

## Section 340B Contract Creation & Management

Section 340B of the Public Service Act makes it possible for Disproportionate Share Hospitals (DSH) and other healthcare-related entities to serve underprivileged populations more cost-effectively. Section 340B requires drug manufacturers provide outpatient medications at lower prices to eligible healthcare organizations, or “Covered Entities.” A 340B contract can provide tremendous savings to a covered entity, and initiating the contract is a relatively straightforward process which can be completed in a few short steps.

## Background

In 1992, section 340B of the Public Service Act began requiring wholesalers to provide front-end discounts on outpatient medications to covered entities. The move was meant to compensate for price increases related to Medicaid reform. The federally-funded program is designed to provide cost savings for covered entities, allowing them to continue serving the underprivileged or fund needed hospital improvements.

*Covered Entities that maintain 340B contracts will typically experience medication cost-savings of about 40% of their entire outpatient drug cost*

Once a hospital or clinic is established as a Covered Entity and has 340B pricing, there are two ways to fulfill the documentation obligations of the contract and maintain manage control over its outpatient drug cost: manual or automated. Manual management delivers the same savings as automated management, but can require maintaining two sets of orders, inventories, and invoices. Automated 340B contract management uses software to track and manage eligible medication orders. There are costs associated with the software, but the automated process reduces the staff time required and can capture savings that manual processes may miss.

The first step toward determining eligibility for the 340B program is to establish Covered Entity status. Then, it’s simply a matter of completing a few forms and implementing a manual or automated tracking and management system. It can be that easy.

## Qualifications

In order to become a qualified 340B Covered Entity, an eligible health care center must either be defined as one of the categories shown here or categorized as a Disproportionate Share Hospital.

The organizations qualified for coverage as a 340B Covered Entity are:

1. **Federal Qualified Health Centers (FQHC)**, including Consolidated Health Centers, Migrant Health Centers, Health Care for the Homeless, Healthy Schools and Healthy Communities, Health Centers for Residents of Public Housing
2. **FQHC Look-a-Likes**, organizations that meet all other eligibility requirements of an organization receiving PHS Section 330 grants, but do not receive grant funding
3. **Office of Tribal Programs** or Urban Indian Organizations receiving funds under Title V of the Indian Health Care Improvement Act
4. **Family Planning** receiving grants or contracts under Sec. 1001 PHSA. Those who are eligible have to submit a registration form
5. **Ryan White Care Act grant recipient** under Title XXVI, part C, subpart II of the RWCA
  - a. A qualified patient under this entity must: Be diagnosed with HIV or AIDS, have an income too low to pay for care, and have no health insurance or not enough insurance to pay for the care needed.
6. **State-operated AIDS Drug Assistance Program (ADAP)** receiving assistance under the RWCA
7. **A Black Lung Clinic** receiving funds under Section 427(a) of the Black Lung Benefits Act
8. **A Comprehensive Hemophilia Diagnostic Treatment Center** receiving a grant under section 501 of the Social Security Act
9. **A Native Hawaiian Health Center** receiving funds under the Native Hawaiian Health Care Act of 1988
10. **Any entity receiving assistance under Title XXVI of the SSA**, other than a State or unit of local government or an entity described in subparagraph (D). Entities must be certified by the Secretary
11. **A Secretary Certified Entity receiving funds** through a State or unit of local government
  - a. relating to treatment of sexually transmitted diseases (**section 318**)
  - b. relating to treatment of tuberculosis (**under section 317(j)(2)**)
12. **Children's Hospitals** defined in the Social Security Act as a hospital whose inpatients are predominantly individuals under 18 years of age.
13. **A Disproportionate Share Hospital**, a hospital which treats a relatively large percentage of underprivileged patients. When a hospital helps the community with healthcare, the government helps the hospital by lowering drug costs.

## Qualifying as a Disproportionate Share Hospital

Disproportionate Share Hospitals (DSH) can receive greatly reduced 340B contract pricing on outpatient medications. In the current economic climate, more hospitals are able to qualify every quarter and it is estimated that up to half of all US hospitals may be eligible for DSH status. Just two years ago only 26.6% of health care centers qualified as DSH. Now, a greater number are discovering that while they may not have been eligible in the past, they may qualify now or soon. All it takes to determine eligibility is the completion of four easy forms and verification of a few qualifications.

