

## MEMORANDUM

**TO:** Wisconsin Pharmacy Cost Committee  
**FROM:** Kirk Williamson, NGA Health & Jane Horvath, Horvath Health Policy  
**CC:** Sandra Wilkniss & Kate Johnson, NGA Health  
**RE:** State Approaches to Leverage the 340B Drug Discount Program

---

This memo is in response to a request for information from the Wisconsin Pharmacy Cost Committee about state strategies to leverage the 340B Drug Discount Program to reduce drug costs. The memo provides (1) an overview of the federal 340B Drug Discount Program, and (2) a brief overview of policy options to consider along with state examples.

### Background

The 340B Drug Discount Program<sup>1</sup> (“340B Program”), administered by the Health Resources Services Administration (HRSA), requires drug manufacturers to provide outpatient drugs to eligible safety-net providers (“covered entities”) at a reduced price, known as the ceiling price.<sup>2</sup>The intent of the 340B Program is to provide those covered entities access to low-cost medications in order to expand the type and volume of care they provide to the safety-net patient populations. There are approximately 53,000 covered entities that fall into 27 categories of eligibility including (not limited to)<sup>3</sup>:

- Disproportionate Share Hospitals
- Children’s Hospitals
- Critical Access Hospitals
- Cancer Hospitals and the Community Oncology Practices owned by Hospital (most group oncology practices are now owned by 340B hospitals)
- Rural Hospitals
- Federally Qualified Health Centers (FQHCs)
- Tribal Clinics
- Ryan White Programs
- Title X Family Planning Clinics

See the full list of eligible organizations/covered entities here:

<http://www.hrsa.gov/opa/eligibilityandregistration/index.html>

---

<sup>1</sup> 42 U.S. Code § 256b ([link](#)).

<sup>2</sup> This is the maximum price that manufacturers can charge 340B covered entities participating for covered outpatient drugs. The 340B ceiling price is the average manufacturer price (AMP) reduced by the unit rebate amount (URA). Because the formula sets a minimum rebate amount for URA, covered entities receive a guaranteed discount off of AMP of 23.1 percent for most brand-name prescription drugs, 17.1 percent for brand-name pediatric drugs and clotting factor, and 13 percent for generic and over-the-counter drugs.

<sup>3</sup> Rough estimate based on [HRSA.gov](http://www.hrsa.gov) website which lists 67,000 covered entities [9/16/2019] and assuming 20% of entities are listed but terminated from the program.

340B covered entities may elect to dispense 340B drugs to patients through contract pharmacy services, and all do. Covered entities may establish agreements either through multiple contracts with individual pharmacies or through a single contract with a chain pharmacy that identifies the specific pharmacy locations that will support the covered entity's 340B program. Based on the regulatory and legislative requirements necessary to minimize fraud and abuse within the program, contract pharmacies may be compensated at a higher dispensing rate to meet such standards and provide indigent care. HRSA guidelines for contract pharmacies may be found here [Notice Regarding 340B Drug Pricing Program — Contract Pharmacy Services](#).

There are approximately 102,000 contract pharmacies<sup>4</sup> which include but are not limited to:

- Walgreens
- CVS
- Kroger
- Independents

Each 340B eligible entity contracts with more than one contract pharmacy. In 2018, 340B discount price sales reached \$24 billion; \$39.2 billion at invoice sales<sup>5</sup>, producing a discount rate of 38-40 percent of Wholesale Acquisition Cost (WAC), however other estimates place the 340B average discount at 50 percent of WAC.

### ***340B Basics: How It Works on The Front End***

340B drugs are ordered directly from wholesalers/distributors by 340B entities, entity 'child sites' (multiple locations of the same eligible entity) and entity contract pharmacies. The drug manufacturers have generally moved to supplying 340B orders with on-invoice discount pricing (rather than back-end rebates). Some manufacturers may use discrete vendors for 340B order fulfillment or use the regular wholesaler channel and reimburse wholesalers for the difference between what the wholesaler paid the manufacturer for the drug and the price at which the wholesaler had to sell to 340B entities. 340B entities can profit from 340B if they bill insurers (except Medicaid and ADAP) at the market price, rather than the lower, 340B acquisition cost.

Contract pharmacies extend the reach of a 340B entity's pharmacy services to patients who might leave the 340B entity before filling their prescription and for subsequent refills. Contract pharmacies may share in the drug revenue that results if a 340B entity buys low (340B prices) and sells high (at market prices) or they may get a flat professional fee from the 340B entity for each 340B prescription filled (which would be in addition to the professional fee billed to, and paid by, the insurer).

340B drugs can be dispensed only to people who are patients of the 340B entity (defined as having regular care with a medical record on site). There are different ways to identify a 340B patient prescription – at the point of service and retrospectively, which is complex and tends to require a separate vendor to review claims and identify 340B eligible dispensing. Bottom line: the prescriber must be affiliated with a 340B entity in order for a 340B drug to be dispensed.

### ***340B Basics: How It Works on The Back End***

If 340B patients have insurance, the 340B entity (or pharmacy on behalf of the entity) may bill insurance at market prices. Presumably, a pharmacist will know whether a patient's prescription is tied to a 340B entity with which they have a contract for dispensing by the letterhead on the prescription. The difference between its (low) acquisition cost and market prices becomes revenue for the 340B entity. Due to the large number of 340B entities

---

<sup>4</sup> Rough estimate based on [HRSA.gov](http://HRSA.gov) website which lists 135,000 contract pharmacies [9/16/2019] and assuming 25% of listed entities are terminated from the program

<sup>5</sup> [Drug Channels](#), this indicates an average discount of 38% in the 340B channel

in the US, the likelihood is high that individuals covered by state, local, and federal government health benefit programs are treated at 340B entities and prescribed drugs for which 340B stock can be dispensed and billed at market price to government payors (other than billing Medicaid and ADAP, which is not allowed under federal law). Full description may be found here:

[https://www.ncdp.org/NCPDP/media/pdf/340B\\_Information\\_Exchange\\_Reference\\_Guide.pdf](https://www.ncdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf)

### **Leveraging 340B: Policy Options and State Examples**

Included below are policy considerations for leveraging the 340B program – a brief summary of policies under discussion or pursued by other states and a more detailed discussion of leveraging 340B in corrections settings, given significant activity in that domain. Navigating federal and state law to pursue these policies is important and beyond the scope of this memo. For a detailed legal analysis of the alternative payment possibilities in the Medicaid Drug Rebate Program, 340B program and in the context of other federal and state laws relevant to Medicaid drug coverage and payment in order to identify legal pathways for establishing prescription drug payment/purchasing approaches, see: <http://centerforevidencebasedpolicy.org/wp-content/uploads/2018/12/SMART-D-Legal-Report-Sept-13-2016.pdf>

#### **Policy Option: Create 340B centers of excellence to treat diseases reliant on high cost drugs**

Because 340B drugs can only be dispensed or administered to patients of a 340B facility, there is a need to link specialists treating diseases with costly drugs to 340B entities. States could consider creating conditions under which disease specialists becomes affiliated with the 340B clinics or hospitals so each of their patients is technically a ‘patient’ of the entity. For example, many 340B hospitals now own community-based oncology practices (that were formerly private practices) precisely because of the margin that can be made on 340B cancer products.

Some states have done this in Medicaid by obtaining a freedom of choice waiver from the Centers for Medicare and Medicaid Services through setting up case management waiver programs. Notably, this was necessary so as not to violate the Medicaid law that requires states to allow freedom of choice of providers. However, state employees and other state agencies do not have the same restrictions.

#### **Policy Option: Ensure that 340B entities are billing state programs at 340B acquisition cost**

States could consider enhancing their enforcement of 340B billing through provider network contracts. State Medicaid programs are becoming more aggressive in monitoring whether they are being billed at the 340B drug price. Although the 340B drug price is confidential, even to Medicaid, at least one state (Colorado) has inferred the 340B price by using the drug’s Medicaid Average Manufacturer Price, to which Medicaid has access. Other states may have different ways of addressing the confidentiality.

Because the Medicaid AMP is confidential to Medicaid, and because the 340B drug prices are confidential to 340B entities, sorting out how to ensure that state entities (other than Medicaid) are not paying more than 340B prices will require a thoughtful approach. However, the fact that tens of thousands of commercial chain pharmacies participate in the program without violating privacy indicates that there are ways to run a 340B acquisition cost billing program without running afoul of federal confidentiality provisions. Interestingly, 340B entities will have just as much interest in retaining confidentiality as the manufacturers do.

NOTE: For the options above it will probably be necessary to compensate 340B entities by increasing professional fee payments (for physician administered drugs) as Florida, West Virginia, Massachusetts, and Louisiana are reported to have done in their Medicaid programs.

## **Policy Option: 340B and Departments of Corrections**

Many states are leveraging 340B to reduce drug spending for Departments of Corrections (DOCs) as correctional health spending is almost entirely underwritten by the state.<sup>6</sup>

According to recent estimates, there are at least 16 state DOCs obtaining 340B pricing for certain drugs. Although DOCs do not qualify as 340B entities under federal statute, several have successfully entered into agreements with covered entities or have utilized their existing arrangements with state universities. These states commonly leverage 340B to cover only specific high-cost drugs (such as those for hepatitis C, hemophilia, and HIV) given the complexity and expense of complying with 340B rules and coordinating the provision of services with various covered entities.

