District of Columbia HIV/AIDS Drug Program

Pharmacy Services Protocol

HIV/AIDS Pharmacy Provider Network

Provider Manual September, 2012

Program policies and procedures for approved pharmacy service providers to dispense HIV/AIDS anti-retroviral and other selected medications to eligible and enrolled District of Columbia residents



GOVERNMENT OF THE DISTRICT OF COLUMBIA Department of Health

HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA)



September, 2012

Dear Network Members and Colleagues,

I am very pleased to welcome you to the HIV/AIDS Pharmacy Network, and let me take a moment to express our appreciation for the vital contribution you make to the health and wellbeing of people with HIV/AIDS in the District of Columbia.

The extraordinary advances in the treatment of HIV disease are a promise of longer and healthier lives for people with HIV/AIDS, and none of that would be possible without your active participation in providing drugs to individuals in need, and providing the necessary counseling and assistance to ensure that people with HIV/AIDS can consume drugs effectively and realize the maximum health benefit from them.

As important as this work is, it is also vitally important to achieve the results while offering choice of pharmacies to all clients, improving accountability on the part of all partners, and achieving the maximum cost-effectiveness of program costs.

Development of this approach is a tribute to the commitment to meaningful partnerships among, on the one hand, multiple parts of the Government of the District of Columbia, the Department of Health (Office of the Director, HAHSTA and the Community Health Administration) the Department of Health Care Finance and, on the other hand, the pharmacies that commit to excellent service to clients in need.

Congratulation to all who have worked so hard to make improve services to people with HIV/AIDS. I look forward to our long and productive partnership.

Sincerely yours,

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Vincent C. Gray, Mayor Government of the District of Columbia



District of Columbia HIV/AIDS Drug Program

The early years of the HIV/AIDS epidemic saw an average life span of eighteen months between AIDS diagnosis and death. Dramatic advances HIV detection and treatment – and in particular the development of highly active antiretroviral therapy (HAART) – now offer real hope for a long and healthy life for many people with HIV.

A critical component to improving the health and lives of people with HIV is ensuring ongoing access to HIV/AIDS drugs, along with the essential services necessary to support people with HIV to be active partners in the management of their health care. Access and effective consumption of life-saving HIV/AIDS drugs is critical to every effort in combating the epidemic.

Early treatment with HAART is now (as of 2012) the standard of care established by the U.S. Department of Health and Human Services treatment guidelines. Many people with HIV are uninsured or under-insured and cannot afford HAART without assistance.

To ensure access to and assistance with this vital health effort, the District of Columbia created the HIV/AIDS Drug Program. It is a partnership among local and federal government organizations, health care providers, consumers and other stakeholders to achieve these goals

- Ensure access to HAART therapy for people with early HIV infection without regard to ability to pay for drugs
- Manage the HIV/AIDS Drug Program as a component of an overall health engagement strategy.
- Maximize the use of federal and local funds as appropriate to support these services.
- Improve the coordination of services to people with HIV.

Key Partners

HIV/AIDS, Hepatitis, STD and Tuberculosis Administration (HAHSTA)

An administration within the Department of Health, HAHSTA has responsibility for coordinating the District response to the HIV epidemic. Supported primarily by federal grant funds, HAHSTA manages a wide range of services, including care, treatment, housing, prevention and surveillance. The Care, Housing and Support Services Bureau of HAHSTA manages the AIDS Drug Assistance Program (ADAP), one of several funding sources used to support the District of Columbia HIV/AIDS Drug Program.



Department of Health Care Finance (DHCF)

DHCF oversees the development and implementation of Medicaid in the District of Columbia, and supports a wide range of services for eligible and enrolled people with HIV. The Department of Health Care Finance (DHCF) is the agency responsible for administering Title XIX of the Social Security Act, the Medical Charities program and other health care financing initiatives of the District of Columbia.

Services supported through DHCF are by far the largest financial contribution to HIV/AIDS services in the District of Columbia.

In 2010 and in response to the passage of the Affordable Care Act (ACA), the District of Columbia expanded Medicaid eligibility to allow enrollment for individuals at or below 200% of the Federal Poverty Level, without a disabling condition. Approximately 1,100 individuals served by the HAHSTA ADAP were enrolled into Medicaid during 2010.

Pharmaceutical Warehouse

The DOH Pharmaceutical Warehouse ("Warehouse") is a licensed drug distribution center that administers the drug component of the Department of Health, the Department of Health Care Finance and other DC government programs that require prescription medications as part of their protocol. The Warehouse

- Purchases, receives, stores and distributes drugs for ten District programs.
- Manages drug formularies, vaccines for immunization and secure addiction and recovery medications.
- Procures drugs for the DC Department of Corrections, Fire and EMS Services, emergency response services.
- Facilitates Strategic National Stockpile (SNS) medications for the CDC and HEPRA as required.

Under the management of the Warehouse, the District HIV/AIDS Drug purchases pharmaceuticals at significantly discounted prices and use these savings to allow low income HIV-infected, District residents access to full benefits, while simultaneously maintaining fiscal responsibility.

The Warehouse is responsible for acquiring, storing and distributing pharmaceuticals in a manner that exacts maximum fiscal and operational efficiencies. The monitoring, clinical interventions, fiscal reporting and logistical support provided by the Warehouse are critical to the program success. The Warehouse also assists these programs in maintaining regulatory compliance as required by the Health Regulatory and Licensing Administration (HRLA).

