

POWERS

POWERS PYLES SUTTER & VERVILLE PC

ATTORNEYS AT LAW

Recommendations for a 340B Correctional Partnership in North Carolina

May 20, 2019

Recommendations for a 340B Correctional Partnership in North Carolina

**Prepared by
Powers Pyles Sutter & Verville PC**

SUMMARY

The NC Legislative Services Commission (the “Commission”) engaged the Powers Law Firm to develop a proposal for a correctional partnership through which drugs purchased under the federal 340B drug pricing program (“340B program”) can be used for the North Carolina prison population. In preparing this report, we spoke with various stakeholders, including the NC Department of Public Safety (“DPS”), NC Department of Health and Human Services (“DHHS”), and University of North Carolina Health System (“UNC”). Our review of the information provided by these stakeholders, combined with our understanding and analysis of 340B program requirements, has led us to offer three recommendations, which would allow DPS to partner with 340B program participants in order to maintain or improve care and significantly reduce drug costs for the North Carolina inmate population.

- **Recommendation 1. The General Assembly Should Direct DPS to Partner With NC DHHS to Enroll In the 340B Program as an STD Sub-Grantee and Use the Program to Purchase Medications, Including HIV and HCV Drugs, for the STD Inmate Population.** We recommend that the General Assembly direct DPS to apply for a sub-grant from DHHS so that DPS may enroll in the 340B program and access 340B pricing for medications used to treat the human immune deficiency virus (“HIV”) and the hepatitis C virus (“HCV”). This partnership with DHHS would allow DPS to access 340B pricing on HIV and HCV, which are among the most expensive medications provided to inmates, leading to an estimated \$8.25 to \$8.5 million in annual savings. Access to 340B savings on HCV medications will likely be even more financially impactful in light of recent class action litigation.
- **Recommendation 2. The General Assembly Should Direct DPS to Issue an RFP for a Partnership With One or More 340B Hospitals to Serve Non-HIV/HCV Inmates.** With respect to the non-HIV/HCV inmate populations, we recommend that the General Assembly direct DPS to issue a request for proposals (“RFP”) for one or more 340B hospitals to partner with DPS in order to provide both hospital specialty care and 340B pharmacy services to the target population. The correctional partnership could be based on a telemedicine model, a visiting professional model, or some other partnership model that is currently being used in other states. The RFP process would incentivize bidding hospitals to pass much of their 340B discounts to the State in order to win the bid, which should generate significant savings.
- **Recommendation 3. The General Assembly Should Direct that DPS Partner With UNC to Receive 340B Savings on Non-HIV/HCV Retail Medications Prescribed As a Result of Treatment Provided at 340B-Registered UNC Locations.** For retail prescriptions currently written by a DPS provider following a consult with UNC, we recommend that the General Assembly direct that the prescribing authority be shifted from the DPS provider to a UNC provider in a manner that improves or maintains quality and continuity of care. Shifting the prescribing authority for these medications would generate additional 340B savings as a result of treatment that is currently being provided at 340B-registered UNC sites. Although a savings estimate is not available, the savings could be significant for high cost medications.

MEMORANDUM

To: North Carolina Legislative Services Commission
Joint Legislative Oversight Committee on Justice and Public Safety

From: Powers Pyles Sutter & Verville, PC

Date: May 7, 2019

Subject: Recommendations for a 340B Correctional Partnership in North Carolina

The NC Legislative Services Commission (the “Commission”) engaged the Powers Law Firm to develop a proposal for a correctional partnership under which drugs purchased under the federal 340B drug pricing program (“340B program”) can be used for the North Carolina prison population. In preparing this report, we spoke with various stakeholders, including the North Carolina Department of Public Safety (“DPS”), the North Carolina Department of Health and Human Services (“DHHS”), and the University of North Carolina Health System (“UNC”).

I. FACTUAL BACKGROUND

A. Program Evaluation Division Report and State Legislation

In 2018, the Program Evaluation Division (“PED”) of the North Carolina General Assembly’s Legislative Services Office conducted a study on the efficiency and economy of inmate pharmacy purchasing at the direction of the Joint Legislative Program Evaluation Oversight Committee (the “Committee”). PED’s final report, titled “Modifications to Inmate Pharmacy Purchasing and Monitoring Could Save \$13.4 Million Annually” (“PED Report”), found that DPS’s failure to participate in the 340B program caused the State to pay more for inmate prescription medications than necessary.¹ The PED Report recommended that DPS establish a correctional partnership arrangement with UNC under which DPS could access 340B discounts. PED estimated that if DPS participated in a 340B correctional partnership, it would save the State approximately \$13.3 million annually on HCV and HIV medications and potentially more if DPS could access 340B discounts for other medications.

In response to the PED Report, the Committee recommended legislation to implement PED’s recommendations, which became House Bill 1108, enacted December 6, 2018. The legislation directed the Commission to engage a 340B consultant to prepare a “proposal for the HRSA-compliant purchasing of inmate medications through a Disproportionate Share Hospital (DSH), including, but not limited to, the University of North Carolina Health System.” After issuing a request for proposals, the Powers Law Firm was hired to prepare the proposal for a 340B correctional partnership in the State. Powers has direct experience designing and

¹ https://www.ncleg.net/PED/Reports/documents/InmateHealth_Rx/Report2_Pharma.pdf.

implementing a number of 340B program correctional partnerships, including the first correctional partnership in the country involving the University of Texas Medical Branch at Galveston (“UTMB”) and the Texas Department of Criminal Justice. Since then, we have used our Texas experience to assist dozens of other states, cities, and counties with designing, implementing, and/or assessing 340B correctional partnerships of their own. Our experience advising clients on correctional partnerships extends to defending covered entities against audit findings from the Health Resources and Services Administration (“HRSA”) related to the entity’s 340B correctional program.²

B. DPS Facilities and Pharmacies

In contrast to many other state correctional programs, DPS provides a significant amount of health care services “in house” through its Health Services staff. For example, DPS Health Services provides all primary care to state prisoners via DPS-employed physicians.³ For specialty care, DPS typically uses an external provider or contracted provider. The external provider does not write prescriptions but issues “consult orders,” or recommendations which the DPS primary care physician considers in determining whether to write a prescription based on the patient’s drug profile and broader medical history. The exception is for HIV and HCV medications, which are written by outside providers who are currently contracted through UNC.

As of June 2018, DPS provided supervision and services to 37,104 inmates across 55 prison sites. A total of 1,058 inmates received either HIV or HCV medications in State fiscal year (“SFY”) 2017.⁴ DPS Health Services operates three pharmacies:

- Central Pharmacy in Apex (“Apex Central Pharmacy”),
- a pharmacy located on-site at Central Prison in Raleigh (“Central Prison”), and
- a pharmacy located on-site at the North Carolina Correctional Institute for Women (“Women’s Prison”) in Raleigh.

Apex Central Pharmacy processes medication orders for the vast majority of the State’s prison population. Medications dispensed by Apex Central Pharmacy are distributed to inmates through a private shipping vendor, the State’s courier system, or via pickup by prison staff. The two additional pharmacies located on site in Raleigh primarily dispense medications for inmates in those prisons or in health centers within those prisons.

The three DPS pharmacies dispense in aggregate approximately 6,000 orders per day. The majority of orders are filled by Apex Central Pharmacy, at an average of 5,125 orders per day. The Central Prison pharmacy dispenses an average of 489 orders per day, and the Women’s Prison pharmacy dispenses an average of 369 orders per day. A DPS-employed pharmacist

² HRSA is the agency within the U.S. Department of Health and Human Services that is responsible for administering the 340B program.

³ Some DPS-employed physicians are employed through agreements with staffing agencies.

⁴ NC’s fiscal year begins July 1 and runs through June 30 of the following year. SFY17 was the period from July 1, 2016 through June 30, 2017. This is a duplicated count and some inmates might have co-occurring conditions.

processes and reviews each order for compliance with DPS's formulary, pharmacy and therapeutic committee decisions, DPS policies and procedures, and clinical practice guidelines. DPS also provides starter packs at its outpatient prison facilities that provide an initial few days' supply of commonly used medications for orders that need to be started immediately. DPS has indicated that it does not use any special packaging for medications.

DPS participates in the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"), through which DPS currently orders the majority of its medications. MMCAP is a voluntary group purchasing organization for governmental entities that provide health care services. MMCAP negotiates discounts based on the volume purchasing powers of its members. DPS reported receiving a discount of 6.12% above and beyond contract prices. The MMCAP website lists the "340B Program" as one of the programs available to its members.⁵ An MMCAP presentation from October 2017 lists "corrections use of 340B" as a "national value opportunity" and states that "340B through MMCAP adds to state volume discount," suggesting that members can purchase 340B drugs through MMCAP and those purchases would contribute to the aggregate state volume on which discounts are based.⁶

C. Services Currently Provided by UNC to Inmates

DPS has contracted with UNC to provide specialty clinic and inpatient care on-site at DPS locations as well as off-site at UNC locations. UNC physicians provide the bulk of infectious disease treatment to inmates. UNC practitioners staff on-site infectious disease clinics at Central Prison and the Women's Prison. The infectious disease clinics located on-site at DPS are not UNC hospital-based clinics. A UNC specialist conducts an initial in-person evaluation of inmates referred for HIV or HCV treatment and develops a treatment plan. The treatment plan is implemented by a DPS primary care physician at the prison facility. However, the UNC specialist writes the prescription for HIV or HCV medications.

No infectious disease services are provided to inmates via telemedicine. In fact, the only treatments currently provided to inmates through telemedicine are psychiatric and urology services. DPS has contracted with UNC as well as other providers for these services. All telemedicine services are provided on a DPS laptop using DPS equipment. The prescription is recorded in the DPS electronic medical record.

UNC also provides other specialty services to inmates on site at DPS, including neurology, urology, cardiology, gastroenterology, orthopedic, general surgery, otolaryngology, OB/GYN, anesthesiology, and radiology services. Inmates also receive specialty services at UNC hospitals and off-campus locations. For example, DPS indicated that almost all cancer care is provided at UNC and infusions are performed at UNC. We understand that many, if not most, of these services are furnished in UNC facilities that are registered and participating in the 340B program.

⁵ <http://www.mmd.admin.state.mn.us/MMCAP/Programs/Programs.aspx>.

⁶ <http://jhc.virginia.gov/4.%20Overview%20of%20Minn%20Multistate%20Contracting%20Alliance.pdf>.

DPS also partners with other 340B facilities, including Duke University Hospital, to provide health care to inmates.

D. High Cost Disease States, Recent Judicial Action, and Drug Spending

In SFY17, a total of 752 inmates received either HIV or HCV medications. DPS's total spending on both HIV and HCV medications in SFY17 was \$31.6 million. In the following year, DPS's overall spend on HIV and HCV medications decreased to \$26.7 million. DPS indicated that its per unit cost for HCV medications decreased in SFY18, which contributed to the decline in overall drug spend for these medications.

DPS estimates that approximately 10,000 to 12,000 inmates are infected with HCV, based on the Centers for Disease Control and Prevention's ("CDC") estimate that one in three prisoners in the U.S. are infected with HCV.⁷ Currently, UNC providers treat approximately 300 HCV patients per year at DPS. On March 20, 2019, the U.S. District Court for the Middle of District of North Carolina issued an order in a class action lawsuit brought by DPS inmates who had been diagnosed with HCV and had not received treatment.⁸ The court ordered DPS to provide treatment to the plaintiffs and to cease denying treatment based on contraindications other than patient refusal. The court also ordered DPS to cease denying HCV treatment based solely on a prisoner's FibroSure score, which is a measure of the degree of liver damage for individuals infected with HCV. The court, however, stopped short of ordering DPS to institute universal opt-out HCV screening for all inmates. Prior to the issuance of the order, DPS estimated the fiscal impact of the lawsuit to be approximately \$300 million if DPS was required to test and treat all inmates infected with HCV.

Beyond HIV and HCV, DPS identified seven conditions which had a high amount of drug spend in SFY18. Those seven disease states are:

- Cancer;
- Cardiovascular disease/hypertension;
- Chronic obstructive pulmonary disease ("COPD")/asthma;
- Epilepsy;
- Mental health;
- Multiple sclerosis; and
- Rheumatology.

A table illustrating the total amount spent and the number of prescriptions filled by DPS for each of these disease states, as well as HIV and HCV, is below. The table is based on SFY18 data.

⁷ <https://www.cdc.gov/hepatitis/hcv/pdfs/hepcincarcerationfactsheet.pdf>.

⁸ *Buffkin v. Hooks*, No. 1:18CV502 (M.D.N.C. 2019).

Disease States	Number of Fills	Total Amount Spent
Cancer	1,918	\$ 761,820
Cardiovascular disease/Hypertension	213,138	1,917,418
COPD/Asthma	35,061	4,358,063
Epilepsy	56,788	1,918,141
Hepatitis C	798	8,243,523
HIV	11,217	18,473,318
Mental Health	156,453	2,441,873
Multiple Sclerosis	334	1,144,102
Rheumatology	75,536	3,187,660
Grand Total	551,243	\$ 42,445,920

DPS also provided data on the top ten specialty drug purchases from 2017-2018 based on total spend. The top specialty drugs, including total spend and per unit prices, are listed in the table below. These drugs are generally used to treat cancer, multiple sclerosis, or urea cycle disorder.

Drug	Total	Current Unit Price
Lenalidomide	\$492,181.99	\$760.13
Abiraterone	\$424,361.74	\$81.03
Ibrutinib	\$411,952.26	\$142.91
Teriflunomide	\$198,782.80	\$238.02
Glycerol Phenylbutyrate	\$178,890.75	\$4,160.25
Dimethyl Fumarate	\$164,835.63	\$135.53
Axitinib	\$146,341.30	\$252.81
Enzalutamide	\$113,869.79	\$95.97
Dalfampridine	\$84,875.58	\$45.23
Mechlorethamine gel	\$72,887.00	\$70.04

II. 340B CORRECTIONAL PARTNERSHIPS USED IN OTHER STATES

The 340B program was established in 1992 under the Veterans' Health Care Act. The program was created to enable certain safety net providers, called "covered entities," to purchase covered outpatient drugs at discounted prices.⁹ General background on the 340B program can be found in [Appendix A](#) to this report.

Some covered entities and state or local correctional agencies have recognized that, when they jointly serve the health care needs of inmates, the 340B program can help improve or maintain the quality of care for inmates while lowering drug costs. These correctional institutions

⁹ Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4967. It is called the "340B Program" because it is governed under Section 340B of the Public Health Service Act. 42 U.S.C. § 256b.

have found that it can be more cost-effective to contract with a covered entity to treat inmates than to provide the care itself. As a result, numerous 340B correctional partnerships have been established throughout the country, many of which have been in operation for over a decade.

In addition, some influential organizations have been encouraging states to utilize the 340B program in order to cut rising costs for pharmaceuticals in our nation's jails and prisons. For example, in its report "Pharmaceuticals in State Prisons," the Pew Charitable Trust identified sixteen state departments of corrections that have been successful in reducing correctional drug costs through the 340B program.¹⁰ Pew noted that most reported the tendency "to restrict its use to individuals with expensive-to-treat diseases, such as hepatitis C, HIV/AIDS, or hemophilia, because of the expense and complexity of complying with some of 340B's rules."¹¹ Pew noted that even those programs that limited 340B to high cost drugs were able to "reap financial benefits."¹² Of the eleven correctional departments that were able to report pharmaceutical spending as a percentage of overall health care in 2015, the highest ten varied from as low as 15 percent to as high as 32 percent.¹³ "Texas, on the other hand, spent only seven percent of its health care budget on pharmaceuticals, pointing to its extensive use of the HRSA's 340B purchasing program as the explanation for its comparatively low figure."¹⁴ Furthermore, Texas did not see an increase in the pharmaceutical percentage of the health care budget between 2010 and 2015.¹⁵ In SFY18, 20% (\$64.2 million) of North Carolina's \$327.6 million health care spending was for pharmacy services.

More recently, the National Governor's Association ("NGA") has endorsed 340B partnerships between state correctional programs and covered entities as a way to control state drug costs. The NGA identified maximizing discounts for the incarcerated population through the 340B program as an effective strategy to address public health crises and pharmaceutical interventions.¹⁶ The evaluation was evidence based and vetted by representatives of eleven different states, namely, California, Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington.¹⁷ Much of the information in the NGA report mirrors that in the Pew Report.¹⁸ Some stakeholders commented on the overall concerns being expressed about the program in Congress, while reiterating that when the requirements

¹⁰ Pew Charitable Trusts, *Pharmaceuticals in State Prisons: How departments of corrections purchase, use, and monitor prescription drugs*, p.9 (2017) <https://www.pewtrusts.org/~media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf>.

¹¹ Pew Charitable Trusts at 8.

¹² *Id.* at 1.

¹³ *Id.* at 3.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ NGA, *Public Health Crises and Pharmaceutical Interventions: Improving Access While Ensuring Fiscal Sustainability* at 27 (2018) <https://www.nga.org/wp-content/uploads/2018/08/Public-Health-Crises-and-Pharmaceutical-Interventions.pdf>.

¹⁷ *Id.* at 5.

¹⁸ *Id.* at 28.

are met, extension of the 340B program is an effective strategy in controlling pharmaceutical costs for incarcerated populations.¹⁹

340B correctional health care partnerships vary significantly in how they are structured. They might involve state correctional departments, county jails, juvenile detention facilities or municipal jails. In some cases, the unit of state or local government and the covered entity are part of the same legal entity, and the partnership is simply an intragovernmental arrangement. In these arrangements, the 340B program allows both the correctional facility and the covered entity to save on the cost of drugs because they are part of the same legal entity. In others, the correctional unit might contract with a local hospital or clinic to provide certain types of care for inmates. The 340B program allows the correctional agency to save on the compensation that must be paid to the covered entity. Either way, the taxpayers who pay for correctional care can benefit from the lower cost drugs and the inmate population benefits in terms of quality and continuity of care.

The manner in which the care is provided to the inmate population can vary as well. The 340B statute is clear that participating hospitals and clinics, referred to as “covered entities,” may only dispense, administer or otherwise transfer 340B drugs to their patients. Covered entities can care for inmates in a number of ways that would make the individual a “patient” of the covered entity for 340B program purposes. Whether a particular inmate is a patient of a covered entity turns on a number of factual questions, including:

- Has the individual received face-to-face care with a provider employed by or under contractual or other arrangements with the covered entity?
- Is the face-to-face care provided in person, via telemedicine or through a combination of the two?
- Does the covered entity own or have access to the health care records pertaining to the inmate?
- Is the individual treated within a covered entity location?
- Are prescriptions for the individual written by covered entity personnel in a covered entity location and do the prescriptions relate to the care provided during face-to-face care?
- Does the covered entity retain responsibility for the care it provides to the inmate?

The correctional partnerships must be carefully structured to ensure that the relationship between the covered entity and inmate satisfies each element of the patient definition guidelines issued by the Health Resources and Services Administration (“HRSA”), the agency within the U.S. Department of Health and Human Services charged with administering the 340B program. Under HRSA’s patient definition guidelines, an individual must satisfy the following requirements in order to be eligible to receive the discounted drugs.

¹⁹ *Id.*

- First, the covered entity must maintain records of the individual’s health care.²⁰ This requirement is sometimes referred to as the “maintenance-of-record” or “record maintenance” test.
- Second, the individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that responsibility for the individual’s care remains with the covered entity.²¹ The second requirement is sometimes called the “professional care test.”²²
- The third requirement is known as the “scope of grant” test and requires that an individual must receive health care services that are consistent with the services for which grant funding or federally qualified health center look-alike status has been provided to the covered entity.²³

A. Partnerships with State Sexually Transmitted Disease Programs

Sexually transmitted disease (“STD”) clinics receiving funds under 42 U.S.C. § 247c, also known as section 318 of the Public Health Service Act (“PHSA”), are eligible to participate in the 340B program, provided the entity is certified by HRSA.²⁴ We understand that HRSA normally checks with the State official responsible for administering the STD grants to verify that the clinic is receiving funds under section 318. STD grantees may confer 340B eligibility to other entities by awarding them a sub-grant. Additionally, an FAQ on the HRSA website states that in-kind contributions through either section 317 (tuberculosis) or 318 (STD) of the PHSA may qualify an entity for the 340B program.²⁵ A covered entity that receives section 318 funding may only dispense 340B drugs to individuals that meet HRSA’s patient definition. Stated differently, an STD clinic covered entity may only use 340B drugs to treat an individual if the relationship between the STD clinic and the individual meets all three prongs of the patient definition guidance, including the scope of the grant test.

The STD partnership model is unique because it is the only one that allows the correctional facility to enroll in the 340B program as a covered entity. This type of partnership involves correctional facilities receiving either a sub-grant or in-kind contribution from a state STD program, typically operated by the state’s department of health, that is funded under section 318 of the Public Health Service Act. As an STD sub-grantee, correctional facilities are eligible to enroll in the 340B program and use 340B drugs to fill inmate prescriptions, provided that the inmate “receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding . . . has been provided.”²⁶

²⁰ *Id.* at 55,157.

²¹ *Id.*

²² *Id.* at 55,157-58.

²³ *Id.*

²⁴ 42 U.S.C. § 256b(a)(4)(K).

²⁵ HRSA, OPA, FAQs, 340B Program Eligibility, Question 1, at <http://www.hrsa.gov/opa/faqs/index.html> (last visited April 30, 2019).

²⁶ 61 Fed. Reg. at 55,157 – 58.

Additional details about partnerships with state STD programs can be found in [Appendix B](#) to this report.

B. Partnerships with 340B Hospitals

In contrast to section 318 grantees, hospitals are not subject to the “scope of the grant” test that requires an individual to receive health care services consistent with the services for which grant funding has been provided. As a result, a partnership with a 340B hospital would enable the state’s correctional program to access 340B discounts on potentially all medications, not only medications needed by the prison STD population. Although HRSA has not issued guidance specifically addressing the 340B eligibility of correctional facilities and inmates in partnership with a 340B hospital, we are aware of a number of states that have implemented a 340B hospital correctional partnership and have passed HRSA audits. As mentioned above, Texas was the first state to implement a 340B correctional partnership, which involved a 340B hospital. Since then, Illinois, California, Virginia, New Jersey, Washington, Connecticut, and Georgia have all implemented correctional partnerships with 340B hospitals in their states.

Our experience is that hospitals participating in 340B partnerships with correctional facilities in other states pass through most or all of their 340B savings to the state department of corrections. This is distinguishable from the growing threat of third-party payors and pharmacy benefit managers (“PBMs”) unilaterally reducing reimbursement to covered entities and their pharmacies to take advantage of lower cost 340B drugs, commonly referred to as “discriminatory reimbursement.” Discriminatory reimbursement practices by payors and PBMs are a real and growing threat to 340B providers.²⁷ 340B correctional partnerships involving two entities within state government do not pose the same type of threat, however. Whereas the intent of discriminatory reimbursement is to confer the 340B benefit to insurers – often commercial payors or PBMs – the purpose of a 340B correctional partnership is to improve or maintain the quality of care while reducing the cost of drugs for taxpayers. Unlike a typical payor arrangement, a 340B hospital partnership is an arrangement between two state entities that are seeking to save taxpayer dollars and support the care provided to inmates. Moreover, the payment provided by the correctional facility to the 340B hospital for non-pharmacy services typically generates a revenue stream that supports the hospital’s safety net mission. For these reasons, we do not think that a 340B hospital correctional partnership can be analogized to the threat of discriminatory reimbursement.

340B hospital correctional partnerships vary in structure and design, with each partnership model posing differing levels of compliance risk. We describe the various hospital correctional partnership models, and the compliance risks associated with each, in [Appendix C](#).

²⁷ HRSA views discriminatory reimbursement as a threat to the 340B program. HRSA is concerned that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings from them. HRSA explains that “if covered entities were not able to access resources freed up by the drugs discounts when they . . . bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.” HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005).

III. RECOMMENDED DPS PARTNERSHIP ARRANGEMENTS

Based on our discussions with various stakeholders, we have identified three strategies that would allow DPS to partner with 340B program participants in order to improve care and reduce drug costs for the North Carolina inmate population. Our recommendations to the Commission are intended to implement these three strategies as the following table summarizes.

Recommendation	DPS Partners With	Target Disease States/Drugs	Date of Implementation
1	DHHS	HIV/HCV	October 1, 2019
2	One or more 340B hospital(s)	Non-HIV/HCV	Dependent upon RFP
3	UNC	Non-HIV/HCV Medications Prescribed as a Result of Treatment Provided at 340B-Registered UNC Sites	As soon as possible, but presumably by October 1, 2019 if dispensing through UNC's pharmacy, or January 1, 2019 if dispensing through DPS's pharmacy

Under Recommendation One, DPS would receive a sub-grant from DHHS and register as a STD clinic covered entity in the 340B program. This partnership with DHHS would allow DPS to access 340B pricing on HIV and HCV, which are among the most expensive medications provided to inmates. Under Recommendation Two, DPS would issue an RFP for one or more 340B hospitals in the State to enter into a correctional partnership with DPS for the non-HIV/HCV inmate population. The correctional partnership could be based on a telemedicine model, a visiting professional model, or some other partnership model that is currently being used in other states (as described in [Appendix C](#)). Under Recommendation Three, DPS would shift the prescribing authority from a DPS provider to a UNC provider for prescriptions written as a result of a consult at a 340B-registered UNC location, but only if such change improves, or at least does no harm, to the quality and continuity of patient care. Shifting the prescribing authority for these medications would generate additional 340B savings as a result of treatment that is currently being provided at UNC.

The first goal of any 340B correctional partnership is to improve or at least preserve the standard of care provided to inmates. Our recommendations are based on the assumption that the State's correctional population will continue to receive the same, or better, quality of care under a correctional partnership than they currently receive. To be sure, access to 340B savings frees up state resources that can be used in part to support correctional care. Supporting quality and continuity of care is an important priority for each of our three recommendations.

Each part of our proposal is described in more detail below. We also set forth a proposed timeline and, where possible, list the estimated costs and savings associated with each recommendation. To assure necessary changes are made in a timely manner to achieve cost savings as soon as possible, the General Assembly should consider taking the following actions.

A. Recommendation One: The General Assembly Should Direct DPS to Partner with NC DHHS to Enroll In the 340B Program as an STD Sub-Grantee and Use the Program to Purchase Medications, Including HIV and HCV Drugs, for the STD Inmate Population

DHHS receives grant funding from HRSA under sections 317 and 318 of the PHSA. DHHS confirmed with the CDC project officer that its STD grant applies to HIV and HCV treatment, in addition to treatment for other STDs. Following the lead of other state correctional programs, DPS can partner with DHHS to receive a sub-grant from DHHS, and thereby be eligible to register as a covered entity under the 340B program. We understand that DHHS partners with local health departments in the same manner, by providing them with sub-grants which confer eligibility to the local health departments to register and participate in the 340B program.

This partnership would enable DPS to gain access to 340B pricing on costly HIV and HCV medications.²⁸ In its 2018 report, PED estimated that the potential annual savings on HIV and HCV medications, based on SFY17 data, was \$13.3 million. More recently, DHHS conducted an analysis of estimated savings based on SFY18 data by comparing DPS's cost to the 340B price on the top HIV and HCV medications provided to inmates. The average savings based on DHHS's analysis was 47%. DHHS estimates that the annual savings on HIV and HCV medications would be approximately \$8.25-\$8.5 million per year.²⁹ There are operational and administrative costs associated with establishing and operating a compliant 340B pharmacy program but, in our experience, such costs are far outweighed by the reduction in drug spend. Moreover, the number of inmates that DPS is required to treat for HCV will likely increase as a result of recent class action litigation, which means that DPS's pharmacy and non-pharmacy costs for treating inmates with HCV will also increase. Access to 340B savings on HCV medications will be even more financially impactful in light of the class action litigation. The 340B savings will help to

²⁸ It is important to note that use of 340B drugs for the STD inmate population is not limited to STD medications, although HIV and HCV drugs are typically the most costly STD medications. We confirmed with HRSA's prime vendor, Apexus, that a Section 318 grantee may dispense "any" 340B drug to an individual who receives a health care service or range of services consistent with the service or range of services for which grant funding has been provided to the entity. See also Apexus FAQ 1565 (last modified 9/15/2014) and FAQ 1568 (last modified 3/7/2019).

²⁹ DPS estimated savings of 16-18% on STD medications based upon other state correctional programs that have access to 340B pricing. However, we are unable to validate DPS's estimated savings because DPS has not provided the data that formed the basis of its estimate. We note that the minimum 340B discount is 23.1% of the average manufacturer price ("AMP") for brand name drugs and 13% of AMP for generic drugs. Although there are generic versions of HIV medications on the market, we are not aware of any traditional generic versions of HCV drugs coming to market. Gilead introduced authorized generic versions of its HCV drugs in January 2019; however, authorized generics are considered brand name drugs which carry a minimum 340B discount of 23.1%. See 42 C.F.R. § 447.502. Ultimately, the amount of DPS's 340B discount on HCV and HIV medications will depend on how similar its current MCCAP prices are to the drugs' AMP.

offset the increased costs associated with treating the new inmate population entitled to HCV care as a result of the litigation.

DPS currently purchases medications through its participation in MMCAP, through which DPS receives additional discounts based on aggregate state volume of purchases. It is our understanding based on MMCAP's website and previous presentation materials that purchases of drugs under the 340B program continue to count toward a state's aggregate purchasing volume for purpose of MMCAP, but DPS would need to confirm this assumption. If this is correct, the purchasing of HIV and HCV medications for inmates through the 340B program should not affect pricing on other MMCAP purchases by DPS and other State agencies. This would be another advantage to DPS enrolling directly in the 340B program as a covered entity.

UNC providers can continue to provide infectious disease treatment to inmates and write their prescriptions. The prescriptions will meet HRSA's 340B patient definition requirements because the prescriptions will be written by UNC contracted providers pursuant to care provided on site at DPS, and DPS maintains records of the care provided. DPS can also continue to dispense HIV and HCV medications using its existing pharmacies. We do not believe DPS will need to contract with an outside pharmacy to dispense these medications unless DPS cannot accommodate the increased volume or there are special handling or packaging requirements.

DPS would need to use either a physically separate inventory or install software to implement a "virtual" inventory to keep track of 340B inventory. We have provided DPS with a list of 340B split-billing software vendors, as well as a list of 340B consultants that can assist DPS with developing a 340B program and registering with HRSA. DPS may also need to hire a part-time or full-time employee to assist with 340B program operations and compliance. Based on our experience, the 340B savings typically far outweigh the technology, consulting, and compliance costs associated with an entity enrolling in the 340B program as a covered entity. An initial conversation with a 340B consultant suggests that the start-up consulting fee would be in the \$10,000 range, the split-billing software purchase would be approximately \$10,000, and the fee for a 340B administrator would be approximately \$1,000 per month. A second consultant with whom we spoke confirmed the \$10,000 consulting fee but speculated that the split-billing software fees could be avoided by using a physically separate 340B inventory rather than a virtual inventory system. We understand that DPS may be able to reallocate internal funds to help pay for these costs without seeking additional appropriations. We also understand that DPS may be able to access existing State contracts with 340B split-billing software vendors and 340B consultants (*e.g.*, UNC's contracts) that may provide favorable rates and help to expedite the contracting process.

We recommend that the General Assembly direct DPS to partner with DHHS as an STD sub-grantee and use the program to purchase medications, including HIV and HCV drugs, for the STD inmate population. DPS should partner with DHHS as soon as possible so that it can enroll in the 340B program during the July 1-15, 2019 quarterly registration window. DPS would then be able to begin purchasing HIV, HCV and other STD medications through the 340B program beginning October 1, 2019. DPS should engage a 340B consultant to assist with establishing and

implementing the partnership as soon as possible. On or before October 1, 2019, DPS should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on implementation of this recommendation. Since DPS will not have begun dispensing 340B drugs before October 1, 2019, the initial report would simply be an update on the steps DPS has taken to prepare for its participation in the 340B program as a covered entity. On October 1, 2020 and annually thereafter, DPS should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on savings achieved based on this recommendation.

B. Recommendation Two: The General Assembly Should Direct DPS to Issue an RFP for a Partnership with One or More 340B Hospitals to Serve Non-HIV/HCV Inmates

Since the partnership with DHHS would be limited to the STD population, including inmates with HIV or HCV, we explored options for DPS to partner with 340B hospitals, such as UNC, to serve the non-STD population. Specifically, we targeted the conditions and specialty drugs that had the highest spend based on data provided by DPS (described in Section II.D of this report). UNC conducted an analysis of potential 340B savings and found that there may be opportunity in the areas of COPD/asthma, rheumatology, and multiple sclerosis. UNC did not believe there would be opportunity in the areas of mental health, epilepsy, and cardiovascular disease/hypertension. However, UNC identified a number of factors that, according to UNC, would make it difficult, if not impossible, to quantify the potential savings that would be generated by forming a partnership around one or more non-HIV/HCV inmate populations. The factors identified by UNC include the possibility of reduced 340B savings attributable to the entry of lower-cost, generic drugs in the market; the need to offset potential pharmacy savings with the non-pharmacy and administrative costs associated with providing care to these patient populations; and the shifting prevalence of different disease states within the inmate population over time. While we agree that each of these factors should be considered and that their impact on overall savings may be challenging to predict, we do not believe they pose an insurmountable obstacle. We therefore encourage UNC to do its best to estimate the potential savings that a 340B partnership could generate in these non-HIV/HCV areas.

It is worth noting that, in addition to the difficulties inherent in quantifying potential savings, UNC identified several barriers that UNC itself would face in developing a 340B partnership with DPS. Among those barriers are concerns about complying with 340B program requirements, UNC's limited footprint in telemedicine, resource and provider capacity limitations, and potential security and transportation costs relating to transporting inmates between DPS and UNC. The appeal of the RFP process is that, among other things, it would solicit interest from other covered entities in North Carolina that may face fewer barriers to entering into a 340B correctional partnership.

We are aware of several successful 340B partnerships between state correctional departments and 340B hospitals that have resulted in significant savings to those states. In Texas, for example, UTMB has partnered with the state's correctional department for the eastern

half of Texas and purchases all medications through the 340B program. UTMB has expressed that 340B savings are particularly significant in the following areas (in addition to HIV and HCV):

- Factor products for any inmate with hemophilia;
- Oral suppressive therapy medications for inmates with cancer;
- Biologics for inmates with inflammatory disease such as Crohn’s disease, irritable bowel syndrome, and rheumatoid arthritis;
- Brand name inhalers for inmates with COPD and asthma; and
- Psychotropic drugs for inmates with schizophrenia, bipolar disorder, and other mental health conditions.³⁰

To assess whether a 340B hospital partnership in North Carolina is feasible for the non-HIV/HCV correctional population, we recommend that the General Assembly direct DPS to issue an RFP for one or more 340B hospitals in the State to enter into a correctional partnership with DPS for these inmates. The hospital, as the 340B covered entity, would purchase medications under the 340B program and pass on its savings to the State. The RFP should request that bidding hospitals include in their proposals a description of the 340B correctional partnership model they would use based on the seven hospital correctional partnership models described in Appendix C, as well as the potential savings and costs. The advantage of the RFP process is that it would allow each respondent to assess the operational and administrative costs associated with treating the target populations and to propose a reasonable compensation arrangement based on those costs. Each respondent would need to make its own assessment of the potential net savings it could offer DPS as part of its correctional partnership bid. In general, our experience is that the 340B savings allow the parties to negotiate a “win-win” relationship in which the correctional institution saves on the cost of drugs and the covered entity generates a new revenue stream by providing health care services to new patient populations, which it can use to support or improve patient care.

DPS should solicit bids for each of the four prison regions (Mountain, Central, Triangle, and Coastal). However, hospitals interested in providing telemedicine services could bid on more than one region and potentially all four prison regions since telemedicine services are not geographically limited.³¹

The RFP for the Triangle region may need to be tailored to avoid disrupting existing patient care services because many of those services are currently furnished by UNC. To meet HRSA’s patient definition requirements, the successful bidder would assume responsibility for providing many of the specialty care services currently provided by UNC on site at DPS or via

³⁰ UTMB is responsible for all health care services needed by inmates in the eastern region of Texas. Although Texas’s care delivery model for inmates is different from North Carolina’s model, we discuss the Texas correctional partnership because the 340B prices that Texas receives are the same as any other covered entity participating in the 340B program. Therefore, the 340B discount for medications prescribed to treat the disease states that UTMB identified as high opportunity disease states should be the same for both Texas and North Carolina.

³¹ We are aware that some 340B hospitals are already under contract with DPS to provide health care services to inmates, so these hospitals may be particularly interested in responding to the RFP.

telemedicine. If UNC responds to the RFP and is awarded the contract for the Triangle region, then UNC would continue to be the specialty care provider on site at DPS and via telemedicine. DPS could continue to serve as the main pharmacy provider for the correctional population by entering into a contract pharmacy arrangement with the 340B hospital. Thus, the RFP could express a preference for the hospital using DPS as a contract pharmacy, but remain open to the bidder using its in-house pharmacy to dispense 340B drugs.

DPS should develop a plan by December 1, 2019 to issue an RFP in accordance with the above. DPS's plan should address all of the following:

- Hiring a consultant to issue and manage the RFP process;
- Having the same consultant work with the selected 340B hospital, along with DPS, to implement the transition; and
- Estimating DPS's costs to hire the consultants, issue the RFP and evaluate proposals, and implement the 340B correctional partnership.

Beginning December 1, 2019 and quarterly thereafter until RFPs are awarded, DPS should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on implementation of this recommendation. On October 1, 2021 and annually thereafter, DPS should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on savings achieved based on this recommendation.

C. Recommendation Three: The General Assembly Should Direct DPS to Partner with UNC to Receive 340B Savings on Non-HIV/HCV Retail Medications Prescribed As a Result of Treatment Provided at a 340B-Registered UNC Location

The final part of our proposal involves a partnership with UNC for specialty retail prescriptions that are written as a result of care provided at a UNC location that is registered and participates in the 340B program. Currently, UNC providers that see inmates on site at UNC provide "consult orders" or recommendations for prescriptions. The UNC provider's recommendations are sent to the DPS primary care physician, who determines whether to write the prescription based on the patient's drug profile and general medical history. If the prescribing authority were shifted from the DPS physician to the UNC physician, then UNC would be able to purchase the medications pursuant to its participation in the 340B program for inmates treated at the registered 340B location. The General Assembly should direct DPS to partner with UNC by July 1, 2019 to receive 340B savings on non-HIV/HCV medications prescribed as a result of treatment provided at a 340B-registered UNC site. We understand that care for certain disease states associated with high drug spend, such as cancer, is currently provided at UNC. Prescriptions written as a result of that care, such as oral suppressive therapy drugs to treat cancer, would qualify for 340B pricing if the prescribing authority were shifted from the DPS provider to UNC. Once again, UNC would pass through all or most of the 340B discount on these drugs to DPS. This recommendation would not require UNC to expend any additional provider resources since the care is already being provided to inmates.

DPS should develop mechanisms to ensure that the communication between the UNC prescriber and DPS physician does not interfere with the quality and continuity of care that inmates currently receive. It is critical to this recommendation that the UNC specialist and the DPS primary care physician maintain clear and open channels of communication. Shifting prescriptive authority to UNC would likely result in the UNC specialist assuming primary responsibility for treatment of the inmate's condition, which could actually improve the inmate's care for that condition. But the parties will need to accommodate the important role of the DPS primary care physician in coordinating the patient's overall health care. We think this can be easily achieved by establishing a clear method of communication between the UNC specialist and the DPS primary care provider.

DPS should determine whether the prescriptions should be filled through UNC's retail pharmacy or DPS's Apex Central Pharmacy.

- UNC could contract with Apex Central Pharmacy to fill prescriptions written as a result of care provided at UNC. Under this arrangement, Apex Central Pharmacy would act as a 340B contract pharmacy to UNC. UNC would purchase the drugs under its participation in the 340B program, but the drugs would be shipped to Apex Central Pharmacy for dispensing. UNC has indicated that it would incur incremental costs if the 340B prescriptions are filled through DPS's pharmacy instead of UNC's pharmacy. For example, UNC estimated it would need to pay its third party 340B administrator a couple thousand dollars to add DPS's pharmacy as a contract pharmacy and monitor 340B inventory. We also note that if UNC were to fill the prescriptions using its in-house or contract pharmacies, it would not be subject to any 340B registration waiting periods and could theoretically begin filling prescriptions with 340B drugs immediately.
- If DPS were to fill prescriptions acting as a contract pharmacy to UNC, the earliest DPS could begin filling 340B prescriptions is October 1, 2019 since the DPS pharmacy would need to first be registered through HRSA. Given these considerations, and the fact that DPS indicated it does not have any special packaging or handling requirements for prisoners, it may be simplest for UNC to fill the prescriptions through its own 340B pharmacy network. UNC would need to coordinate shipping the prescriptions to the prison facilities, or alternatively, arrange for DPS pharmacy staff to pick them up from UNC.

In our conversations with UNC and DPS, stakeholders expressed potential challenges in identifying the UNC inmate patients for whom shifting prescriptive authority to UNC is feasible. DPS currently retains records of the prescriptions written by DPS providers but cannot easily extract the prescriptions that were written following a consult order provided during care the inmate received at UNC. UNC indicated that the consult order from its physicians may be noted in their electronic medical records. The parties will need to conduct further analysis to identify the relevant opportunities for a UNC provider to serve as the inmate's prescriber, which will also inform the determination of estimated savings. If an external IT consultant will need to be hired

to identify these opportunities, DPS could use some of its 340B savings achieved under the first three recommendations to help pay for the consultant.

The implementation timeline for this recommendation depends on how quickly DPS and UNC are able to accomplish the following three tasks:

1. Identifying the UNC inmate patients for whom shifting prescriptive authority to UNC is feasible and appropriate;
2. Establishing a method for improving and/or maintaining quality and continuity of patient care once the prescriptive authority is shifted from the DPS physician to a UNC physician; and
3. Selecting the pharmacy (UNC pharmacy or DPS pharmacy) through which the drugs will be dispensed.

We believe it is reasonable for DPS and UNC to aim to complete these tasks by October 1, 2019, even if the parties are only able to implement this recommendation for a subset of potentially eligible drugs by that date. If the drugs are dispensed through DPS's pharmacy serving as a contract pharmacy to UNC, then UNC would need to register the DPS pharmacy as a contract pharmacy during the October 1-15, 2019 HRSA registration window, and the earliest DPS could begin dispensing the 340B medications is January 1, 2020. If the drugs are dispensed through UNC's existing 340B pharmacy network (in-house or contract pharmacies), then UNC could begin dispensing the 340B drugs beginning October 1, 2019, or as soon as the three tasks listed above are completed.

DPS and UNC should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on their progress in implementing this recommendation on or before October 1, 2019, and monthly thereafter until implementation. On October 1, 2020 and annually thereafter, DPS should report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division on savings achieved based on implementation of this recommendation.

About the Authors:

William von Oehsen is a Principal at Powers, Pyles, Sutter & Verville, PC. Bill has extensive experience in general health law, legislation and policy, especially in the areas of pharmaceutical pricing, food and drug law, materials management, managed care and third party reimbursement.

Education:

- J.D., Georgetown University, 1988
- M.T.S., Harvard University, 1984
- A.B., Princeton University, 1981

Bill has more than 20 years experience on pharmaceutical pricing and reimbursement matters, including the 340B drug discount program, the Medicaid drug rebate program, Medicare Part D, Robinson-Patman, and state Medicaid and pharmacy laws. He helped establish and serves as outside counsel to 340B Health, formerly Safety Net Hospitals for Pharmaceutical Access, an advocacy organization of more than 1,200 public and private nonprofit hospitals participating in the 340B program. He played a key role in helping to enact the 340B program in 1992, as well as to expand the law in 2010 under the Affordable Care Act. In 1997, he helped organize the 340B Coalition, which now represents a dozen national organizations whose members comprise virtually all of the safety net providers participating in the 340B program. Bill co-founded and served as co-editor of the *Drug Discount Monitor*, the first publication to focus specifically on the 340B program and other pharmacy access issues.

In addition to representing 340B Health and other clients on 340B matters, Bill provides guidance to pharmacies, pharmacy-related vendors and consultants, states, local governments, and other healthcare entities in their efforts to improve access to pharmaceutical care and to ensure compliance with drug pricing laws. He has experience in counseling clients on matters involving the federal supply schedule and federal ceiling price programs, state pharmaceutical assistance programs, manufacturer patient assistance programs, the Prescription Drug Marketing Act, Medicare Part B, managed care and related authorities. Bill has testified before the U.S. Congress and numerous state legislatures and provides technical assistance to federal and state policy makers in both the legislative and executive branches. He has handled litigation matters involving pharmaceutical pricing. He also practices in the area of food and drug law.

In the food and drug area, Bill guides companies through the FDA's premarket clearance process; assists companies with product development strategies; provides labeling, advertising, manufacturing and import/export advice; and handles other issues that arise during the progression from initial clinical testing through commercial distribution. He has assisted clients with respect to the development and distribution of medical devices, biologics, food, food additives, dietary supplements, animal feeds, and cosmetics. He has also defended clients against FDA enforcement actions.

Bill is a member of the District of Columbia Bar. He earned his law degree at Georgetown University Law Center in 1988 and a master's degree from Harvard University in 1984. He earned his undergraduate degree from Princeton University in 1981. Bill participates in a number of

professional organizations including the Food and Drug Law Institute (where he was an Annual Scholar) and the American Health Lawyers Association. He was also a founding director of the Family AIDS Housing Foundation, now called Building Futures: Family AIDS Housing.

Bill is the co-author of a book titled *Managed Care Manual: Medicaid, Medicare and State Health Reform*. He has lectured and published numerous articles on issues relating to pharmaceutical pricing and food and drug law. His 2001 publication, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, is available through the National Conference of State Legislatures and was cited in briefs submitted to the US Supreme Court in connection with the celebrated case of *PhRMA versus the State of Maine*. Bill joined the Firm in January 2002.

Shuchi Parikh is an Associate at Powers, Pyles, Sutter & Verville, PC. Shuchi focuses on drug pricing and reimbursement matters, including the rapidly evolving 340B drug discount program.

Education:

- J.D., with honors, George Washington University Law School, 2013
- B.A., Duke University, 2010

Shuchi is passionate about helping safety net providers navigate the changing legal and regulatory landscape to better serve their patient populations. She has a broad range of experience providing operational guidance and compliance advice to health care entities. Her particular areas of expertise include drug pricing and reimbursement, health care fraud and abuse, and pharmacy law.

Shuchi has deep knowledge of the 340B program, Medicaid, and Medicare Parts B and D. She regularly counsels 340B providers and other stakeholders – including contract pharmacies, third-party administrators, split-billing software companies, and pharmacy services providers – on regulatory and transactional matters. Shuchi closely follows state developments on Medicaid policies related to billing and reimbursement of 340B drugs and has presented on this topic at multiple 340B Coalition conferences. A large part of Shuchi's practice involves drafting and negotiating contracts on behalf of health care providers and related entities.

In addition, Shuchi advises clients on general fraud and abuse matters, including compliance with the federal Anti-Kickback Statute and the Stark Law. She helps clients prepare self-disclosures under the Stark Law and structure complex arrangements with physicians and other potential referral sources. Prior to joining Powers, Shuchi worked in the healthcare investigations and compliance practice at a nationally recognized law firm, where she focused on fraud and abuse issues for a range of clients in the pharmacy and pharmaceutical space.

Shuchi received her J.D., with honors, from The George Washington University Law School. While in law school, she interned with the Office of the General Counsel for the Centers for Medicare and Medicaid Services and the Department of Justice's Civil Fraud Section. Shuchi graduated from Duke University in 2010 with a degree in Public Policy Studies and Global Health.

Shuchi was recognized as a Super Lawyers Rising Star in 2018 and 2019.

APPENDIX A

340B PROGRAM OVERVIEW

This appendix provides general background on the federal 340B drug discount program (“340B program”), including explanations of the patient definition guidelines issue by the Health Resources and Services Administration (“HRSA”), 340B contract pharmacy relationships, and registration deadlines.

A. 340B Program Overview

Congress created the 340B program under section 602 of the Veterans’ Health Care Act of 1992.¹ The 340B program takes its name from section 340B of the Public Health Service Act, codified at section 256b of title 42 of the United States Code.² The program is administered by the Office of Pharmacy Affairs (“OPA”), a unit of HRSA within the Department of Health and Human Services (“HHS”). HRSA has, from time to time, published informal guidance—including Federal Register notices, Policy Releases, and Frequently Asked Questions (“FAQs”)—to implement and clarify the requirements of the 340B program.

Providers that participate in the 340B program are called “covered entities.”³ The 340B statute affords discounts on outpatient drugs dispensed to individuals receiving services from covered entities, but it prohibits covered entities from “resell[ing] or otherwise transfer[ing]” a drug purchased at the 340B discount to “a person who is not a patient of the entity.”⁴ In other words, a covered entity may only dispense or administer drugs purchased at 340B pricing to individuals who are its “patients.”⁵ Violation of this provision is called diversion. HRSA may audit covered entities to determine whether they are complying with the diversion prohibition.⁶ A drug manufacturer may also conduct an audit if it has cause to believe violations are occurring or have occurred and HRSA approves its audit plan.⁷ If an audit uncovers evidence of diversion, HRSA may order the covered entity to repay the 340B discount on the diverted drugs to all affected drug manufacturers.

The 340B statute also empowers HRSA to sanction providers that “knowingly and intentionally” violate the diversion prohibition.⁸ The sanctions take the form of a monetary penalty in the form of interest, compounded monthly, on any amounts that must be repaid to

¹ Pub. Law No. 102-585, 106 Stat. 4943, 4967-71.

² *Id.* 106 Stat. at 4967.

³ 42 U.S.C. § 256b(a)(4).

⁴ *Id.* § 256b(a)(5)(B).

⁵ *Id.*

⁶ *Id.* § 256b(a)(5)(C).

⁷ *Id.*; see also *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406 (Dec. 12, 1996); HRSA, 340B Drug Pricing Program Notice, *Clarification of Manufacturer Audits of 340B Covered Entities*, Release No. 2011-3 (Nov. 21, 2011).

⁸ *Id.* § 256b(d)(2)(B)(v)(I).

manufacturers.⁹ If the diversion is also deemed “systematic and egregious,” the covered entity can be removed from the program and/or disqualified from re-entering it for a reasonable period of time.¹⁰

HRSA recently updated its website to include a statement that suggests that it would consider a covered entity to be subject to these additional sanctions only when the covered entity is found to have engaged in “same exact” non-compliant conduct in a second audit.

Covered entities with a re-audit that identifies the same exact finding of non-compliance, may be subject to additional audits. A finding of non-compliance in two or more audits, depending on the type of violation, may be considered systematic and egregious, as well as knowing and intentional, which may result in the covered entity being removed from the 340B Program in accordance with section 340B(d)(2)(B)(v) of the Public Health Service Act. Such a finding may also disqualify the covered entity from re-entry into the 340B Program for a reasonable period of time.¹¹

Since HRSA began auditing covered entities in 2012, we are not aware of any circumstances in which HRSA required a covered entity to pay interest on 340B discounts that it received or terminated a covered entity from the 340B program. In cases in which a covered entity has a reasonable basis for qualifying prescriptions for 340B but HRSA disagrees after audit, we think that it is very unlikely that HRSA would require the covered entity to pay interest to the manufacturer or terminate the covered entity. Of course, HRSA’s policy may change in response to increasing scrutiny from Congress.

B. HRSA’s Patient Definition Guidance

HRSA issued a notice on October 24, 1996 defining a “patient” for purposes of the 340B program.¹² According to that notice, an individual must satisfy the following requirements in order to be eligible to receive the discounted drugs. First, the covered entity must maintain records of the individual’s health care.¹³ This requirement is sometimes referred to as the “maintenance-of-record” or “record maintenance” test. Second, the individual must be under the care of a physician or other health care professional who is employed by, under contract with, or in a referral relationship to the covered entity such that responsibility for the individual’s care remains with the covered entity.¹⁴ The second requirement is sometimes called the “professional care test.”¹⁵ The third requirement is known as the “scope of grant”

⁹ *Id.*

¹⁰ *Id.* § 256b(d)(2)(B)(v)(II).

¹¹ See <https://www.hrsa.gov/opa/program-integrity/index.html>. (Click on “Audit Process” – last paragraph).

¹² Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility 61 Fed. Reg. 55,156 (Oct. 24, 1996).

¹³ *Id.* at 55,157.

¹⁴ *Id.*

¹⁵ *Id.* at 55,157-58.

test and requires that an individual must receive health care services that are consistent with the services for which grant funding or FQHC look-alike status has been provided to the covered entity.¹⁶

1) Grantee and Sub-Grantee Patients

Some types of covered entities become 340B eligible based on receipt of a Federal grant or sub-grant. In cases in which a grantee provides grant funds to a sub-grantee, HRSA has not provided clear guidance as to whether the scope of grant test should be applied with reference to the primary grant or the sub-grant. HRSA proposed guidance in 2007 that would have made the sub-grant, rather than the primary grant, the relevant reference for purposes of the scope of the grant test; however HRSA withdrew the 2007 proposed guidance, without finalizing it.¹⁷ In 2015, HRSA proposed through its Omnibus Guidance that a 340B eligible child site that receives a sub-grant in which the “scope of grant, project, or contract is more limited than that of the parent site, *individuals will be considered patients if they are receiving health care at the child site which is consistent with the healthcare service or range of services delegated to the child site*”¹⁸ (emphasis added). Although the Omnibus Guidance was also withdrawn, these two guidances provide insight into how HRSA intends to apply the scope of the grant test. Given this insight, a good argument can be made that when determining patient eligibility, HRSA would reference the sub-grant rather than the primary grant when applying the scope of the grant test.

2) Hospital Patients

HRSA has also issued guidelines used to determine whether a particular part of a 340B hospital is eligible to participate in the 340B program. Hospital-affiliated outpatient facilities may only purchase and use 340B drugs if they are an “integral part” of the hospital. According to a 1994 Federal Register notice, an outpatient facility is considered an integral part of the hospital and eligible to participate in the 340B program if it is reimbursable on the hospital’s Medicare cost report.¹⁹ If an off-site facility or clinic, referred to as a “child site,” meets this criterion, it must be registered in the Office of Pharmacy Affairs Information System (“OPAIS”), the online 340B database maintained by HRSA, under the hospital’s main facility which is the “parent site.”

HRSA has refined this test over time, though it has not published any new guidance. Currently, HRSA requires the facility to appear on the covered entity’s most recently filed cost

¹⁶ *Id.*

¹⁷ OIRA Conclusion of EO 12866 Regulatory Review: Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient” – Withdrawal of Previous Notice, REGINFO.GOV (Jan. 21, 2011), available at <http://www.reginfo.gov/public/do/eoDetails?rrid=119855>.

¹⁸ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,307 (Aug. 28, 2015).

¹⁹ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 – Outpatient Hospital Facilities, 59 Fed. Reg. 47,884, 47,886 (Sep. 19, 1994).

report.²⁰ HRSA also requires that the outpatient facility have both reimbursable costs on an outpatient or ancillary line of Worksheet A of the Medicare cost report, **and** corresponding charges, shown on Worksheet C. Outpatient facilities that meet the Medicare “provider-based” rules would typically meet this requirement.²¹

HRSA’s policy is reflected in an FAQ on its website:

Q: If a covered entity has physician clinics, do they need to register them as child sites?

A: Only hospital outpatient facilities that appear as reimbursable cost centers on the hospital’s most recently filed Medicare cost report are eligible to be listed and participate in the 340B Program. HRSA requires each hospital to register all of **its** off-site outpatient facilities **where 340B drugs are purchased and/or provided to patients of that facility**. This will ensure that each facility has been reviewed and verified by HRSA OPA as eligible to participate in the program, thereby strengthening the hospital’s compliance efforts.²²

As a practical matter, HRSA interprets its patient definition and eligible facility guidance documents as allowing any prescription that is written in OPAIS-registered hospital outpatient department or clinic to be filled with 340B drugs. Presumably, HRSA’s position is that, if a hospital has a medical record that demonstrates that a prescription was written within a hospital outpatient department, the hospital is responsible for the care relating to the prescription and therefore the prescription may be filled with 340B drugs. The location, however, must be registered on the OPA database.

C. Contract Pharmacy Guidelines

In 1996, HRSA published the first contract pharmacy services guidelines permitting covered entities to dispense 340B drugs through community pharmacies under contract with the covered entities.²³ Under the 1996 guidance, a covered entity may enter into a “ship to, bill to” arrangement with a pharmacy contractor in which the covered entity’s wholesaler bills the covered entity for 340B drugs purchased by the covered entity but ships the drugs to the covered entity’s contract pharmacy. The contract pharmacy may then dispense 340B covered outpatient drugs to patients of the covered entity. In 2010, HRSA expanded its contract pharmacy program by issuing new guidance that superseded the 1996 guidelines and permitted covered entities to contract with multiple pharmacies.²⁴

²⁰ See HRSA, OPA, FAQs, available at <http://www.hrsa.gov/opa/faqs/index.html>.

²¹ See 42 C.F.R. § 413.65.

²² See HRSA, OPA, FAQs, available at <http://www.hrsa.gov/opa/faqs/index.html> (emphasis added).

²³ 61 Fed. Reg. 43,549, 43,552, 43,555 (Aug. 23, 1996); see also <https://www.hrsa.gov/opa/implementation/contract/index.html>.

²⁴ 75 Fed. Reg. 10,272 (March 5, 2010).

All contract pharmacies must register for the 340B program and be listed on the 340B OPAIS before dispensing 340B drugs. HRSA requires covered entities to ensure that dispensing of 340B drugs remains compliant with the diversion prohibition.²⁵ Additionally, HRSA encourages covered entities to perform annual audits of their contract pharmacy.²⁶

To ensure compliance with the diversion prohibition, contract pharmacies primarily manage 340B drug inventory in one of two ways: the pre-purchased inventory model or the replenishment inventory model. With the pre-purchased inventory model, a contract pharmacy will maintain a physical inventory of 340B drugs in the name of the covered entity that is segregated from the contract pharmacy's own inventory. The covered entity will maintain title to the 340B drugs at all times, which makes the contract pharmacy the custodian of, but not the owner of, the drugs.

Alternatively, the replenishment inventory model allows the contract pharmacies to utilize a virtual inventory system in which the 340B and non-340B drugs are tracked and maintained separately through a split-billing computer software program rather than being kept physically separate. The pharmacy then maintains a single physical inventory from which it dispenses drugs to each customer who presents a prescription. The pharmacy and covered entity determine whether the customer is a patient of the covered entity, typically retrospectively but occasionally in real-time, and often with the help of a third party administrator. If the customer is a patient of the covered entity, and other contractual and operational requirements are met, the contract pharmacy will replace the drug by ordering the same drug on the covered entity's 340B account and transferring the third-party reimbursement obtained for the drug to the covered entity. The replenishment drug is virtually swapped with the drug that was dispensed to the patient – the parties treat the dispensed drug as the 340B drug and the replenishment drug as a non-340B drug that is later merged into the pharmacy's single inventory. In this way, the transaction is treated as though the covered entity's 340B drug was on the shelf and dispensed to the covered entity patient. The vast majority of contract pharmacies rely on a virtual inventory system rather than a physical inventory system.

D. Registration Timelines

Providers have four 15-day periods per year to enroll themselves, outpatient facilities, or their contract pharmacies in the 340B program. The time periods are as follows:

- January 1-January 15 for an effective start date of April 1;
- April 1-April 15 for an effective start date of July 1;
- July 1-July 15 for an effective start date of October 1; and
- October 1-October 15 for an effective start date of January 1.²⁷

²⁵ *Id.* at 10278.

²⁶ *Id.*

²⁷ HRSA, OPA, Registration, available at <https://www.hrsa.gov/opa/registration/index.html>.

Covered entities are required to submit all supporting documents for their own enrollment, as well as enrollment of a child site, on the same day.²⁸ HRSA will not consider incomplete registration packages.²⁹

²⁸ *Id.*

²⁹ *Id.*

APPENDIX B

340B CORRECTIONAL PARTNERSHIPS WITH STATE SEXUALLY TRANSMITTED DISEASE PROGRAMS

This document provides additional background on 340B correctional partnerships with state sexually transmitted disease (“STD”) programs.

Florida was the first state to use the 340B status of its STD program to extend 340B pricing to correctional mediations. It implemented its STD 340B program through a collaborative effort between Florida’s Department of Health (“DOH”) and Florida’s Department of Corrections, where eligibility flowed from an STD grant to the DOH. The Florida Department of Corrections entered into an interagency agreement with DOH under which county health department physicians treated inmates through the STD program. Florida DOH qualified as a 340B covered entity and medications were dispensed through DOH’s central fill pharmacy. The effort reportedly resulted in decreased spread of human immunodeficiency virus (“HIV”) in the Florida inmate population as well as in the community surrounding the Florida prisons. The partnership also resulted in substantial savings to the state. The average savings on HIV medications were 40-45% relative to the prices the state previously received through MMCAP.

Following Florida’s lead, several other states have implemented similar STD partnership models with their state health departments. In some states, the state’s STD program provides a sub-grant to the department of corrections, which enables the department of corrections to enroll in the 340B program directly. For example, Iowa, North Dakota, Rhode Island, and Utah have implemented this type of STD sub-grantee partnership model, under which their state departments of corrections receive a sub-grant from the STD programs and dispense 340B drugs to inmates. Similarly, a handful of county and city jails have also formed STD sub-grantee relationships with their state or local department of health.

The North Dakota Department of Corrections and Rehabilitation (“DOCR”) participates in the 340B program on the basis of an in-kind grant from the North Dakota Department of Health, (“ND DOH”) which receives funding through section 318 of the Public Health Service Act. The ND DOH certified to the Secretary of Health and Human Services that the DOCR provides payment-in-kind services under section 318. HRSA accepted DOCR’s certification that it received payment in-kind from section 318 and permitted DOCR to register as a STD covered entity in the 340B program. The DOCR performs universal testing of inmates upon arrival and identifies and treats a large number of adults and adolescents who have STDs, including gonorrhea and chlamydia. The ND DOH provides these tests at a steep discount in order to support its program of universal testing on admission.

APPENDIX C

340B HOSPITAL CORRECTIONAL PARTNERSHIP MODELS

This appendix provides an overview of potential partnership models between a state or local correctional facility and a disproportionate share hospital (“DSH”) that would allow drugs purchased under the federal 340B drug pricing program (“340B program”) to be used for inmates of the facility.

The Health Resources and Services Administration (“HRSA”) is the agency within the U.S. Department of Health and Human Services that administers the 340B program. There is no HRSA guidance specifically addressing the 340B eligibility of correctional facilities and inmates. HRSA’s prime vendor, Apexus, previously issued an FAQ on the topic which stated, in relevant part, that “correctional facilities are not 340B covered entities eligible to purchase drugs under the 340B Drug Pricing Program” and that “in the case of DSHs, the clinic at which the covered entity provides healthcare services to incarcerated persons must be an integral part of the hospital, listed as reimbursable on its Medicare cost report.”¹ However, the Apexus FAQ has since been withdrawn. Accordingly, applicable law and policy is not sufficiently granular to allow one to draw clear conclusions about when an inmate’s prescriptions are eligible and when they are not. The best way to address this question is to analyze the results of HRSA’s audits of covered entities that participate in 340B correctional partnerships.

Although HRSA did not begin auditing covered entities until 2012, many of the hospitals selected for a HRSA audit operate 340B correctional pharmacy programs. The results of those audits afford important insights into how HRSA draws the line between eligible and ineligible correctional prescriptions. An analysis of HRSA audit results is hampered by HRSA’s opaque summary of those results on the Office of Pharmacy Affairs (“OPA”) website and by the unavailability of the audit reports themselves for inspection. We think it’s reasonable to assume, however, that if a hospital participating in a correctional partnership is audited by HRSA and does not receive a diversion finding, the partnership arrangement is compliant. Analysis of these audit results reveals essentially seven different approaches to establishing 340B correctional partnerships, each of which poses varying levels of compliance risk. A description of each model is set forth below starting with the least risky and ending with the riskiest.

Model One – Inmates are transported to the hospital’s parent site and the prescription is written within the parent site.

Prescriptions written in Model One fit squarely within HRSA guidance and, absent unusual circumstances, should always be 340B eligible. They are written in a facility that not only is the covered entity’s primary registered location in the 340B database – called the Office of Pharmacy Affairs Information System (“OPAIS”) – but is also the site of care for the individual receiving the prescription. Prescriptions written for non-correctional patients under the same

¹ Apexus, FAQ 1900, <https://www.340bvpv.com/resourceCenter/faqSearch.html?category-content&Ntt-1900> (withdrawn).

circumstances will also be eligible. The site satisfies HRSA's eligible facility guidance and the individual meets HRSA's patient definition notice. So Model One prescriptions would only be ineligible for inmates if either the 340B statute or HRSA guidance specifically excludes prisoners from 340B program eligibility which neither does.

Model Two – Inmates receive both health care and prescriptions at a 340B-registered hospital child site.

Models One and Two are identical except that, in Model Two, the registered site of correctional care is the hospital's child site rather than parent site. Child sites enjoy the same 340B benefits as parent sites so prescriptions originating from child sites should be just as eligible as parent site prescriptions. We are aware of at least one hospital that has a registered correctional care child site. The hospital, located in Texas, was audited by HRSA in 2013. Although the hospital received a diversion finding, the finding was unrelated to the hospital's use of the 340B program for inmates receiving services at the correctional child site. We assume that the auditor was aware of the registered site but we cannot guarantee it.

Child sites must generally meet the requirements of the Medicare provider-based rule before they can be registered in the 340B program. This means they must be organizationally, operationally, financially and clinically integrated with the main hospital in order to be 340B eligible.² Facilities used exclusively to care for inmates and prisoners do not have to meet, and usually cannot meet, the more stringent safety and physical design standards applicable to provider-based hospital outpatient departments. It is possible for such facilities to qualify for 340B participation by meeting these more rigorous standards, but the more common Model Two scenario is that the child site serves both correctional and non-correctional patients.

Model Three – Inmates receive their health care and prescriptions from a mobile facility enrolled in the 340B program.

A careful review of covered entity entries in the OPAIS database reveals that several covered entities have registered their mobile vans in the 340B program. At least one of these covered entities, a children's hospital in California, was audited by HRSA and received no diversion finding. The audit took place in 2016. Although there's no indication that the hospital used its mobile van to serve incarcerated juveniles or other correctional populations, prescriptions written in the van in connection with care rendered therein should be 340B eligible irrespective of the recipient's incarcerated status. The advantage of Model Three over Models One and Two, of course, is that the delivery of correctional care can occur within the secured confines of the prison rather than within the unsecured walls of a hospital. The hospital can literally travel to the inmate patient rather than the other way around.

Model Four – Inmates are seen in person at least once a year at a 340B-registered hospital site, are routinely monitored and treated via telemedicine from a 340B-registered parent or child site and receive prescriptions that are written either during the in-person encounter or as part of the hospital's telemedicine program.

² See 42 C.F.R. § 413.65.

We are aware of two hospitals – one in Virginia and the other in New Jersey – that have based their 340B correctional care programs on Model Four. Both were audited by HRSA and passed their audits. In each case, the hospital limits its 340B program to inmates with HIV and/or hepatitis C. The services rendered by the hospitals, whether during the in-person evaluations or the telemedicine consultations, are furnished by infectious disease specialists. With respect to the New Jersey hospital, the cost centers relating to the telemedicine suite and correctional care clinic include costs associated with serving non-correctional patients which, in turn, allows the hospital to list the cost centers on a reimbursable line of the hospital’s cost report. Although Model Four prescriptions are always written within 340B-registered hospital facilities in accordance with HRSA guidance, use of the 340B program to fill those prescriptions is somewhat riskier. Hospital use of telemedicine to establish a patient relationship within the meaning of the program is a somewhat recent phenomenon and is not specifically addressed in any HRSA or Apexus FAQ nor in any other kind of program guidance. For that reason, writing the 340B prescription during the in-person visit at the hospital is probably safer than issuing it during the telemedicine encounter. In 2015, HRSA issued draft 340B omnibus guidelines stating that, among other things, the use of telemedicine to establish 340B eligible patient relationships is permitted, as long as the practice complies with federal and state law and otherwise complies with 340B program requirements.³ The proposed guidelines were withdrawn in 2017.⁴ There is still some level of uncertainty therefore whether HRSA considers telemedicine services as being provided at the location of the provider, the location of the patient, or both.

Model Five – Hospital care for inmates is based solely on the delivery of telemedicine services and the inmates’ prescriptions are written in the hospital’s 340B-registered telemedicine suite.

Model Five relies exclusively on the telemedicine component of Model Four and thereby avoids the time, cost and security risks associated with transporting prisoners to the hospital for in-person care. This is the model established by an Illinois hospital in 2012. The Illinois hospital publicly acknowledged that it was using a telemedicine-only model to extend its 340B program to correctional populations.⁵ It passed its HRSA audit in 2016. Model Five is obviously more aggressive than Models One through Four because it relies exclusively on telemedicine services to establish the patient-provider relationship. Its compliance status rests entirely on HRSA’s comfort with the use of telemedicine to satisfy patient definition requirements. HRSA has not clarified its position on this issue in any official capacity, although the Illinois hospital’s successful HRSA audit bodes well for the viability of Model Five. We are aware of at least one other hospital using Model Five and it provides correctional telemedicine services across state lines. As far as we know, this out-of-state use of Model Five has not been audited by HRSA.

³ 80 Fed. Reg. 52,300, 52,306-07 (Aug. 28, 2015).

⁴ <https://www.reginfo.gov/public/do/eoDetails?rid=126712>.

⁵ See M. Badowski & C. Nyberg, *Establishing a Telemedicine Clinic for HIV Patients in a Correctional Facility*, AM J HEALTH-SYST PHARM, 69:1631-33 (Oct. 1, 2012).

Model Six – The hospital cares for inmates at the prison and the inmates’ prescriptions are written by a covered entity professional in a non-340B-registered site that is staffed and managed by the 340B hospital.

We are aware of four hospitals that use Model Six to deliver health care and 340B medications to prisoners. All four hospitals have been audited by HRSA and, to the best of our knowledge, none of their 340B correctional programs resulted in a diversion finding. We are most familiar with the programs established by a Texas hospital – different from the Texas hospital discussed in connection with Model Two – and a hospital located in Washington State.

The Texas hospital is required under Texas law to provide health care services to Texas prison inmates. In accordance with this law, the hospital employs the physicians, nurses and other caregivers who render services to the inmates at the correctional facilities. The hospital supplements these services with telemedicine furnished by its physician located in a registered facility. Under this model, 340B prescriptions are written either by hospital-employed physicians who work onsite at the correctional facilities or by hospital telemedicine doctors. HRSA audited this Texas hospital in 2014 and did not issue any findings in connection with its correctional practices.

The hospital in Washington State was audited by HRSA for a six month period in 2016. The HRSA auditor was aware of the correctional program, but did not issue a finding pertaining to it. Significantly, the hospital had registered its correctional program on OPAIS in 2014. It provided care at four jail facilities. However, rather than registering those facilities, it registered the on-site location from which the correctional health program was managed, even though no health care was provided at that site. The salaries for the professionals who provided care at the jail facilities were included on an outpatient line of Worksheet A of the Medicare cost report and charges were recorded on corresponding lines of Worksheet C. The HRSA auditor visited that site and did not express any concerns that care was not provided at the location.

The other two hospitals are located in Connecticut and Georgia. Their 340B correctional partnerships survived HRSA audits in 2015 and 2017, respectively.

Model Seven – The hospital cares for inmates at the prison and the inmates’ prescriptions are written by a hospital professional in a non-340B site that is managed by the correctional facility rather than the hospital.

Models Six and Seven are similar except that, in Model Seven, the facility where prisoners are treated is managed by the correctional institution, not the covered entity. Model Seven is sometimes referred to as the “visiting professional” or “house call” model because the hospital caregiver involved in the partnership often travels to the correctional facility to provide care. We know of several county hospitals using this approach to serve their county jails but, to our knowledge, only one of them, located in California, has been audited. The California hospital received a diversion finding as a result of its HRSA audit in 2014, but it was successful in reversing the finding upon appeal. The prescriptions were written in the county jail, not in the hospital, and the correctional sites were not registered on the OPAIS. The sample of

prescriptions that HRSA reviewed included five that were written for inmates at the correctional facility. For four of the five inmates, the covered entity provided significant services at the hospital as well as at the jail facility. The hospital was able to provide documentation that four of five of the inmates included in the diversion finding had received services at the hospital facility before or after incarceration or both, and sometimes after the prescription was filled.

HRSA reversed its diversion finding with respect to all five prescriptions. HRSA determined that the services were “part of” the outpatient services from the main hospital and that the prescriptions in question were provided in the physician’s capacity as a designee of the health care system of which the hospital was a part.