M E M O R A N D U M

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[1] ("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. [2]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)[3]:

- 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

[1] 42 U.S. Code § 256b (link).
[2] 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.
[3] Rough estimate based on 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[4] 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[5], 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

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[4] Rough estimate based on HRSA.gov website which lists 135,000 contract pharmacies [9/16/2019] and assuming 25% of listed entities are terminated from the program
[5] 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.ncpdp.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.[6]

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 sextually 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

[6] 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.

Wisconsin Medicaid implemented 340B billing and claim-level identifier requirements on April 1, 2017. During the implementation of this policy, Medicaid staff held meetings with various 340B covered entities and learned the following takeaways:

- Margin from 340B-purchased drugs can be the primary funding for other services or costs
- Medicaid and 340B covered entities interpret 340B requirements differently
    - It is Medicaid's interpretation of 340B requirements that if a covered entity has identified they will use 340B-purchased drugs for Medicaid members then all drugs dispensed to Medicaid members should be 340B unless there is an exception or the drug is unavailable, e.g. shortage
    - Covered entities interpret 340B requirements to support that they can selectively determine which products should be dispensed from 340B stock vs. regular stock based on cost savings
- 340B covered entities reported it is a challenge to determine the actual cost at which they acquire 340B drugs
- There is no public list of 340B ceiling prices, so 340B covered entities cannot confirm whether manufacturers are supplying 340B drugs above or below the ceiling price
- 340B discounts vary among covered entities
- General hesitance to pass along 340B savings to another program

Since the implementation of the 340B billing and claim-level identifier requirements we have observed the following:

- Under the pharmacy benefit, reported costs of 340B-purchased drugs are at a much steeper discount than was forecast
    - Medicaid estimated providers could purchase drugs at a rate around WAC -50%, but it seems to be closer to WAC -85%
- Low volume of claims
- Participation varies based on covered entity type
- For some drugs covered under the medical benefit, covered entities do not seem to pass along any discount
    - For some provider-administered drugs, reported costs for 340B drugs are higher than reported costs for non-340B drugs.
    - For hospital claims, we do not require claim-level identifiers so it is unclear if providers are utilizing 340B

Overall, it appears significant cost savings are available to covered entities under the 340B program. However, covered entities rely on these savings for general operations and are hesitant to engage in any practice that would jeopardize the margin they receive on 340B-purchased drugs.

340B Acronym Guide

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Purpose: The purpose of the 340B Acronym Guide is to define common acronyms used in the 340B Program.

Acronym	Definition
AAC	Actual acquisition cost
ACA	Affordable Care Act (abbreviation of PPACA)
ACO	Accountable care organization
ADT	Admission, discharge, transfer system
AGP	Apexus Generics Portfolio
AHF	AIDS Healthcare Foundation
AMCP	Academy of Managed Care Pharmacy
AMP	Average manufacturer price
APhA	American Pharmacists Association
ASHP	American Society of Health-System Pharmacists
ASP	Average sales price
Avg AC	Average acquisition cost
AWP	Average wholesale price
BIN	Bank identification number
BL	Black Lung Clinics Program
BP	Best price
BPHC	Bureau of Primary Health Care
CAH	Critical access hospital
CAN	Free-standing cancer hospital
CAP	Corrective action plan
CBO	Congressional Budget Office
CDM	Charge description master or Charge drug master
CE	Covered entity
CH	Consolidated Health Center Program (now combines 340B eligible entity types: federally qualified health centers (FQHCs), FQHC lookalikes, school-based programs, Health Care for the Homeless Program, Migrant Health Program, and Public Housing Primary Care Program entities)
CIA	Corporate integrity agreement
CMS	Centers for Medicare & Medicaid Services
COD	Covered outpatient drug