The key activities of the Warehouse associated with the HIV/AIDS Drug Program are:

- Procures and disperses HIV antiretroviral medication to pharmacies participating in the HIV/AIDS Program Pharmacy Network
- Obtains electronic drug replenishment reports for DHCF and HAHSTA weekly and monthly to facilitate drug replenishment and remittance reconciliation.
- Works collaboratively with DHCF and HAHSTA to assure all point of sales systems are functioning properly.
- Reviews drug utilization reports generated by each program for quality assurance purposes

Pharmacy Benefit Manager (PBM)

The Pharmacy Benefit Manager (PBM) designated by the District of Columbia, Xerox ACS, will work collaboratively with the District of Columbia to maintain support of the delivery of the required information management and claims payment services.

Network pharmacy provider will utilize the PBM designated by DOH for insurance eligibility determination and for prior authorizations of all DOH program prescription requests based on the coverage. The PBM will integrate and interface with the District's Medicaid Management Information System (MMIS) for the purpose of receiving and transmitting applicable information.

The PBM will maintain an online ADAP eligibility file for claims adjudication purposes, maintain compliance with HIPAA Regulations and maintain all required DC Medicaid eligibility file for claims adjudication purposes.

Network pharmacies will also provide to the contract administrator real time access to information pertaining to ADAP related PBM activities for the following purposes:

- a. Client eligibility.
- b. Data system queries.
- c. Claims processing data, including client, practitioner and pharmacy.
- d. Other specialized functions by the CA, to include but not be limited to:
 - 1. Overriding standard dispensing rules on a one-time basis for a specific client.
 - 2. Exercising approval authority for drugs requiring prior authorization.

In the event of an emergency or unusual incident, including a breach of confidentiality or any IT system compromise associated with services supported by the Human Care Agreement, the pharmacy provider must notify the contract administrator by telephone and electronic mail within thirty (30) minutes of the time the pharmacy provider first becomes aware of the emergency or unusual incident. Providers will also follow-up with a detailed written report within two (2) business days of such knowledge as necessary.

Pharmacy Network

The District of Columbia has enhanced its provision of services by contracting with a network of selected pharmacy providers to dispense HIV anti-retroviral and other HIV-related medications to eligible District residents living with HIV. Pharmacies participating in the Network will also participate in the ADAP co-payment assistance program.

The network of community pharmacies is utilized by ADAP clients and DC Medicaid fee-for-service beneficiaries living with HIV. The District of Columbia replenishes drugs dispensed to clients by participating pharmacies. See the "Replenishment Model" below for additional information.

Technical Assistance

The District of Columbia has contracted with Clinical Pharmacy Associates (CPA) to provide technical assistance to the District of Columbia HIV/AIDS Drug Program. Key components of that assistance include

- Technical review of drugs under consideration for inclusion on the ADAP formulary.
- Review of drug regimens and patterns of prescription, with a view towards identifying non-standard practices.
- Assistance with implementation of an e-prescribing methodology to improve communication between prescribing physicians and pharmacy points of sale.
- Regular meetings with participating pharmacies to
- Facilitation of semi-annual medication management groups with pharmacists.
- Training and in-service programs for health professionals at clinic sites.
- Programs for medical case management, treatment adherence and peer support service providers

Key Program Components

AIDS Drug Assistance Program (ADAP)

DOH HAHSTA provides pharmaceutical assistance to eligible District residents through federal grant funds. DC ADAP also works with the providers members of the HIV Pharmacy Provider Network to distribute HIV-related medications on the District's ADAP formulary to enrolled clients. The DC ADAP program covers the cost of drugs through two pharmacy payment methodologies:



• An inventory replenishment model for medications that are non-controlled substances

In addition to the replenishment of drugs, the pharmacy is paid a \$10.50 dispensing fee.

• Monetary reimbursement at the prevailing Medicaid rate for medications that are controlled substances.

The current pharmacy reimbursement rate for Medicaid is Wholesale Acquisition Costs (WAC) plus 3% plus a \$4.50 dispensing fee. DOH currently purchases all non-controlled substances.

ADAP also provides assistance with co-payments and deductibles to eligible and enrolled clients with private health insurance or Medicare Part D coverage. Co-payment assistance is available for medications on the District of Columbia ADAP formulary at the time the prescription is filled. After billing the private insurance or Medicare, the pharmacy bills the co-payment or deductible portion monthly to DOH.

Understanding the many healthcare needs of persons living with HIV/AIDS and the everincreasing epidemic in the District, DHCF and HAHSTA are collaborating to allow low income persons infected with HIV access to full medical benefits. The program seeks to sustain budget accountability and DHCF and DOH continue to explore creative options to maintain fiscal responsibility with the HIV program. Instead of paying full retail prices for the antiretroviral medication, the programs purchase pharmaceuticals via the DOH Pharmaceutical Warehouse (DOH PW) and will contract with the retail pharmacy sector for drug distribution. The resultant drug savings is used to obtain budget savings for the District.

Medicaid Fee-For-Service

Generally, Medicaid services are offered through two models of service: A fee-forservice model that pays a fee for each service provided to an enrolled client, and a managed care model that pays a rate for each client enrolled.

Medicaid beneficiaries receiving services under the fee-for-service model receive HAART drugs under the District of Columbia HIV/AIDS Drug Program. Under the fee-forservice program, the District will replenish HAART drugs dispensed to beneficiaries, and pay a dispensing fee.

Replenishment Model

Pharmacies currently under contract to act as dispensing agents for DOH and DHCF programs receive medications via the DOH Pharmaceutical Warehouse replenishment process. When prescriptions are filled at the participating pharmacies, the pharmacy accepts as payment, return product for the medication dispensed and the pharmacy receives an enhanced dispensing or service fee for their professional services. The replenishment process allowing DOH to maintain its preferred drug pricing and the dispensing fee covers all operating expenses the pharmacy incurs related to filling the prescription. The dispensing fee covers administrative

cost, prescription supplies, labor, distribution, overhead and profit. We do not provide product replenishment for controlled substances covered by the DC ADAP.

