

Interoffice Memorandum

AGENDA ITEM

March 3, 2023

TO: Mayor Jerry L. Demings

-AND-

County Commissioners

THRU: Raul Pino, MD, MPH, Department Direct

Health Services Department

FROM: Claudia Yabrudy, Manager

Fiscal and Operational Support Contact: (407) 836-6583

SUBJECT: Florida Department of Health AIDS Drug Assistance Program (ADAP) Pharmacy

Program

Consent Agenda - March 21, 2023

The Ryan White AIDS Drug Assistance Program (ADAP) is a federally funded program run by the Florida Department of Health that provides medication, including antiretrovirals, to individuals with HIV. Traditionally, when individuals in this program are incarcerated, ADAP stops providing medication and the county starts to provide medication through the Corrections Health Services Division (CHS). However, a recent rule change, now allows ADAP to ship medication to our pharmacy, which can then be dispensed to eligible individuals at no cost to the county.

To be eligible to participate in the ADAP program, CHS must become a member of its pharmacy network, which is operated by ADAP's pharmacy benefit manager MagellanRx Management. MagellanRx Management will check individuals' eligibility for the program and will provide CHS medication to dispense.

We are requesting approval to enter into an agreement with the Florida Department of Health, which will allow CHS to become an ADAP participating pharmacy.

ACTION REQUESTED: Approval and execution of Memorandum of Agreement Between

the State of Florida, Department of Health and (Orange County Correctional Facility Pharmacy) and authorization for the County Mayor or designee to sign amendments to this agreement.

(Fiscal and Operational Support Division)

Cc: John Goodrich, Deputy Director, Health Services Department



OFFICE OF COMPTROLLER

ORANGE COUNTY FLORIDA Phil Diamond, CPA

County Comptroller as Clerk of the Board of County Commissioners

201 South Rosalind Avenue

Post Office Box 38 Orlando, FL 32802

Telephone: (407) 836-7300 Fax: (407) 836-5359

DATE:

March 23, 2023

TO:

Claudia Yabrudy, Manager

Fiscal and Operational Support, BCC

FROM:

Jennifer Lara-Klimetz, Assistant Deputy Clerk 25 for 12K

Comptroller Clerk of BCC

SUBJECT:

Request for Execution of Document, Health Services Department Consent

Item 3, Legislative File # 23-516, March 21, 2023

Enclosed is the Memorandum of Agreement (1 original) which was approved by the Board of County Commissioners (BCC) at its regular meeting held on March 21, 2023.

Please forward the document to all required parties for signature.

Email copies of the fully-executed documents to <u>ClerkofBCC@occompt.com</u> and copy jennifer.mcgill@ocfl.net. Note: <u>ClerkofBCC@occompt.com</u> is <u>used only</u> for County staff submission of pending documents.

Please include in cover memo or subject line identification of the document by name, agenda item number, and date of BCC approval. Emailed copies must be in full-size PDF format. The document will be processed and filed for the record upon receipt.

If you are unable to return a copy of the fully-executed document before April 21, 2023, notify Jennifer Lara-Klimetz by email of the reason for the delay prior to that date.

If you have any questions, please do not hesitate to call.

jlk:np

Enclosure (1)

dl: Raul Pino, Department Director, Health Services Department [email]
Daniel Banks, Deputy County Administrator, BCC [email]
Sandra Roe, Executive Assistant, Health Services Department, BCC [email]
Pending File

BCC Mtg. Date: March 21, 2023

MEMORANDUM OF AGREEMENT BETWEEN THE STATE OF FLORIDA, DEPARTMENT OF HEALTH and (Orange County Correctional Facility Pharmacy)

This Memorandum of Agreement (Agreement) is entered into between the State of Florida, Department of Health (Department), Bureau of Communicable Diseases, HIV/AIDS Section, AIDS Drug Assistance Program (ADAP), and (Orange County Correctional Facility Pharmacy) (Contract Pharmacy), each a "Party" and jointly referred to as the "Parties."

WHEREAS, the 1992 Veteran's Health Care Act created Section 340B of the Public Health Services Act, which classifies certain health care organizations eligible to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into drug purchasing agreements with the United States Department of Health and Human Services.

WHEREAS, the Department's ADAP is a 340B Covered Entity as defined in section 340B(a)(4) of the Public Health Service Act, that allows drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at reduced pricing. The Department's ADAP is registered as a direct purchase ADAP in accordance with the requirements of Section 340B of the Public Health Service Act. The Office of Pharmacy Affairs (OPA) added the Department's ADAP as a Ryan White HIV/AIDS Program ADAP Covered Entity with the unique 340B ID number RWIID32304.