*In 2009, the drug spend in the US will be \$11.3B, up to \$4B of which will be outpatient medications at 340B-eligible care facilities.*

DSH hospitals in the United States for Fiscal Year 2009 have a drug spend of \$11.3B, and about \$3.5B to \$4B is comprised of outpatient medications at 340B care facilities. Calculated at the average expected savings of 40%, the 340B savings at a 350 bed hospital could be \$1.5m in hard dollars, recurring every year.

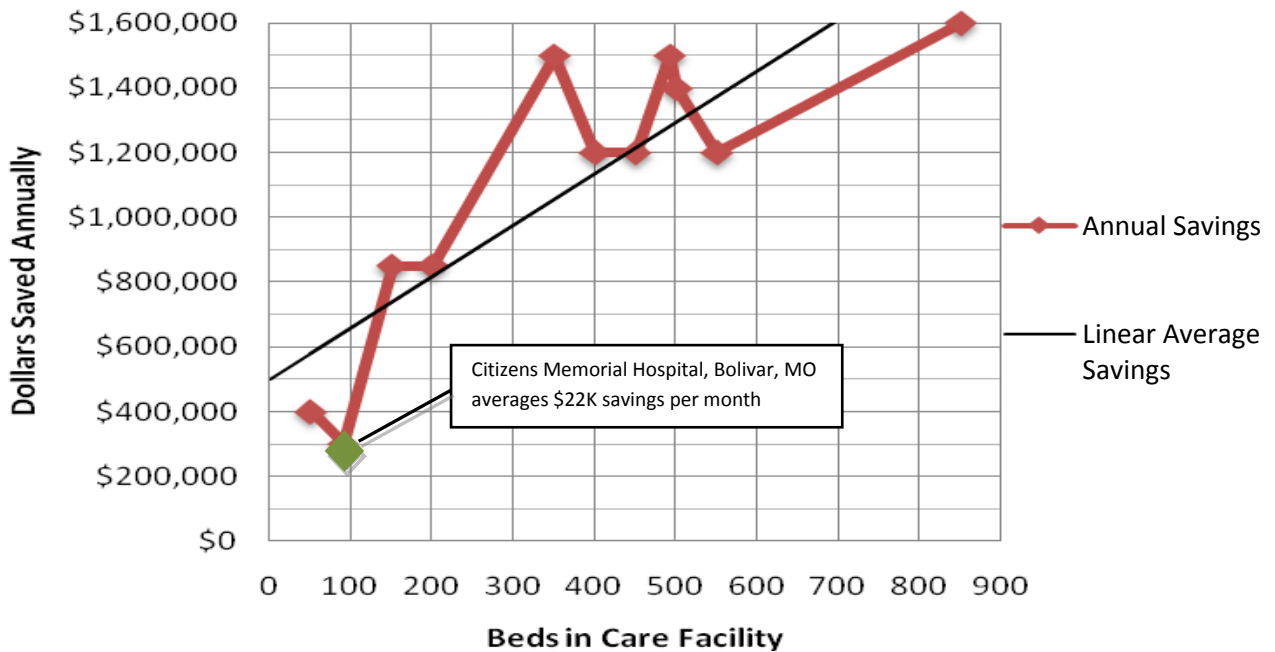


Fig. 1 - Example of potential 340B Program savings based on beds.

DSH hospitals are determined by the percentage of underprivileged patients they treat. A DSH adjusted percentage above 11.75% qualifies an entity for a 340B contract. A patient’s income does not affect whether or not they are covered by 340B; outpatients are covered, inpatients are not.

The Covered Entity is the qualification and must maintain control of the patient's care and medical records for the patient to be covered. If the outpatient is referred to a specialist, the patient is covered under 340B as long as the Covered Entity has responsibility for the patient.