All of the replenishment programs will run through the District's current PBM, Xerox ACS. The PBM sends dispensing data to DOH weekly in a predetermined format. No client level data is received on a weekly basis. However the Warehouse reserves access to patient claims data when needed for drug utilization or quality assurance review. The PBM has an online data repository capable of providing the patient profile information as necessary.

All of our replenishment capability is for program specific line items. The replenishment process is labor intensive on our part, because we monitor partial bottle and carry-overs from week to week. Specialized computer programming is used to generate and maintain ongoing provider weekly reconciliation and carry-over reports for each program provider.

The replenishment program began for the District's HIV/AIDS Programs in September 2003. In order to monitor for quality assurance in these programs, the DOH PW has an established, ongoing continuous quality improvement (CQI) program which focuses on proper management of the HIV/AIDS and other medications provided to the contracted pharmacies.

Inventory and Deliveries

The DOH Pharmaceutical Warehouse provides for emergency and just-in-time deliveries to providers on an as needed basis.

Inventory

The HIV Pharmacy Provider is required to maintain a sufficient on hand drug inventory of medications to support the dispensing of anti-retroviral, HIV related, and other formulary medicines to eligible District beneficiaries at least 95% of the time. The DC Department of Health will not replenish the Pharmacy Provider's stock for controlled substances.

Deliveries

The DOH Pharmaceutical Warehouse uses a courier service to deliver weekly drug orders. Each Pharmacy Provider identifies the pharmacy delivery site located within the District of Columbia where the DOH Pharmaceutical Warehouse will make weekly delivery of replenishment medication orders. A weekday will be designated for the delivery of ADAP and DC Medicaid orders.

Dispensing

The Pharmacy Provider must adhere to all applicable federal and District of Columbia laws and regulations regarding dispensing of medications. ADAP and DC Medicaid policies and procedures must also be adhered to for the payment of dispensing fees.

Eligible Clients

A key feature of the HIV/AIDS Drug Program is to encounter clients, and assess each client for likely eligibility for enrollment into a number of programs. The intent of the program is to maximize the ability of individual clients to receive and consume drugs, while at the same time maximizing the cost-efficiency of the overall program.

The steps and methods for determining eligibility for and enrollment into programs can vary significantly depending on the client circumstances. In broad terms, eligibility includes documentation of

- Residency within the District of Columbia
- Income and assets
- HIV infection

ADAP Eligibility

In addition to the general eligibility criteria above, eligibility for ADAP requires compliance with the specific requirements of the CARE Act (Part B) legislation and regulations, and includes

- Review and documentation of all other payor sources for drug assistance. This is necessary to ensure compliance with the "payor of last resort" provisions of the CARE Act.
- Documentation that the client personal income is at or below 500% of the federal poverty level.

There is a two-step procedure for determining eligibility for the AIDS Drug Assistance Program component of the larger HIV/AIDS Drug Program.

- Clients complete often with the assistance of their care providers an application for ADAP, and submit it to the ADAP unit in HAHSTA.
- HAHSTA staff review the application for completeness, and work the client or service providers to fill any gaps in the application.
- In the event a client is eligible for another program (usually Medicaid) HAHSTA refers the application for review by the other program.
- In the event a client is determined to be eligible for ADAP, HAHSTA staff complete their review and transmit the completed application to ESA (see below) for entry and enrollment.
- Each client is required to re-certify ADAP eligibility at least every six months. This re-certification is conducted by HAHSTA.

Medicaid Eligibility

Generally, eligibility screening for Medicaid is very well established, and may include pregnancy, disability, blindness or an aged individual. Income and assets are also considered.. As of December 2010, DC residents with a household income at or below 200% of the Federal Poverty Level are eligible for Medicaid without a disabling condition. Medicaid is available only to citizens of the United States or lawfully admitted immigrants.

Economic Security Administration

The District of Columbia Economic Security Administration (ESA) processes application for these (and many other) programs, and enrolls eligible clients in the programs covered under the human care agreement (HCA). ESA will designate client eligibility for enrollment in the DC ADAP or DC Medicaid Fee-for-Service or any other covered and specified District indigent care program.

Eligibility and the Pharmacy Network

Clients frequently migrate among programs, and it is essential that each participating pharmacy reviews the current enrollment status of each client prior to dispensing prescriptions Each pharmacy must dispense to eligible clients all HIV and HIV-related medications according to the client's enrollment status as designated by ESA. Pharmacy Providers must verify primary health insurance, Medicaid coverage, Medicare Part D coverage, and ADAP enrollment status and ADAP Co-pay enrollment status through Xerox ACS prior to dispensing each prescription.

There is no co-payment collected for approved medications that are dispensed to those eligible ADAP and Medicaid HIV clients including ADAP Co-pay enrollees.

Coordination of Benefits

Under some circumstances, the payor source for a given prescription may require adjustment after having been dispensed. The most frequent occurrence of this is when a client is appropriately served by ADAP while awaiting enrollment into Medicaid. Typically, following enrollment, the drug costs paid by ADAP will be transferred to Medicaid back to the date of the Medicaid application.

The PBM will provide assistance in making these adjustments, and will work to minimize the burden on participating pharmacies.

Approved Medications

There is some variation among the drugs that are included on the specific components of the overall District of Columbia HIV/AIDS Drug Program. The intent of the program is to ensure that the drug assistance needs of all people with HIV/AIDS are addressed by the most appropriate program and funding source, and that coordination among multiple programs may be necessary and appropriate.

AIDS Drug Assistance Program (ADAP)

Residents of the District of Columbia with HIV may be eligible for ADAP. The ADAP is supported by Ryan White CARE Act funds (Part B), and is governed by its legislative and regulatory requirements. One of the core federal requirements is that ADAP is treated as the "payor of last resort." This provision disallows the use of ADAP for any beneficiary with another funding source to pay for HIV/AIDS drugs, including Medicaid, Medicare and private insurance.

Some of the drugs included in ADAP may be different than those on other programs. See the appendix for the current formulary for drugs included on ADAP, which is current as of the date noted on the formulary.

The District of Columbia has convened an HIV/AIDS Drug Advisory Committee (HADAC) to assist in managing ADAP. One of the key responsibilities of HADAC is to review each new drug, assess its likely benefit as an addition to ADAP, project the cost implications and develop a recommendation on inclusion. HADAC has a regular meeting schedule of four times per year. Its recommendations are reviewed by the Department of Health and posted for public comment, which can delay inclusion of a new drug on ADAP.

ADAP and the Alliance

The District of Columbia Indigent Care Program, commonly known as "the Alliance," provides a wide range of health care services to low-income residents. The Alliance does not support HIV anti-retroviral medications, however. Alliance beneficiaries with HIV are typically eligible for enrollment into ADAP, and because the Alliance does not support HIV anti-retroviral medications, ADAP is typically the payor of last resort for these beneficiaries.

Medicaid Fee for Service

All FDA-approved medications are included on the formulary available to Medicaid beneficiaries. Please note, however, that the District of Columbia HIV/AIDS Drug Program supports HIV anti-retroviral medications only. At of the date of this protocol, Medicaid beneficiaries served under a fee-for-service model participate in the District of Columbia HIV/AIDS Drug Program. This means these beneficiaries must go to a HIV/AIDS Pharmacy Network to receive their HIV/AIDS anti-retrovirals.

Fee-for-service Medicaid beneficiaries remain eligible for drugs other than HIV antiretroviral medications, and are served in the same manner as all other Medicaid beneficiaries.

Related Services

• ADAP Co-payment Assistance Program (ADAP Co-pay), The amount of the copayment and deductible coverage for drugs included on the ADAP formulary. • Co-payments and deductible claims for ADAP and or Medicaid Fee-For-Service are not subject to a dispensing fee or replenishment and do not generate a claim for replenishment.

Pharmacy Provider Protocols

Each pharmacy that participates in this program has entered into an agreement (a "Human Care Agreement") with the District of Columbia to provide services. That agreement is the controlling authority for these services, and lists the mutual obligations of the pharmacy and the District of Columbia. The narrative descriptions below are intended to offer an



easy-to-use format for the various requirements, but do not alter or supersede any of the provisions of the Human Care Agreement. Please note the date of this manual, as some of the specific information is subject to change over time.

Pharmacy Services Requirements

The HIV network pharmacy providers offer the following pharmacy services to all eligible DOH clients upon receipt of medication:

- Client counseling including the ability to solicit and effectively respond to all medication-related questions and client concerns
- Refill compliance Taking pro-active initiatives to increase timely refills and to identify and respond to late refills, especially for clients on antiretroviral medications
- Drug interaction monitoring highlighting the ability to identify specific protocols for responding to drug-drug interactions
- Maintain up-to-date client medication records and an active prescription profile
- Ongoing drug utilization review (DUR) to identify incomplete or substandard HIV medication regimens
- HIV adherence counseling including standard adherence counseling to all clients on anti-retroviral and opportunistic infection prophylaxis or treatment drugs, with targeted adherence counseling for clients demonstrating adherence difficulties including late refills.

Provider Reimbursements

Claims reimbursement to pharmacy providers that dispense anti-retroviral, HIV related, and other selected medications meet the reimbursement requirements of the HAHSTA ADAP and the Department of Health Care Finance Medicaid regulations. These requirements include the following:

- 1. ADAP reimbursement claims for controlled substances are restricted to those controlled substances drugs supplied from manufacturers that have signed a national agreement or an approved existing agreement, as specified in Section 1927(a) of the Social Security Act.
- 2. Reimbursement for dispensing fees related to antiretroviral prescriptions are be restricted to only those antiretroviral prescriptions replenished by the Department of Health (DOH) Warehouse.
- 3. To be reimbursable, all prescriptions that have been written, verbally ordered or electronically initiated by a licensed prescriber and must contain the following information on the prescription form:
 - Name and address of patient.
 - Individual Prescriber's Name and the National Provider Identifier (NPI).
 - Name, strength and quantity of the medication.
 - Directions for use.
 - Number of refills, if any.
 - Indication for "brand medically necessary," when applicable.
 - Signature of the prescriber and date of the prescription.
- 4. To be reimbursable, prescriptions for controlled substances ordered by a licensed prescriber shall contain the following additional information:
 - The Drug Enforcement Agency (DEA) number of the licensed prescriber.
 - The District of Columbia controlled substance registration number of the prescriber.
- 5. Reimbursement for pharmacy claims submitted by a provider for a controlled substance will be reimbursed at the lower of the following:
 - The allowable cost, established pursuant to the methodology described in the District's pharmacy regulations.
 - A dispensing fee of four dollars and fifty cents (\$4.50) per prescription.
- 6. Reimbursement for pharmacy claims submitted for each antiretroviral medication will be appropriate replenishment and a reasonable dispensing fee of ten dollars and fifty cents (\$10.50) per prescription.

7. Reimbursement for pharmacy claims submitted for all other approved medications on the ADAP formulary will be appropriate replenishment and a reasonable dispensing fee of ten dollars and fifty cents (\$10.50) per paid prescription.

Pharmacy providers approved for the network are prohibited from submitting multiple claims for a short fill or partial fill of medication, a service, which should have been covered as one claim but is dispensed and covered on different dates or at different times as multiple claims.

Cost Reimbursements

Cost reimbursement ceiling for this program are described in the Human Care Agreement. Pharmacy providers agree to use their best efforts to perform the work specified in the agreement and to meet all obligations established in the cost reimbursement ceiling.

Pharmacy providers may communicate with the contract administrator (CA), in writing, whenever there is reason to believe that the total cost for the performance of the Human Care Agreement will be either greater or less than the cost reimbursement ceiling. As part of the notification, the provider should provide the CA a revised estimate of the total cost of performing the agreement.

The District is not obligated to reimburse the pharmacy providers for costs incurred in excess of the cost reimbursement ceiling unless and until the CA notifies the provider, in writing, that the estimated cost has been increased and provides a revised cost reimbursement ceiling for performance with their HCA.

No notice, communication, or representation in any form from any person other than the contract administrator will change the cost reimbursement ceiling. In the absence of the specified notice, the District is not obligated to reimburse the pharmacy provider for any costs in excess of the costs reimbursement ceiling, whether the costs were incurred during the course of contract performance or as a result of termination of the agreement.

If the cost reimbursement ceiling is increased, any costs the pharmacy provider incurs before the increase is in excess of the previous cost reimbursement ceiling will be allowable to the same extent as if incurred afterward, unless the CA issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

A change order will not be considered an authorization to exceed the applicable cost reimbursement ceiling unless the change order specifically increases the cost reimbursement ceiling.

Only costs determined in writing to be reimbursable in accordance with the cost principles set forth in rules issued pursuant to Title VI of the D.C. Procurement Practices Act of 1985 are reimbursable.

Pharmacy Network Services Assessment and Summary

Pharmacy providers have 30 days following contract award to provide to the CA a Pharmacy Services Assessment and Summary to describe how the site currently delivers each of the pharmacy services and any plans to change or enhance the delivery of the above services during the effective period of performance.

The Pharmacy Network Pharmacy Services Assessment and Summary should include, as appropriate

- Availability of specialty staff with expertise in HIV.
- Written protocols for refill compliance and HIV adherence counseling activities.
- Written protocol for responding to and documenting response to drug interactions.
- Quality assurance plan for internally monitoring or supervising the delivery of services.

Pharmacy Network Services Findings and Improvement Plan

Network providers will assess and provide comment on the adequacy of their pharmacy delivery site in the Pharmacy Network Services Assessment, and should define the criteria by which the adequacy of the delivery of pharmacy services was assessed.

The Pharmacy provider will monitor clients' prescription history and use due diligence to determine and avoid contraindicated drug combinations. Network pharmacists should routinely contact a client's physician via telephone anytime a question arises based on either the pharmacist's or client's review of the client's HIV medication regimen.

Network providers must ensure, as a component of quality improvement activities, that the pharmacy site enters current, correct physicians' names, National Provider Identifier (NPI) and current DEA numbers for every prescription. Prescriptions entered with invalid or outdated prescriber information may be subject to rejection for replenishment and reimbursement and are subject to regulatory review and audit.

Pharmacy Providers will have 60 days after the award of contract to provide a plan to monitor the accuracy of prescribing physicians details and the adequacy of response to contraindicated drug combinations.

Quality Assurance and Pharmacy Services Monitoring and Reporting Plan

Pharmacy providers will receive a template for the Quality Assurance and Pharmacy Services Monitoring and Reporting Plan within 60 days of the inclusion into the network. The plan should detail any quality assurance activities, including but not limited to peer-to-peer technical assistance, on-site support, infrastructure interventions, and other activities that can facilitate improved patient utilization of HIV medications at each pharmacy provider location. Providers should document successful interventions and share the successful interventions with the CA in the quarterly quality assurance reports.

Providers will submit their plan for review and approval to the CA.

Pharmacy Network Related Services

Work Plan

The Pharmacy Provider are required to prepare and provide a detailed work plan within five (5) days of contract award. The work plan shall address, at a minimum, the major tasks to be completed, timeline for completion, and the responsible parties for the following:



- a. Identification and description of the pharmacy including the following:
 - 1. Current licenses
 - 2. Name and address of pharmacy
 - 3. Geographical Location (s), and Capacity
 - 4. Identification of the Participating pharmacy provider's maintain hours of operation on Saturdays and Sundays
 - 5. Identification of the Pharmacy Provider's plan to provide drug delivery services to the client's home or office within the District of Columbia
 - 6. The Pharmacy Provider's Policies and Procedures to fulfill the delivery requirements
 - 7. Foreign language capabilities and compliance with the District's Language Access Act of 2004
- b. Staffing Information including the following:
 - 1. Identification and licenses for Pharmacist
 - 2. Staffing Pattern
 - 3. Organizational Structure
- c. Medication delivery site and delivery procedures.
- d. Pharmacy Services
 - 1. Description of the Pharmacy Provider's Medicaid Management Information System (MMIS) including maintenance of the MMIS system
 - 2. The Pharmacy Provider's Pharmacy Benefit Manager's Name.
 - 3. The Pharmacy Provider shall participate in any Prior Authorization Program established for the HIV/AIDS Program and have on hand all appropriate policies and procedures.
 - 4. Pharmacy Evaluation Process.
 - 5. Reporting Requirements.

Pharmacy Benefit Manager (PBM)

The Pharmacy Benefit Manager (PBM) designated by the District of Columbia, Xerox ACS, will work collaboratively with DOH to maintain MMIS support of the delivery of the required information management and claims payment services.

Network pharmacy provider will utilize the PBM designated by DOH for insurance eligibility determination and for prior authorizations of all DOH program prescription requests based on the coverage. The PBM will integrate and interface with the District's Medicaid Management Information System (MMIS) for the purpose of receiving and transmitting applicable information.

The PBM will maintain an online ADAP eligibility file for claims adjudication purposes, maintain compliance with HIPAA Regulations and maintain all required DC Medicaid eligibility file for claims adjudication purposes.

Network pharmacies will also provide to the contract administrator real time access to information pertaining to ADAP related PBM activities for the following purposes:

- a. Client eligibility.
- b. Data system queries.
- c. Claims processing data, including client, practitioner and pharmacy.
- d. Other specialized functions by the CA, to include but not be limited to:
 - 1. Overriding standard dispensing rules on a one-time basis for a specific client.
 - 2. Exercising approval authority for drugs requiring prior authorization.

In the event of an emergency or unusual incident, including a breach of confidentiality or any IT system compromise associated with services, the pharmacy provider must notify the contract administrator by telephone and electronic mail within thirty (30) minutes of the time the pharmacy provider first becomes aware of the emergency or unusual incident. Providers will also follow-up with a detailed written report within two (2) business days of such knowledge as necessary.

Prior Authorizations

The Pharmacy Provider shall participate in any prior authorization programs for special or limited use medications that may exist or be developed by the HIV/AIDS Program.

The Pharmacy Provider shall develop and provide to the CA within 5 days after contract award the prior authorization policies and procedures to ensure that medications requiring prior authorization are not dispensed without prior approval from the HIV/AIDS Program.

Client Confidentiality

The Pharmacy Provider shall maintain strict confidentiality of all client information and shall not use that information in connection with any other matters, nor shall any such information be disclosed to any other firm or corporation in accordance with the District of Columbia's policy regarding the sharing of client information. The Pharmacy Provider will sign and abide by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Business Associate's Agreement which shall be incorporated into the final contract (Section 37).



Evaluation

The Pharmacy Provider shall at the request of the CA participate in HIV/AIDS Program evaluation activities that require the collection and analysis of data related to program operations and may be used to modify the program design or delivery system.

The Pharmacy Provider shall conduct a Customer Service/Satisfaction Survey specific to the District HIV/AIDS Program at least annually. The Pharmacy Provider HIV client Customer Service and Satisfaction Survey shall address at a minimum the following:

- a. HIV client wait time.
- b. Availability of required medication availability.
- c. Pharmacy Services provided including
 - 1. Client counseling
 - 2. Refill compliance
 - 3. Drug interaction monitoring
 - 4. Drug Utilization Review (DUR)
 - 5. HIV adherence counseling.

Reporting Requirements

Required information shall be retrieved by the Pharmaceutical Benefits Manager the following reports:

Monthly Reports

The Pharmaceutical Benefits Manager designated by DOH will provide the following required monthly reports beginning after one month of operational phase for ADAP and DC Medicaid:

- a. Client Activity Report.
- b. Claims Summary Report.

- c. Member Claims Report.
- d. Administrative Report.
- e. Pharmacy Location Summary Report.
- f. Dispensed Drugs by Provider.
- g. Claims Summary.
- h. Dispensed Drugs by Provider Insurance Co-Pay Program.
- i. Claims Summary Insurance Co-Pay Program.
- j. Exceptions Report.

Quarterly Reports

The Pharmaceutical Benefits Manager is responsible for regular and ad hoc reports to the District of Columbia, and in large measure produces the reports based on data gathered from Pharmacy Providers. Following are the quarterly reports for ADAP and DC Medicaid currently required from the PBM.

- a. Drug Utilization Report
- b. ADAP Client Quarterly Report
- c. Client Wait Time Report
- d. Quality Performance Report highlighting the provision of and quality of services shall be provided to the CA to document quality assurance activities performed at each pharmacy within the Participating pharmacy provider's network.

Pharmacy Services Reports

The Pharmaceutical Benefits Manager is also responsible for providing the following reports as required by the District of Columbia:

- a. Quality Assurance and Pharmacy Services Monitoring and Reporting Plan.
- b. Pharmacy Network Pharmacy Services Assessment and Summary
- c. Pharmacy Network Pharmacy Services Findings and Improvement Plan.
- d. Monitoring report to report accuracy of prescribing physicians details and the adequacy of response to contraindicated drug combinations

Inspection Report

Each Pharmacy Provider is responsible for providing to the District of Columbia a copy of the report of the annual inspection conducted by the District of Columbia Health Regulations and Licensing Administration (HRLA). A copy of this report will be submitted by the Pharmacy Provider to the Warehouse within five (5) business days of receipt from HRLA.

HIV/AIDS Program Provider Deliverables

The following deliverables are to be provided to the Contract Administrator for review and approval by the due dates presented in the following table. The Pharmacy Provider will provide one (1) hard copy and one (1) electronic copy of each deliverable and provide revisions to the deliverables in accordance with the written comments provided by the CA.

Program Deliverable	Due Date
Annual DC HRLA Inspection Report	Prior to award, and as revised
Certification as a Medicaid Provider	
First Source Agreement	
Organizational Chart	
Monitoring and Reporting Plan	Within ten days of award, and as revised
Emergency and Unusual Incident Plan	
Prior Authorization Policies and Procedures	
Pharmacy Services Assessment Summary	
Work Plan	
Findings and Improvement Plan	Coordinated with
Client Wait Time Report	
Weekly Reports	Contract
Monthly Reports	Administrator
Quarterly Reports	

Quality Assurance

The District of Columbia has consolidated its approach to quality assurance for the HIV/AIDS Drug Program, and implements it through the Pharmaceutical Warehouse. The ultimate goal of the program is to promote medication safety.

In addition, it seeks to develop, implement and revise (as needed) continuous quality improvement (CQI) guidelines with which to measure current quality and patient safety standards against established quality standards and thresholds to measure the performance of our current HIV/AIDS drug delivery programs. Part of this QA function also involve a minimum of one site visit each year to each pharmacy participating in the Network.

The CQI program focuses on medication management and prevention of errors related to inventory management and the dispensing of medications. The CQI program focuses on contractual quality assurance requirements and nationally recognized best practice standards of quality assurance in the pharmacy industry. Processes to identify trends in prescription incidents will be established that will assist in the development of new procedures and more systematic processes for medication management and oversight. The findings will be considered by the District of Columbia partners to ensure a consistently high quality of services provided.

