Roy Cooper, Governor Erik A. Hooks, Secretary Timothy D. Moose, Chief Deputy Secretary Todd E. Ishee, Commissioner of Prisons

MEMORANDUM

TO:

Joint Legislative Oversight Committee on Justice and Public Safety

Fiscal Research Division

FROM:

Erik A. Hooks, Secretary SAN for AH Todd E. Ishee, Commissioner of Prisons

RE:

340B Program Savings

DATE:

October 1, 2020

Pursuant to N.C.G.S. §143B-707.10(a), the Department of Public Safety shall report to the Joint Legislative Oversight Committee on Justice and Public Safety and the Fiscal Research Division by October 1, 2020, and annually thereafter, regarding:

(1) Savings achieved from its partnership with the Department of Health and Human Services for the purchasing of certain medications for inmates under the federal 340B Program.

(2) Savings achieved from its partnership with the University of North Carolina Health Care System for the provision of inmate medications and services under the federal 340B Program.

Notwithstanding the challenges associated with the COVID-19 pandemic, the Division of Prisons, Health and Wellness Section has been working diligently towards 340B program participation. Please find attached a report on 340B program participation.



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(1) Savings achieved from its partnership with the Department of Health and Human Services for the purchasing of certain medications for inmates under the federal 340B Program.

Due to the complexities associated with 340B program participation, the Department of Public Safety (DPS) continues working in partnership with DHHS towards achieving full implementation. At this time no cost savings have been realized. However, the Division of Prisons has undertaken the following actions:

- Successfully hired a pharmacist, Dr. Shaw to lead our 340 effort. Dr. Shaw has a wealth of
 experience and will begin in early October.
- DPS Central Pharmacy has contributed to the progress for initiation of the DPS 340B Federal Drug Pricing Program through the following actions.
 - o Initial registration of the Department and the eight DPS HIV/Hepatitis C treating facilities
 - Update the Covered Entity Point of Contacts
 - o Transfer registrations to an Authorizing Official with contract binding authority
 - o Recertify the nine registrations during the STD Grantee 2020 recertification period
 - Initiate development of policies and procedures
 - Collaborate with the Electronic Healthcare Record/Pharmacy Software Vendor for programing requirements
 - Consult with Cardinal Health Drug Wholesaler for establishing a 340B account
 - Assist with the establishment of the 340B Pharmacy Consultant and 340B Pharmacy Technician positions
 - Conduct the interview process for the 340B Pharmacy Consultant and 340B Pharmacy Technician

The above Departmental completed actions, in conjunction with the expertise of the newly hired 340B Pharmacy Consultant, will move forward the following implementation steps that have been previously identified:

- Submission of DPS Grantee Combined Purchasing and Distribution application and approval by HRSA
- Establishment of Multidisciplinary Team and discipline assignments
- Development of covered entity policies and procedures
- Revision of existing policies and procedures
- Development of a process to ensure every patient meets the 340B patient definition including patient, provider, and service eligibility prior to each dispense
- Establishment and implementation of a 340B training program for providers, nurses, and pharmacy
- Establishment and implementation of covered entity self-audit program
- Activate Cardinal Health 340B account
- Secure funding for software programing. Consult with software vendor for completion of software programing and software system testing of additional programing.
- (2) Savings achieved from its partnership with the University of North Carolina Health Care System for the provision of inmate medications and services under the federal 340B Program.

The federal government has provided guidance outlining a three-part test to determine if an "individual" is a "patient" of a 340B covered entity.

Per 61 FR 55157-8 (October 24, 1996):

An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if: 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and 3. the individual 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 or Federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

The University of North Carolina Health Care System (UNC-HCS), the 340B covered entity, does not maintain the healthcare records of state inmates in custody of the Division of Prisons. <u>Under the currently established care delivery model between UNC-HCS and DPS</u>, a 340B partnership is prohibited.