

**Pharmacy Planning and Partnership Committee**

**Implementation Strategies**

**December 2016**

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## **Focus Area 1: Reduce Medication Access Issues Related to Prior Authorization**

The Prior Authorization (PA) process has become a major medication access barrier for people living with HIV (PLWH). In a recent NYSDOH AIDS Institute survey of PLWH in New York, the most common ARV medication access barrier respondents encountered was related to prior authorization. PA's can be particularly detrimental to PLWH, as they are on strict medication regimens, are medically fragile, and are often the first to use the newest drugs on the market. Obtaining a PA can lead to gaps in medication for patients while this authorization process is implemented and can prevent PLWH from accessing medication that is best suited to their particular needs. For this reason, the pharmacy committee proposes implementation strategies to prevent or quickly resolve PA issues and minimize the administrative steps required between the prescription and delivery of HIV-related medications.

### **Applicable Blueprint Goals/Sections**

BP5: “[c]ontinuously act to monitor and improve rates of viral suppression”. This includes the recommendation to “[identify] additional actions related to *pharmacy* practice that will improve ongoing access to medication...”

CR9: “eliminate prior authorization...for antiretroviral drugs for treatment.”

### **Implementation Strategies:**

#### ***Short-term***

- **Eliminate PAs for cost neutral drugs**
- **Allow non-physicians to process PAs.** PBM’s which decline information from non-physicians place undue administrative burden on physicians and are an additional barrier to access.
- **Improve communication from pharmacists about when a PA is required**
  - Better communication and follow-up to patients about rejected claims: notify patients of the reason why their claims are rejected and contact the provider when scripts do not go through. Oftentimes patients are told their medication needs a PA, but they do not know what that means and do not mention it until their next visit.
  - **Pharmacists should contact providers** indicating which medication needs a prior authorization, what the rejection is, the phone number the provider needs to call and the patient's ID number. Many clinics practice out of multiple locations so voicemails and faxes are often missed or received much later than they should be.
- **Reimburse pharmacies for emergency ARV medication fills**
  - Allow pharmacists to dispense an emergency 72 hour supply of prescribed ARVs before it is cleared by the patient’s insurer.
  - Grant pharmacists permission to override PA requirement in cases when the patient is out of ARVs to guarantee reimbursement for this emergency 3 day supply. [see #3 of evidence section]
- **Require PBMs to publish PA guidelines**
- **Monitor PBM PA approvals/rejections.**

### **Long-term**

- **Require payers to remove PA processes for ARVs and medications for common HIV comorbidities.**
- **Remove “step therapy” or “fail first” requirements for PLWH.**

### **Evidence:**

1. In a recent NYSDOH AIDS Institute survey of PLWH in New York, the most common ARV medication access barrier respondents encountered was related to prior authorization (out of 18 possible categories of access issues). Furthermore, 93 out of 149 (62%) access issues were insurance related. 25 of these insurance-related issues (27%) were directly linked to prior authorizations.<sup>1</sup>
2. In a study at the University of Alabama, researchers monitored the resources used on PA-associated processes at an HIV Clinic over a 2-year period. For each PA, a nurse practitioner spent an average of 26.8 minutes and a clerk spent 6.5 minutes. The average number of pages of paperwork that were filled out for each PA was 5.8. 73% of PAs were approved, 18% were denied, and 10% were voided. The researchers calculated that the overall cost to the clinic for each PA was \$41.60, concluding that, “Although evidence supports that PA reduces third-party expenditures, it significantly delays medication accessibility for patients and imposes high costs that negatively impact operating margins for health care providers” (Raper et al., 2010) [1].
3. Coverage for emergency billing of 72 hour supplies of medication already exists in other contexts. For example, a number of insurance companies in Mississippi give pharmacies calling in for 72 hour emergency override supply the ability to insert the override on their end without a call for non-preferred, prior authorization required, and step therapy required rejections.<sup>2</sup> While this procedure is only available under official states of emergency, it may serve as an example for the development of emergency billing for HIV medication.

### **Context:**

#### *Definition of Key Terms*

- **Prior Authorization:** a practice by which PBMs and government programs require special authorization when a medication is prescribed before the drug formulary of that plan will cover it for a patient. Prior Authorization (PA) - or Prior Approval - efforts take many forms, including required step therapy, requirements for generic prescriptions, quantity and dose limits, and the restriction of some prescriptions to certain types of providers.<sup>3</sup>

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<sup>1</sup> Please note that this was a limited, non-randomized sample. Out of 2,101 patients given the survey, 149 reported issues accessing their HIV medication in the past year which had caused a lapse in adherence of three days or more. Of these 149 patients, 174 access issues were reported, of which 17 were related to mail order pharmacy, 24 were related to changing insurance plans, and 25 were related to prior authorization. Surveys were administered by providers, case managers and nurses to increase reporting accuracy.