There are two methods used to determine DSH status. The primary method is for hospitals to calculate their DSH patient percentage based on a standard formula. The DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. The DSH patient percentage is defined as:

$$\begin{aligned}
 & \text{(Medicaid, Non-Medicare Days / Total Patient Days)} \\
 & + \text{(Medicare SSI Days / Total Medicare Days)} \\
 & \hline
 & = \text{DSH Patient Percent}
 \end{aligned}$$

The second method is designed for large, urban hospitals able to show that more than 30 percent of their total net inpatient care revenues come from State and local governments for indigent care (other than Medicare or Medicaid). Hospitals able to demonstrate this are eligible for a DSH payment adjustment.

## Checks to 340B Qualification

- Be a qualified entity**
  - Operate as qualified entity, as listed under “Qualifications” above or qualify as a Disproportionate Share Hospital (DSH). DSH hospitals must have a DSH adjustment above 11.75%, using an adjusted formula, the results of which can be found in an Excel spreadsheet at:
    - <http://www.hrsa.gov/opa/dsh.htm> under “Disproportionate Share Hospitals & Their Disproportionate Share Adjustment Percentage”
- Fulfill obligations to provide healthcare to indigent populations**
  - Must be owned and operated by state or local government -OR-
  - Must be a private non-profit hospital, under contract with the state to provide for low income people not covered by SSA XVII.
- Must be granted government powers by the State at local level**
  - This is a formal recognition that the entity will provide healthcare for the medically indigent population in the State
  - Must choose to not take part in Group Purchasing Orders (GPO). The Prime Vendor Program fights for even more affordable medications for 340B eligible entities, acting along the same lines as a GPO, but legal and encouraged
- Send a letter to enroll in the 340B drug pricing program**
  - A blank letter is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHEnroll.pdf>
- Complete the certification regarding non-participation in a Group Purchasing Organization (for All Hospitals)**
  - A blank declaration is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHNonPartGPO.pdf>
- Complete forms for inclusion of Outpatient DSH Facilities**
  - A blank form is available at <http://www.hrsa.gov/opa/dsh.htm> Click “Inclusion of Outpatient DSH Facilities”
- For Private, Non-Profit Facilities only**
  - Certification of a Contract between a Private Non-Profit Hospital and Local Government
  - A blank declaration is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf>
- Have all forms completed and submitted one month before the start of the next quarter**
- Investigate automated software to manage your 340B contracts**

## What's the Next Step?

Implementing a system of documentation and reporting is the next step. It will be important to keep 340B-eligible medications separate from the more expensive inpatient medications. Remember, a patient's income level does not determine their eligibility for the 340B program; it's whether they are an inpatient or outpatient. Tracking and management of 340B-eligible medications can be accomplished by either manual or automated processes.

The manual process typically works best if a Covered Entity maintains a separate 340B medication inventory for outpatients, keeping the inpatient inventory in another location. Nurses manually designate each patient as inpatient or outpatient, and later separate their medication bills according to whether or not they are 340B eligible. It is labor intensive and time-consuming, and maintaining separate inventories and billing can pose problems should the Covered Entity be audited by the Centers for Medicare & Medicaid Services (CMS). Common problems with a manual process include the increased expense and potential for waste maintaining different inventories. Even with extra hours of pharmacist sorting, separate billing, and expiring medications, if you maintain careful records and have a diligent staff, the manual method will capture enough of your potential 340B savings to make it worthwhile.

*Eligible facilities can be reimbursed for 340B drug rebates from previous months when they did not capture all of the savings, as long as they were a 340B-eligible hospital at the time.*

An automated system could simplify the entire process. With the right software, only one physical inventory is required, while two virtual inventories are managed by software. When it's time to bill patients, an automated system could match 340B medications to outpatients, separate the orders for billing, and document the transaction for auditing. The 340B software will recognize when the virtual inventory of 340B medication is depleted, dispense a non-340B pill, and then bill Medicaid for the 340B rebate. Automated systems eliminate duplicate inventories and duplicated efforts, and tend to capture more 340B-eligible transactions than manual systems. Another benefit of an automated system is the general ease of collecting accurate documentation for CMS audits.