WHEREAS, the Department executed Contract No. CODTN with Magellan Rx, Management L.L.C. (Magellan) on January 20, 2022, which is incorporated by reference, for the provision of 340B Pharmacy Benefits Management (PBM) services and Pharmacy Network services for uninsured Department Eligible Clients (Eligible Clients).

WHEREAS, the Contract Pharmacy is a member of Magellan's Pharmacy Network under Contract No. CODTN and desires to receive drugs purchased by the Department's ADAP at 340B Ceiling Price to Replenish their stock dispensed to Eligible Clients.

NOW THEREFORE, in consideration of the mutual promises contained herein, the Parties agree as follows:

- I. **RECITALS**: The above recitals are incorporated and made a part of this Agreement.
- II. SCOPE OF THE AGREEMENT: The Department's ADAP will purchase drugs and assume responsibility for establishing the price of the drugs, pursuant to the terms of its Ryan White HIV/AIDS Program Part B Care and AIDS Drug Assistance Program Grant and any applicable Federal, State, and local laws. Contract Pharmacy will dispense prescribed drugs on the ADAP Formulary from existing pharmacy stock to the Eligible Clients. A "ship to, bill to" procedure shall be used in which the Department's ADAP purchases the 340B Covered Drug and the manufacturer/wholesaler must bill the Department's ADAP for the 340B Covered Drug that it purchased and ship the 340B Covered Drug directly to the Contract Pharmacy.
- III. AUTHORITY: Sections 381.003 and 465.0265, Florida Statutes; Chapter 64D-4, and Rule 64B16-28.450, Florida Administrative Code; section 340B of the Public Health Service Act; and sections 2604(b), 2613(a)(1), 2651(e)(3), and 2652(b)(1)(B), of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009.

IV. DEFINITIONS OF TERMS:

- A. 340B Ceiling Price: Pursuant to section 340B(a)(1) of the Public Health Service Act, 340B Ceiling Price and Civil Monetary Penalty final rule (82 FR 1210, January 5, 2017), the 340B Ceiling Price for a covered outpatient drug is equal to the average manufacturer price from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount. The 340B Ceiling Price is calculated using six decimal places and Health Resources and Services Administration (HRSA) publishes the price rounded to two decimal places.
- B. 340B Covered Drug(s): Covered outpatient drug(s) as defined in section 1927(k)(2) of the Social Security Act, which is specific to each National Drug Code (NDC) Number to eleven digits.
- C. 340B Covered Entity: An entity registered for the 340B Drug Pricing Program that receives a unique 340B identification number to purchase and use 340B drugs for its Eligible Clients. Ryan White HIV/AIDS Program grantees including ADAP are eligible to register as 340B Covered Entities.
- D. 340B Drug Pricing Program: Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992. Section 340B requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called "340B Covered Entities," that serve the nation's most vulnerable populations. According to congressional report language, the purpose of the 340B Drug Pricing Program is to enable 340B Covered Entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."
- E. ADAP Formulary: A list of U.S. Food and Drug Administration approved drugs and vaccines approved by ADAP to serve Eligible Clients of Florida ADAP, which only includes drugs that can be dispensed or vaccines that can be administered as ordered by the Health Care Practitioner or in accordance with a protocol outlined in section 465.189, Florida Statutes. The updated formulary is posted to www.floridaadap.org.
- F. Business Day: Monday through Friday excluding State of Florida holidays.
- G. Claims: The information that conforms to the National Council for Prescription Drug Programs standards, which has been properly transmitted to Contract Pharmacy's claims processor and the content thereof, indicating among other things that a prescription has been submitted for payment.
- H. Eligible Client: A person who is actively enrolled in the ADAP in accordance with Chapter 64D-4, Florida Administrative Code, and eligible to receive 340B Covered Drugs as determined by the Department in accordance with HRSA's patient definition criteria set forth at 61 Fed. Reg. 55156 (Oct. 24, 1996), as may be amended by HRSA, who otherwise is unable to access ADAP Formulary drugs and vaccines and who resides in the state of Florida. All Eligible Clients who are Medicaid beneficiaries and for whom Claims for pharmaceuticals are

- reimbursed by a state fee-for-service Medicaid program are expressly excluded from this definition unless the Department and Contract Pharmacy have established an arrangement to prevent duplicate discounts and ADAP notifies HRSA of the arrangement.
- NDC Number: A number to the 11th digit, assigned by the U. S. Food and Drug Administration.
- J. Office of Pharmacy Affairs Information System (OPAIS): A database for the registration of 340B Covered Entities, Contract Pharmacies, and Covered Drug Manufacturers.
- K. Pharmacy Network: The pharmacies that have contracted with Magellan Rx to provide 340B Contract Pharmacy services and dispense 340B Ceiling Price Drugs to Eligible Clients.
- L. Replenish: The process where Magellan Rx will order drugs from the pharmaceutical wholesaler through the Department's ADAP account, purchased at the 340B Program Ceiling Price.
- V. **TERM OF THE AGREEMENT**: This Agreement will begin on the date last signed by both Parties and will continue until the Contract Pharmacy is no longer a member of the Pharmacy Network.