Consistent with standard practices and District expectations, each participating pharmacy remains responsible for implementing its own quality assurance program, either by internally contracting or otherwise arranging for personnel or resources with QA skill or expertise to satisfy QA requirements at the store level. A record of any such quality assurance activities should be made available for review in the pharmacy, and should contain the pertinent data and other information summarizing the findings and determinations generated by the quality assurance activity and the recommended changes to pharmacy policy, procedure or systems.

A copy of the internal QA report should be forwarded to the Pharmacy Warehouse within fifteen business days of completion.

Best Practices and Industry Standards in Pharmacy Quality Assurance

The CQI program emphasizes the prevention of procurement and inventory management errors through several checks and balances:

- 1. Adherence to written policies and procedures intended to standardize the procurement process, maximize positive outcomes and decreasing the probability of ordering errors.
- 2. Utilization of recognized outcome measures along with established standards of care and practice, to identify critical treatment indicators in HIV medication management.
- 3. Meet and collaborate with the program managers regularly and communicate information regarding ordering anomalies and other quality assurance concerns identified in report reviews and during the ordering process.
- 4. Each participating pharmacy will adhere to all applicable Federal, District of Columbia laws, policies and procedures regarding the maintenance, dispensing and distribution of medications. Each participating pharmacy will also provide clinically appropriate dispensing services in support of these requirements.
- 5. Medication management protocols to include clinically appropriate dispensing services:
 - **a.** Refill compliance pro-active steps taken to increase timely refills and to identify and respond to late refills, especially for clients on antiretroviral medications.
 - **b.** Each participating pharmacy will ensure, as a component of quality improvement activities, that the pharmacy sites enter, validate and retain current, accurate physicians' names, DEA numbers and NPI for every prescription.
 - **c.** Each participating pharmacy will maintain a sufficient on hand inventory of antiretroviral medications to fill "on demand" requests for antiretroviral medications at least 95% of the time and receive replenishment in the following week's order.



Appendices

GOVERNMENT OF THE DISTRICT OF COLUMBIA Department of Health



HIV AIDS, Hepatitis, STD and Tuberculosis Administration (HAHSTA)

HIV/AIDS Drug Program Pharmacy Directory as of September 11, 2012

For an updated list of ADAP Pharmacies please visit http:/doh.dc.gov/HAHSTA, look for "News, Hot Topics and Updates" and click on "New ADAP Pharmacies"

1. AIDS Healthcare Foundation

Blair Underwood Healthcare Center 2141 K Street NW Suite 606 – RX Washington, DC 20037 Phone: 202/293-8695 Fax: 202/293-8699

2. Apex Care Pharmacy

3839 Minnesota Avenue NE Washington, DC 20019 Phone: 202/388-1900 Fax: 202/388-8099

3. Capitol Hill Pharmacy

650 Pennsylvania Avenue SE Washington, DC 20003 Phone: 202/548-0008 Fax: 202/548-0017

4. Columbia Heights Pharmacy

3316 14th Street NW Washington, DC 20010 Phone: 202/232-1455 Fax: 202/232-1453

5. Goodcare Pharmacy I

2910 MLK, Jr. Ave SE Washington, DC 20032 Phone: 202/561-4343 Fax: 202/561-5061

6. H Street Care Pharmacy & Wellness Center

812 H Street NE Washington, DC 20002 Phone: 202/621-9667 Fax: 202/621-9703

7. Morgan Pharmacy

3001 P Street NW Washington, DC 20007 Phone: 202/337-4100 Fax: 202/337-4102

8. Mount Pleasant Pharmacy

3169 Mount Pleasant Street NW Washington, DC 20010 Phone: 202/387-3100 Fax: 202/387-2435

9. Mt. Olivet Pharmacy

1809 West Virginia Avenue NE Washington, DC 20002 Phone: 202/529-7001 Fax: 202/529-7005

10. Nations Care Pharmacy

3818 12th Street NE Washington, DC 20017 Phone: 202/621-6325 Fax: 202/621-7874

11. Neighborhood Pharmacy

1932 MLK Jr, Ave SE Washington, DC 20020 Phone: 202/889-1119 Fax: 202/889-1560

12. Pharmacare @ DC

651 Florida Avenue NW Washington, DC 20016 Phone: 202/387-1600 Fax: 202/387-1800

13. Seat Pleasant Pharmacy

350 Eastern Avenue NE Washington, DC 20019 Phone: 202/396-3400 Fax: 202/396-0085

14. State Pharmacy

2041 Martin Luther King Jr. Avenue, SE Suite 100 Washington, DC Phone: 202/610-2100 Fax: 202/610-1078

15. Sterling Care Pharmacy

1647 Benning Road NE Suite 101 Washington, DC 20002 Phone: 202/399-7876 Fax: 202/388-3157

16. Super Pharmacy and Medical Equipment

1019 H Street NE Washington, DC 20002 Phone: 202/388-0050 Fax: 202/388-0047

17. Community, a Walgreen's Pharmacy

1325 14th Street, NW (First Floor) Washington, DC 20005 Phone: 202/332-8811 Fax: 202/332-3880

18. Walgreens Pharmacy

1217 22nd St NW Washington, DC 20037 Phone: 202/776-9084 Fax: 202/776-0969

19. Whitman-Walker Health Pharmacy

1701 14th Street NW Washington, DC 20009 Phone: 202/745-6135 Fax: 202/332-0206

GOVERNMENT OF THE DISTRICT OF COLUMBIA Department of Health



HIV AIDS, Hepatitis, STD and Tuberculosis Administration (HAHSTA)

AIDS Drug Assistance Program (ADAP) Formulary

The following drugs are available through the District of Columbia AIDS Drug Assistance Program as of September 1, 2012.