## What to Avoid

**Wholesaler inflexibility.** While 340B offers immense savings potential, there are some avoidable mistakes which will limit the ability to save. Locking in to a specific wholesaler is not necessarily the best way to maximize savings. While the 340B Program puts ceilings on wholesalers' prices, some wholesalers will lower the cost of various other medications to try and become a sole vendor. Although some companies lock in to contracts with manufactures, Covered Entities should have the freedom to change manufacturers whenever they choose. Better still is to have a mixed-vendor order list to take advantage of all available discounts.

**Missed opportunities from previous months.** The 340B Program is meant to help hospitals save money. It is very difficult to know when waste occurs if there are limited or no records of drug spending patterns and trends. The way the 340B Program is set up, it is possible to collect Medicaid rebates for up to 12 months back, as long as a facility still “qualified” as a Covered Entity during those months. If you are planning to use an automated 340B system, make sure the software has “Look-Back” capabilities. After installing the software, savings can be reclaimed in either one large rebate check or through medication discounts until the total sum has been paid back. Either way, the initial look-back could amount to 40% of the previous year’s outpatient drug spend. Also, having “look-back” access to a year or more worth of records is a great feature in case of an audit. Hospitals on 340B are subject to audit by CMS, and heavy fines can accrue if there is not a long list of transactions depicting all 340B activity in an easily exported excel file. Avoid short-term log files, and seek out software that keeps track of all your drug-related finances for years into the past.

**Double dipping.** This term is used to describe an illegal transaction. It’s when a hospital purchases a 340B drug from a wholesaler at or below the ceiling price, and then receives reimbursement from Medicare as if the drug had been purchased at full value. It is critical to have complete records of all purchase orders for auditing purposes. The benefit of automated 340B software with split-billing capabilities is that it tracks eligible usage and splits your orders automatically. Some split-billing software also allows a “Medicaid Carve-Out”, which enables caregivers to buy outpatient medications at full price, and then later bill Medicaid for the rebate. Diligent inventory management is vital to avoid the illegal resale of 340B medications, especially if you have chosen a manual system of 340B tracking and management.

## Conclusion

A small investment of time and the completion of a few forms is well worth the 40% average return on all outpatient medications. By opting for automated 340B Program management software, you can also save hours of staff time and the related costs. Following the *Checks to 340B Qualification* is the first step toward 340B Program eligibility and more efficient, more effective 340B processing. The next step is implementing a process that avoids negative side effects like getting locked in to a wholesaler, not keeping medication records in case of an audit, and double dipping. The final step to becoming a 340B Covered Entity is preparing the process. If you are processing 340B contracts manually, have your staff trained and in place. If you choose an automated system, consider the ongoing costs and your needs; does the software have look-back capabilities? Can it perform Medicaid Carve Outs? Is the software capable of split-billing for more accurate recordkeeping and easier audits?

## Author

Chris Strandin

## Appendix

### Relevant Internet Links

#### Health Resources & Services 340B Program Information

<http://www.hrsa.gov/opa/introduction.htm>

#### 340B Prime Vendor Program

<https://www.340bpvp.com>

#### Prime Vendor Program 340B Split Billing Software Comparison Chart 2007

[https://www.340bpvp.com/public/agreements/services/340B\\_Split\\_Billing\\_Software\\_Comparison\\_Chart.pdf](https://www.340bpvp.com/public/agreements/services/340B_Split_Billing_Software_Comparison_Chart.pdf)

### Required Forms Checklist

#### For all facilities:

- Letter to Enroll In 340B Drug Pricing Program
  - A blank letter is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHEnroll.pdf>
- Certification Regarding Non-Participation in a Group Purchasing Organization (for All Hospitals)
  - A blank declaration is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHNonPartGPO.pdf>
- Inclusion of Outpatient DSH Facilities (for All Hospitals)
  - A blank form is available at <http://www.hrsa.gov/opa/dsh.htm> Click "Inclusion of Outpatient DSH Facilities"

#### For private, non-profit facilities only:

- Certification of a Contract between a Private Non-Profit Hospital and Local Government
  - A blank declaration is available at <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf>