North Carolina Department of Public Safety

Adult Correction and Juvenile Justice

Pat McCrory, Governor
Frank L. Perry, Secretary

W. David Guice, Commissioner

MEMORANDUM

TO: Chairs of House Appropriations Subcommittee on Justice and Public Safety
Chairs of Senate Appropriations Subcommittees on Justice and Public Safety
Chairs of the Joint Legislative Oversight Committee on Justice and Public Safety

FROM: W. David Guice, Commissioner

RE: Study 340B Drug Pricing Opportunities

DATE: June 22, 2015

Pursuant to Session Law 2014-100, Section 16C.13.
The Department of Public Safety, Division of Adult Correction, shall study opportunities for the State to obtain savings under the federal 340B Drug Pricing Program on drugs provided to prisoners in State correctional facilities. The Division shall conduct this study in conjunction with the University of North Carolina Health Care System. The Department shall report the results of this study by December 1, 2014, to the chairs of (i) the Joint Legislative Oversight Committee on Justice and Public Safety, (ii) the House Appropriations Subcommittee on Justice and Public Safety, and (iii) the Senate Appropriations Committee on Justice and Public Safety.

A memo dated February 12, 2015 was submitted which stated the study was delayed but would be completed and submitted by July 1, 2015. The study has now been completed and follows.

340B Drug Pricing Program

Overview

The 340B Drug Pricing Program is a federal government program created by Congress in 1992 and named after Section 340B of the Public Health Service Act. The 340B Program requires drug manufacturers to provide outpatient drugs to eligible covered entities/healthcare organizations at significantly reduced prices. The Health Resources and Services Administration (HRSA), the federal agency responsible for administering the 340B Program, limits the maximum 340B price (ceiling price) a drug manufacturer may charge a covered entity for select outpatient and over-the-counter 340B purchased drugs. The drug manufacturers submit confidential pricing data to the Centers for Medicare and Medicaid Services (CMS) who use the data to calculate the 340B drug prices. Drug manufacturers participating in 340B must provide outpatient drugs to approved healthcare organizations in order to participate in the Medicaid Drug Rebate Program.

MAILING ADDRESS:
4201 Mail Service Center
Raleigh NC 27699-4201

www.ncdps.gov

OFFICE LOCATION:
512 N. Salisbury St.
Raleigh, NC 27604
Telephone: (919) 733-2126
Fax: (919) 715-8477

Eligibility

The 340B Program qualification for eligibility has been expanded several times since the program was established in 1992 and depends upon the type of facility applying for participation. Entities eligible to participate in the 340B Program as covered entities must meet specific requirements and include the following:

- Federally Qualified Health Centers (FQHC) and FQHC Look-Alikes
- Native Hawaiian Health Centers and Tribal/Urban Indian Health Centers
- Ryan White Care Act (Parts A, B, C, D) Grantees
- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals (DSH>11.75%)
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals (DSH>8%)
- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics (Family Planning under Title X)
- Certified Tuberculosis Clinics

The eligible entities must register and enroll in the HRSA 340B Program and continually meet all 340B requirements. The covered entity must meet the following ongoing requirements in order to purchase drugs at 340B prices:

1. Keep the 340B Database accurate and up-to-date
2. Recertify eligibility every year
3. Prevent duplicate discounts
4. Prevent diversion to ineligible patients
5. Prepare for HRSA 340B Program audits

Patient eligibility is defined in 340B statutes and guidelines and must be met in order for a patient to receive a drug that is purchased by a covered entity at a 340B discount. The patients must not only be an outpatient but must meet the criteria listed below in order to be eligible to receive 340B drugs.

1. The covered entity must have an established relationship with the patient and must maintain the patient's record of care.

2. The individual/ patient must receive healthcare services from a healthcare professional who is employed/contracted with the covered entity so that the responsibility for the patient's care remains with the covered entity.

3. The individual/ patient must receive a healthcare service or a range of services from the covered entity that is consistent with the range of services provided by the covered entity.

The HRSA has implemented new integrity initiatives to improve 340B Program oversight which have resulted in an increase in the number of audits performed on the covered entities. The audits assess 340B compliance and ensure drugs are not being diverted to ineligible patients. Failure to comply with 340B Program rules can result in a covered entity being required to refund discounts to the manufacturers or removal from the 340B Program. A second audit would subsequently follow the initial audit if noncompliance was discovered. Manufacturers are also permitted to audit the records of covered entities to make sure the resale or transfer of 340B outpatient drugs to ineligible patients and duplicate discounting do not occur. In addition, covered entities must recertify their 340B eligibility status every year. The HRSA is required by statute to conduct annual recertification of participating 340B covered entities to ensure the information listed in the HRSA 340B Database is accurate. The ultimate responsibility regarding managing compliance with the 340B Program rests solely with the covered entities and participating manufacturers.