HIV ANTI-RETROVIRALS

CCR5 CO-RECEPTOR ANTAGONIST Maraviroc (Selzentry)

FUSION INHIBITORS Enfuvirtide (Fuzeon)

INTEGRASE INHIBITOR Raltegravir (Isentress)

NUCLEOSIDE & NUCLEOTIDE REVERSETRANSCRIPTASE INHIBITORS (NRTI)

Abacavir (Ziagen) Abacavir/lamivudine (Epzicom) Abacavir/lamivudine/zidovudine (Trizivir) Didanosine (Videx) Emtricitabine (Emtriva) Lamivudine (Epivir) Lamivudine/zidovudine (Combivir) Stavudine (Zerit) Tenofovir (Viread) Tenofovir/emtricitabine (Truvada) Zidovudine (Retrovir, AZT)

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTI) Delavirdine (Rescriptor)

Efavirenz (Sustiva) Etravirine (Intelence) Nevirapine (Viramune)

NNRTI/NRTI COMBINATION Efavirenz/Emtricitabine/Tenofovir (Atripla)

PROTEASE INHIBITORS (PI)

Atazanavir (Reyataz) Darunavir (Prezista) Fosamprenavir (Lexiva) Indinavir (Crixivan) Lopinavir/ritonavir (Kaletra) Nelfinavir (Viracept) Ritonavir (Norvir) Saquinavir (Invirase) Tipranavir (Aptivus)

ADDITIONAL DRUGS

ANALGESICS

Acetaminophen with Codeine (Tylenol w/Codeine)** Fentanyl Patch (Duragesic Patch)** Ibuprofen (Motrin) Morphine Sulfate (MS Contin)**

ANTIBIOTICS

Amoxicillin Clavulanate (Augmentin)

****DENOTES CONTROLLED SUBSTANCES UPDATED 4/20/2010** Azithromycin (Zithromax) Ciprofloxacin (Cipro) Clarithromycin (Biaxin, Biaxin XL) Clindamycin HCL (Cleocin) Doxycycline (Vibramycin) Ethambutol (Myambutol) Isoniazid (INH) Levofloxacin (Levaquin) Linezolid (Zyvox) Pyrazinamide (Pyrazinamide) Pyrimethamine (Daraprim) Rifabutin (Mycobutin) Rifampin (Rifadin, Rimactane) Sulfadiazine

ANTI-DEPRESSANTS

Amitriptyline HCL (Elavil) Bupropion (Wellbutrin SR) Duloxetine (Cymbalta) Fluoxetine(Prozac) Sertraline (Zoloft)

ANTI-DIARRHEAL

Diphenoxylate/Atropine (Lonox, Lomotil)

ANTI-FUNGALS

Clotrimazole (Mycelex, Lotrimin) Fluconazole (Diflucan) Itraconazole (Sporanox) Ketoconazole (Nizoral) Voriconazole (Vfend)

ANTI-PARKINSON'S AGENT

Benztropine (Cogentin)

ANTI-PSYCHOTICS

Aripiprazole (Abilify) Haloperidol (Haldol) Olanazapine (Zyprexa) Quetiapine (Seroquel) Risperidone (Risperdal) Ziprasidone (Geodon)

ANTI-VIRALS

Acyclovir (Zovirax) [oral and topical] Cidofovir (Vistide) Valacyclovir (Valtrex) Valganciclovir (Valcyte)

HEPATITIS TREATMENT

Adefovir (Hepsera) Entecavir (Baraclude) Peginterferon alfa-2a (Pegasys) Peginterferon alfa-2b (Peg-Intron) Ribavirin (Rebetol, Copegus)

HYPOGLYCEMICS

Glipizide (Glucotrol, Glucotrol XL) Metformin (Glucophage, Glucophage XL) Metformin and Pioglitazone (ActoPlus Met) Metformin and Glipizide (Metaglip)

KAPOSI'S SARCOMA TREATMENTS

Alpha Interferon (Intron A) Doxorubicin (Doxil)

LIPID LOWERING AGENT

Atorvastatin (Lipitor) Ezetimibe (Zetia) Fenofibrate (Tricor) Pravastatin (Pravachol)

OPIOID ADDICTION TREATMENT

[Prior authorization required] Buprenorphine (Subutex)** Buprenorphine/naloxone (Suboxone)**

PCP PROPHYLAXIS

Aerosolized Pentamidine (Nebupent) Atovaquone Suspension (Mepron) Dapsone Sulfamethoxazole-Trimethoprim (Bactrim)

TOPICAL STEROIDS

Hydrocortisone 1% (cream, lotion) Hydrocortisone 2.5% (cream, lotion, ointment) Hydrocortisone valerate 0.2% (cream)

TOPICAL ANESTHETICS Lidocaine Patch (Lidoderm)

WEIGHT LOSS/WASTING

Dronabinol (Marinol)** Megestrol (Megace, Megace ES) Oxandrolone (Oxandrin)** Somatropin (Serostim) [Prior auth. required]

MISCELLANEOUS

Formula B Plus vitamins Erythropoietin Alpha (Procrit, Epogen) Gabapentin (Neurontin) Testosterone, topical (Androgel)** Neupogen (Filgrastim) Oseltamivir (Tamiflu) **Contact Information**

as of September, 2012

HIV/AIDS Drug Program Pharmacy Call Center

855-401-3731

HIV/AIDS, Hepatitis, STD and Tuberculosis Administration

District of Columbia Department of Health 899 North Capitol Street NE Fourth Floor Washington, DC 20009 Phone: 202/671-4900

Gunther Freehill

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Christopher Keeys, Pharm D., R. Ph., BCPS President