The organizational structure of a DOC's health care delivery system typically dictates the 340B arrangement pursued by the state. DOC organizational structures include:

- **Direct provision** (examples: NV, ND, SD and WA): all or most care is provided by DOC clinicians.
- **Contracted-provision** (examples: FL, IL, KY, MS and WV): all or most care is delivered by clinicians employed by a private vendor.
- **State university** (examples: CT, GA, NJ and TX): all or most care is delivered by the state's public medical school.
- **Hybrid** (examples: LA, PA and VA): care is delivered by some combination of the above models.

States that either directly provide or use a private vendor to provide health care services may access 340B pricing by contracting with 340B providers. Public medical schools can offer distinct opportunities as they are often 340B providers themselves, and the four states that contract with state universities for correctional health care all make at least some use of the program.

Lastly, some states have leveraged funding relationships with their departments of health for access to 340B pricing in correctional settings for drugs that treat sexually transmitted diseases (STDs). 340B statute notes that entities that receive funding under Section 318 of the Public Health Service Act for the treatment of STDs and tuberculosis are considered 340B covered entities if certified by the Secretary. By establishing or leveraging an existing funding relationship with its department of health a state DOC can obtain 340B pricing for products treating STDs, which include HIV and Hepatitis C (which has more recently been designated as an STD).

## **STATE EXAMPLES**

### **State University Model**

#### **Texas**

Texas has a very unique model whereby a university that is a 340B covered entity is the provider of all correctional health care for the state – the University of Texas Medical Branch (UTMB). This model facilitates an established relationship and contractual commitments between the state and the university that makes use of 340B pricing more seamless (compared with other state efforts to leverage 340B). Further, the state is even more unique in that UTMB owns a disproportionate share hospital and has a specific facility designated for the provision of correctional health care. These factors help mitigate some of the barriers other states face in leveraging relationships across multiple providers and multiple clinics to obtain 340B pricing. UTMB provides about 80 percent of correctional health care services for the state (another non-340B university provides the other 20 percent of services). The Texas Department

---

<sup>6</sup> PEW report (2017). Pharmaceuticals in state prisons: How departments of corrections purchase, use and monitor prescription drugs. <https://www.pewtrusts.org/-/media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf>

of Corrections has been able to obtain 340B pricing on drugs through UTMB since about 1994 and state officials attribute the program's effectiveness to Texas' success at keeping drug spending at 7 percent of its total DOC health budget from 2010 to 2015.

### **Hybrid Model**

#### **Virginia**

The Virginia Department of Corrections (VADOC) has an arrangement with Virginia Commonwealth University Health System (VCUHS), which is a 340B entity, regarding the purchase of 340B drugs. Notably, VCUHS is not the contracted entity providing health care for correctional settings, but rather the state has established an agreement with the university specifically related to 340B. VADOC's arrangement with VCUHS dates back to the 1990s and was encouraged in state legislation. The arrangement began with the purchase of HIV drugs and more recently VADOC started using the program for Hepatitis C drugs (2016). The state has since added Enbrel and Humira slowly over the past year and is working on adding eight other high cost, specialty drugs. Virginia state officials have noted that a key challenge is managing the scope as more drugs are added. The nature of the drugs being pursued (specialty) means relationships must be established with unique clinics that serve different patient populations.

### **STD Partnership Model**

#### **Florida**

Florida was the first state in the country to utilize its STD program to expand the use of 340B for corrections. The Florida Department of Corrections entered into an agreement with the Florida Department of Health (DOH) whereby county health department physicians treat inmates through the state's STD program and medications are dispensed through the health department's central pharmacy. The model allows the state to utilize 340B pricing for these inmates because DOH qualifies as a 340B covered entity given that it receives grant funding for its STD program. The approach has resulted in reduced transmission rates and substantial savings to the state. The state indicated that average savings on HIV medications were much more significant than those previously obtained through the Minnesota Multistate Contracting Alliance for Pharmacy.

#### **Other States**

Several other states have implemented similar models with their state health departments to purchase STD drugs at 340B prices. However, other states have taken a slightly different approach than Florida. Rather than have county health departments provide services, other states have established their DOCs as a subgrantee of the DOH, which enables the DOC to itself be a 340B covered entity for STD drugs and dispense drugs directly to inmates. **Iowa, North Dakota, Rhode Island** and **Utah** are states that have implemented this type of sub-grantee partnership model. Similarly, a handful of county and city jails have also formed STD sub-grantee relationships with their state or local department of health.