Duplicate discount generation which results from taking a 340B discount up-front and a Medicaid rebate on the same transaction is a significant concern. Expanding state Medicaid programs are seeking rebates on all outpatient covered drugs which in turn may affect 340B pricing and compliance in the future. Manufacturers do not want to have to offer a 340B discount to an eligible covered entity and also pay a rebate to a state Medicaid program on the same transaction. This is another reason the HRSA is focused on ensuring program compliance.

NCDPS Cost Containment Measures

Membership in a Group Purchasing Organization

The pharmacies in the Department of Public Safety/Division of Adult Correction participate in the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) program which is a free, voluntary Group Purchasing Organization (GPO) for government facilities that provides pharmaceuticals and healthcare products and services. MMCAP is a cooperative in which all members share equally in benefits. Though it is operated by the State of Minnesota, it does not receive funding from the State of Minnesota or any government source. NCDPS has been a MMCAP member since October 2000.

MMCAP membership includes thousands of participating facilities in all 50 states. Membership is open to entities such as state agencies, counties, cities, school districts, and public higher education facilities. Typical facility types include public health, student health, nursing facilities, hospitals/clinics, corrections, mental health, substance abuse treatment facilities, and facilities for the developmentally disabled. There are two representatives from each state (one purchasing and one pharmacist) who act as liaisons between MMCAP and other state members. In addition, there are eight member-elected representatives (4 pharmacy representatives and 4 procurement representatives) and an appointed chairperson who serve as an Advisory Board to MMCAP and assist in setting strategic direction that is aligned with MMCAP members' needs and the changing face of healthcare. The State of North Carolina pharmacy representative is an elected member of the Advisory Board.

MMCAP negotiates and contracts with prime vendors (wholesalers) who distribute products to members at the manufacturers' contracted price. A MMCAP committee composed of various healthcare and purchasing members has the authority to select a prime vendor based upon a comparison of potential prime vendors' terms and conditions. North Carolina selected Cardinal Health as its primary vendor in January 2015 for a three contract with an effective date of February 1, 2015.

MMCAP Shareback Credits

Not only does the state benefit from the volume contracting and careful contract management, it also benefits from MMCAP Shareback Credit. Administrative fees from the vendors are returned to MMCAP members annually as a wholesaler credit. Vendor administrative fees are collected by MMCAP for its efforts in consolidating and maintaining membership; contracting and negotiating with manufacturers; contracting with wholesalers for distribution; administering and maintaining contracts; resolving issues between vendors, members, and wholesalers; and managing a common set of terms and conditions. MMCAP does not collect any fees from its members. A portion of the vendor fees are used to fund MMCAP operations. All unused vendor fees are returned directly to MMCAP facilities as a wholesaler credit based upon contract purchases. DPS pharmacies diligently monitor the contract/non-contract purchases in order to maximize the amount of the Shareback Credit. In 2014, the total amount of the Shareback Credit received by the Department of Public Safety/Division of Adult Correction Pharmacies totaled $673,812.94.

Prime Vendor Service Fee Discount

The prime vendor/wholesaler offers a service fee discount on products which is calculated quarterly and is applied to purchases for the following quarter. The service fee discount, which is currently between 4.84% and 5.14%, is based on the State of North Carolina's monthly pharmacy purchase volume and the facility payment terms.

Pharmacy Programs and Systems

Internal efforts to control the use and cost of medications include:

1. A prior approval process for non-formulary medications.

2. Recovery of hermetically sealed medications which have never been in the inmate's possession and the return of these medications to the pharmacy inventory for redistribution.

3. Limiting drug quantities which have no scheduled administration and are given on an as needed basis.

4. Providing an ancillary four day supply of commonly ordered medications for immediate use with an accountability mechanism at outlying facilities which prevents the need for outside purchases from local pharmacies.

5. The purchase of Automated Dispensing Cabinets at Central Prison Healthcare Complex and the North Carolina Correctional Institution for Women.

6. The continuous monitoring of contracts and prices when ordering drugs from wholesalers.

7. Formulary management which ensures a high quality of patient care and the effective management of drug costs.

8. Monitoring adherence of established Chronic Disease Guidelines.

9. Policy driven criteria and procedures for treating high dollar disease states, i.e., HIV and Hepatitis C.

10. Participation in Multidisciplinary Comprehensive Site Reviews to monitor drug accountability and documentation.

11. The implementation of a electronic health record facilitates real time patient management though universally available data and joint pharmacy and medical review resulting in improved efficiencies, decreased errors and positive patient outcomes.

Summary

NCDPS Health Services facilities and patients do not meet the stringent eligibility criteria established by Section 340B of the Public Health Service Act. Based upon the current definition of patient, Central Prison Healthcare Complex Hospital cannot qualify as a Disproportionate Share Hospital therefore is not eligible for the 340B Program. The HRSA has renewed its efforts to ensure program integrity and is committed to ensuring the statutes and guidelines encompassing the 340B Program are followed.