VI. RESPONSIBILITIES OF THE PARTIES:

- A. <u>Contract Pharmacy's Responsibilities</u>: The Contract Pharmacy will perform the following tasks:
 - Provide comprehensive pharmacy services to Eligible Clients throughout the term of this Agreement by stocking and dispensing 340B Covered Drugs, providing record keeping, conducting drug utilization review, conducting ADAP Formulary maintenance, providing profiles, providing counseling, and providing drug therapy management services.
 - 2. Dispense only 340B Covered Drugs pursuant to prescriptions in compliance with local, state, and federal regulations.
 - 3. Accept all inventory Replenishments of 340B Covered Drugs from the wholesaler designated by the Department so long as such drugs are identically labeled and have the same NDC Number as those dispensed by the Contract Pharmacy. The Contract Pharmacy will compare all shipments received to the orders and inform the Department of any discrepancy within five (5) business days of receipt.
 - 4. Maintain accurate, complete, up-to-date, pharmacy records for Eligible Clients to permit effective care and quality review in compliance with all applicable laws and regulations. Retain such records for a period of five (5) years from the date of service. Require Eligible Clients to sign a signature log upon delivery of 340B Covered Drug prescriptions and maintain such signatures on file. Notwithstanding the foregoing, as permitted by law, in lieu of a signature log, Contract Pharmacy may maintain an electronic tracking system or use its point of sale to record

- and confirm the receipt of 340B Covered Drugs in accordance with industry standards.
- 5. Provide reports as directed by the Department.
- 6. Establish and maintain a tracking system or customary business records suitable to prevent diversion of 340B Covered Drugs to individuals who are not Eligible Clients. Contract Pharmacy agrees to make any and all adjustments to their tracking system which the Department advises are reasonably necessary to prevent diversion of 340B Covered Drugs to individuals who are not Eligible Clients.
- 7. Restrict access to 340B pricing to Eligible Clients regardless of whether the Eligible Client picks up at the Contract Pharmacy or the Contract Pharmacy ships the 340B Covered Drug(s) to the Eligible Client.
- 8. Represent and warrant that the signatory below is the owner of the Contract Pharmacy or has full right, power, and authority to bind Contract Pharmacy to this Agreement.
- 9. Warrant that (a) professional pharmaceutical services shall only be rendered by licensed pharmacists to Eligible Clients, (b) that each prescription ordered shall be dispensed in accordance with a lawful prescriber's directions, (c) that it is a pharmacy duly licensed under the pharmacy laws of the state in which it operates, and (d) that the Contract Pharmacy hereby states it is not on probation with any State Board of Pharmacy.
- 10. Represent and warrant that Contract Pharmacy can legally dispense prescriptions for Medicare and Medicaid healthcare programs; and that it is not currently subject to exclusion, suspension, or debarment from government healthcare programs. No representations or warranties have been made or relied upon other than those expressly set forth in this Agreement.
- 11. Provide a copy of this Agreement to OPA upon request of the Department.
- B. <u>The Department's Responsibilities</u>: The Department will perform the following tasks:
 - The Department's ADAP will purchase the 340B Covered Drugs and assume responsibility for establishing the price of the drugs in accordance with applicable Florida and federal law.
 - 2. Determine 340B eligibility for 340B Covered Drugs dispensed by Contract Pharmacy for Eligible Clients.
 - 3. Maintain accurate information in the OPAIS, including the Department's contact information and Contract Pharmacy's contact information.
 - 4. Inform Eligible Clients of their freedom to choose a pharmacy provider. If the Eligible Client does not elect to use the contracted service, the Eligible Client may obtain the prescription from the prescribing clinician

- and then obtain the drug(s) from the pharmacy provider of his or her choice. Obtaining the drug(s) outside the Department's Pharmacy Network will be at the expense of the Eligible Client and will not meet the requirements of the 340B Drug Pricing Program.
- Establish a process for periodic comparisons of its prescribing records with Contract Pharmacy's dispensing records to detect potential irregularities.