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Acronym	Definition
CPI-U	Consumer Price Index-Urban
DoD	Department of Defense
DRA	Deficit Reduction Act of 2005
DSH	Disproportionate share hospital
DSH rate	Disproportionate share adjustment rate
EAC	Estimated acquisition cost
EHB	Electronic Handbook (HRSA)
FAR	Federal Acquisition Regulations
FAR	Final audit report
FASHP	Federation of Associations of Schools of the Health Professions
FCP	Federal ceiling price
FDA	Food and Drug Administration
FFS	(Medicaid) fee for service
FP	Family planning clinic (includes only Title X funded clinics)
FPL	Federal poverty level
FQHC/ FQHCLA	Federally qualified health center/federally qualified health center lookalike
FRN	Federal Register notice
FSS	Federal Supply Schedule
FUL	Federal upper limit
GAO	Government Accountability Office
GPO	Group purchasing organization
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
HIBCC	Health Industry Business Communications Council
HIN	Health Identification Number
HIPAA	Health Insurance Portability and Accountability Act of 1996
HM	Comprehensive hemophilia treatment center
HMO	Health maintenance organization
HRSA	Health Resources and Services Administration
HTC	Hemophilia treatment center
HV	Ryan White Part C (formerly Title III)

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Acronym	Definition
IHS	Indian Health Service
IPAP	Institutional Patient Assistance Program
IPPS	Inpatient Prospective Payment System
ISMP	Institute for Safe Medication Practices
MA	Medicare Advantage
MAC	Maximum allowable cost
MCO	Managed care organization
MDRP	Medicaid Drug Rebate Program
MEF	Medicaid exclusion file
MMA	Medicare Modernization Act
MMCO	Medicaid managed care organization
MPN	Medicaid provider number
MTM	Medication therapy management
MUA	Medically underserved area
MUP	Medically underserved population
NABP	National Association of Boards of Pharmacy
NACHC	National Association of Community Health Centers
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NFPRHA	National Family Planning and Reproductive Health Association
Non-FAMP	Non-federal average manufacturer price
NPI	National Provider Identifier
NPRM	Notice of proposed rulemaking
ODA	Orphan Drug Act
OIG	Office of Inspector General
OOPD	Office of Orphan Products Development
OPA	Office of Pharmacy Affairs
OPAIS	Office of Pharmacy Affairs Information System
PAD	Physician-administered drug
PAP	Patient assistance program
PAR	Preliminary audit report

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Acronym	Definition
PBM	Pharmacy benefit manager
PCA	Primary care association
PCN	Processor code number
PDF	Professional dispensing fee
PDL	Preferred drug list
PDP	Prescription drug plan
PED	Children's hospital
PHCP	Public Hospital Pharmacy Coalition
PHS	U.S. Public Health Service
PHSA	Public Health Service Act
PPA	Pharmaceutical pricing agreement
PPACA	Patient Protection and Affordable Care Act (Affordable Care Act)
PPO	Preferred provider organization
PPS	Prospective payment system
PSAO	Pharmacy services administrative organization
PSPC	Patient Safety and Clinical Pharmacy Services Collaborative
PTAN	Provider transaction access number
PVP	Prime Vendor Program
RRC	Rural referral center
RWI	Ryan White Part A (formerly Title I)
RWII	Ryan White Part B (formerly Title II)
RWIID	Ryan White Part B (formerly Title II) ADAP Direct Purchase
RWIIR	Ryan White Part B (formerly Title II) ADAP Rebate Option
RW4	Ryan White Part D (formerly Title IV)
SCH	Sole community hospital
SNHPA	Safety Net Hospitals for Pharmaceutical Access
SPA	State plan amendment
SPAP	State pharmaceutical assistance program
SPNS	Ryan White Part F (formerly Special Projects of National Significance)
SSA	Social Security Act
STD	Sexually transmitted disease clinic

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Acronym	Definition
TB	Tuberculosis clinic (HRSA acronym)
TrOOP	True out-of-pocket cost/spending
URA	Unit rebate amount
VA	Department of Veterans Affairs
WAC	Wholesale acquisition cost

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

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