C. **Both Parties' Responsibilities**: The Parties agree to the following:

- Identify the necessary information for the Department to meet its compliance responsibility relative to this Agreement and to the 340B Drug Pricing Program, to ensure availability of information necessary for audits by the Department or as may be required by HRSA or by a government agency with a right to demand such audit.
- 2. The Parties understand that they are subject to audits by outside parties such as by OPA and 340B participating drug manufacturers, of records that directly pertain to the Department's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts pursuant to U.S.C. § 256b(a)(5)(c). The Contract Pharmacy will ensure that all pertinent reimbursement accounts and dispensing records, maintained by the Contract Pharmacy, will be accessible separately from the Contract Pharmacy's own operations and will be made available to the Department, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State, and local requirements. Any required audits will be conducted during the Contract Pharmacy's regular business hours and at the sole expense of the Department. It is understood that such audits may be made at any time during the term of this Agreement, to ensure the efficacy of the tracking system, and within one year after this Agreement ends.
- 3. Neither Party will use 340B Covered Drugs to dispense Medicaid prescriptions, unless the Department, the Contract Pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts pursuant to 75 Fed. Reg. 10272 (March 5, 2010). Any such arrangement shall be reported to HRSA OPA by the Department.
- 4. Both Parties agree that they will not resell or 340B Covered Drug prices to an individual who is not an Eligible Client.
- 5. Provide pharmacy services contracted for under this Agreement at the locations specified in Schedule A, attached hereto as Attachment I. To ensure compliance with 340B Drug Pricing Program requirements, the Parties acknowledge they are responsible for maintaining an accurate, complete, and up to date list of its respective locations (including names and addresses) relative to this Agreement.
- 6. Contract Pharmacy may provide other services (e.g. delivery) to the Department or its Eligible Clients at the option of the Department.

- Regardless of the services provided by the Contract Pharmacy, access to 340B pricing will always be restricted to Eligible Clients.
- 7. Both Parties will adhere to all applicable federal, Florida, and local laws throughout the term of this Agreement.
- 8. Both Parties are aware of the potential for civil or criminal penalties if either violates federal or Florida law.

VII. GENERAL PROVISIONS:

- A. <u>Drug Ownership</u>: The Department's ADAP will maintain title to the 340B Covered Drugs until they are dispensed to the Eligible Client.
- B. <u>Modification</u>: Neither this Agreement, nor any provision hereof, may be amended or otherwise modified, except by a written instrument signed by the Parties hereto.
- C. <u>Cooperation with the Inspector General</u>: Contract Pharmacy understands its and its subcontractors' (if any) duty, pursuant to section 20.055(5), F.S., to cooperate with the Inspector General in any investigation, audit, inspection, review, or hearing. Contract Pharmacy shall comply with this duty and cause its subcontractors performing services under this Agreement issued under this Agreement, if any, to comply with this duty.
- D. Health Insurance Portability and Accountability Act (HIPAA): The Parties will comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) (Pub. L. No. 104-191, 110 Stat. 1936) and all applicable regulations promulgated thereunder.
- E. <u>Agreement Managers</u>: The following are the Agreement Managers to this Agreement. Either Party's Agreement Manager may be changed by providing written notice to the other Party of the change.
 - 1. Contract Pharmacy's Agreement Manager: Claudia Yabrudy, Manager, Fiscal and Operational Support Division, Orange County Health Services Department, Claudia.Yabrudy@ocfl.net, (Orange County Government Florida)., 3855 S. John Young Parkway, Orlando, FL 32839
 - 2. The name and address of the Department's Agreement Manager is LaCandria Churchill, ADAP Business & Data Integrity Coordinator, Lacandria.Churchill@flhealth.gov Florida Department of Health, 4052 Bald Cypress Way, Bin A-09, Tallahassee, FL 32399 (850-245-4096)
- F. <u>Notices</u>: All notices required or permitted by this Agreement shall be given, in writing, and by certified mail to the respective addresses of the Parties as set forth in Section VII.E., <u>Agreement Managers</u>, above. All notices by email shall be deemed received when they are transmitted and not returned as undelivered or undeliverable.
- G. <u>Public Records</u>: To the extent that information is used in the performance of the resulting Agreement or generated as a result of it, and to the extent that information meets the definition of "public record" as defined in section 119.011,

Florida Statutes, said information is a public record and absent a provision of law or administrative rule or regulation requiring otherwise, must be made available for inspection and copying by any person upon request as provided in Article I, Section 24, Florida Constitution and Chapter 119, Florida Statutes. It is expressly understood that any state contractor's refusal to comply with these provisions of law will constitute an immediate breach of the Agreement, entitling the Department to unilaterally terminate the Agreement. Contract Pharmacy will be required to notify the Department of any requests made for public records.

If the Contract Pharmacy has questions regarding the application of Chapter 119, Florida Statutes, to the Contract Pharmacy's duty to provide public records relating to this Agreement, contact the custodian of public records at (850)245-4005, PublicRecordsRequest@flhealth.gov or 4052 Bald Cypress Way, Bin A02, Tallahassee, FL 32399.

- H. <u>Force Majeure</u>: Neither Party will be liable for the delay or failure in performance of any of its obligations under this Agreement when such delay or failure arises from events or circumstances beyond the reasonable control of such Party, including, without limitation, acts of God, fire, flood, war, explosion, sabotage, terrorism, or embargo.
- Assignments and Subcontracts: Contract Pharmacy must not subcontract or assign any work under this Agreement without the prior consent of the Department.
- J. <u>Financial Specifications</u>: Each Party will be responsible for their own individual costs associated with performing their respective duties under this Agreement.
- K. <u>Sovereign Immunity</u>: Nothing in this Agreement shall be interpreted as a waiver of sovereign immunity, beyond that which is statutorily permitted, or consent by a state agency or political subdivision to suit by third parties.
- L. <u>Scrutinized Companies</u>: By entering into this Agreement, in accordance with the requirements of section 287.135(5), F.S., Contract Pharmacy certifies that it is not participating in a boycott of Israel. At the Department's option, the Agreement may be terminated if Contract Pharmacy is placed on the Quarterly List of Scrutinized Companies that Boycott Israel (referred to in statute as the "Scrutinized Companies that Boycott Israel List") or becomes engaged in a boycott of Israel.
- M. <u>E-Verify</u>: Effective January 1, 2021, Contract Pharmacy is required to use the U.S. Department of Homeland Security's E-Verify system to verify the employment eligibility of all newly hired employees used by the Contract Pharmacy under this Agreement, pursuant to section 448.095, Florida Statutes. Also, Contract Pharmacy must include in related subcontracts, if authorized under this Agreement, a requirement that subcontractors performing work or providing services pursuant to this Agreement use the E-Verify system to verify employment eligibility of all employees used by the subcontractor for the

performance of services under this Agreement.

- N. <u>No Third Party Beneficiaries:</u> Nothing in this Agreement, nor any amendment, or addendum, nor term, provision, or clause contained therein, shall be construed as being for the benefit of, or providing a benefit to, any party not a signatory hereto.
- O. <u>Independent Contractors</u>: The Parties are independent contractors with respect to each other, and this Agreement does not create the relationship of an employer/employee, joint venture, partnership, or association between the Parties.
- P. <u>Waiver</u>: No Party will be deemed to have waived a right, power, or privilege provided for hereunder, unless such waiver is made in writing, and signed by the Party against whom such waiver is sought. The waiver of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of the same or any other provision hereof.
- Q. <u>Severability</u>: If any provision of this Agreement is inconsistent with Florida or federal law, that provision of the Agreement will no longer be effective. The remaining provisions shall remain in full force and effect and shall in no way be affected, impaired, or invalidated.
- R. Governing Law: This Agreement will be interpreted and construed in accordance with Florida law.
- S. <u>Venue</u>: In the event of a dispute under this Agreement, venue must be in Leon County, Florida, to the exclusion of any other jurisdiction.
- T. <u>Entire Agreement</u>: This Agreement contains all the terms and conditions agreed upon by the Parties.

In WITNESS THEREOF, the Parties hereto have caused this nine-page Agreement to be executed by their undersigned officials as duly authorized.

Entity Name	STATE OF FLORIDA, DEPARTMENT OF HEALTH
By: Rumu. Bwohn Byron Brooks, County Administrator Orange County Government Florida	BY: Carina Blackmore, DVM, PhD, Dipl ACVPM State Epidemiologist, Director Division of Disease Control and Health Protection
DATE: March 21, 2023	Control and Floatin Frotestion
FEDERAL ID NUMBER: 59-6000773	DATE:



340B CONTRACT PHARMACY SERVICES AGREEMENT

Schedule A

LOCATIONS

To ensure compliance with 340B program requirements, the Contract Pharmacy acknowledges they are responsible for providing and maintaining accurate, complete, and up to date list of its respective locations (including names and addresses) relative to this Agreement and ensure that all listed locations agree to be bound by such terms. The locations are as follows:

PHARMACY LOCATIONS:	
3855 S. John Young Parkway, Orlando, FL 32839	
DEA Number: B08166781	
NPI Number: 1538376850	
CE Initials/Rx Initials	Date