<sup>2</sup> Pharmacy billing instructions during a disaster or emergency. *Mississippi Division of Medicaid*. Retrieved from <https://medicaid.ms.gov/pharmacy-billing-instructions-during-a-disaster-or-emergency/>

<sup>3</sup> American Academy of HIV Medicine. Prescriber Prevails. Retrieved from <http://www.aahivm.org/prescriberprevails>



- **Step Therapy:** also known as “fail first” - when insurers require patients to begin medication for a medical condition with the most cost-effective drug therapy and progress to other more costly or risky therapies only if necessary.
- **Pharmacy Benefit Managers (PBMs):** a third-party administrator of prescription drug programs whose role has expanded in efforts to achieve cost containment in healthcare. PBMs develop and maintain the formulary, contract with pharmacies, negotiate discounts and rebates with drug manufacturers, influence generic substitution, and may also process and pay claims. PBMs strive to maintain or reduce the pharmacy expenditures of the plan while concurrently trying to improve health care outcomes. Additionally, PBMs offer programs that aim to provide value and increased options to help manage prescription costs.<sup>4</sup>

See **Appendix C** for a graphic of the business relationships in which PBMs play a role

#### Relevant Legislation:

- **Step Therapy Bill (A2834-C Titone/S3419-C Young)**<sup>5</sup>: “This legislation which passed both houses amends utilization review sections of Insurance Law and Public Health Law. It requires insurers to apply evidence-based clinical review criteria in their Utilization Review, provide the criteria to primary care providers upon written request on behalf of their patients and provide a 72-hour expedited UR appeals process. As a result, Pharmacy Benefit Managers will need to be more transparent on their step therapy protocols. The bill will move to Governor Cuomo for his signature or veto”<sup>6</sup>

#### Potential Key Collaborators:

- NYSDOH Medicaid Program
- Pharmacists Society of the State of New York (PSSNY)
- Centers for Medicare & Medicaid Services (CMS)

#### Key References:

- [1] Raper, J. L. et al. (2010). Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic. *Clinical Infectious Diseases* 51, 718–724.
- [2] Schafer, J. J., Gill, T. K., Sherman, E. M., & McNicholl, I. R. (2016). ASHP Guidelines on Pharmacist Involvement in HIV Care. *American Journal of Health-System Pharmacy*, 73(7), 468–494.

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<sup>4</sup> Gryta, T. (2011, July 21). What is a “Pharmacy Benefit Manager?” *The Wall Street Journal*. Online. Retrieved from <http://www.wsj.com/articles/SB10001424053111903554904576460322664055328>

<sup>5</sup> See details of this bill at <https://www.nysenate.gov/legislation/bills/2015/a2834/amendment/d>

<sup>6</sup> PSSNY. Legislative Update. (June 2016). Retrieved from: <http://www.pssny.org/news/295154/2016-Legislative-Session-Update.htm>

## **Focus Area 2: Remove Obstacles Related to Mail Order**

Mandatory mail order pharmacy service creates significant barriers to medication access. This practice can be particularly detrimental to consumers with limited telephone service, unorthodox housing, confidentiality concerns and mental health challenges. In the Anti-Mandatory-Mail Order (AMMO) Bill of 2011, New York State formally acknowledged the need to ensure patient access to pharmacy options.<sup>7</sup> The New York AMMO bill contains problematic exemptions; patients can opt out in any pharmacy *only if* the terms and conditions for medication storage and distribution are met by the local pharmacy of their choice. This has allowed mail order pharmacies to create complex terms and conditions (e.g. 24-hr phone lines, multi-lingual answering services, expensive accreditations etc.) that are difficult for local pharmacies to comply with. For this reason, the pharmacy committee proposes strategies to give PLWH the option to fill their prescriptions at a local pharmacy regardless of their insurance plan or the medication they require. This choice is particularly important for PLWH as it enables them to receive their medication in person, from a pharmacist, as opposed to the US postal service.

### **Applicable Blueprint Goals/Sections:**

BP5: Continuously act to monitor and improve rates of viral load suppression

CR9: “Eliminate...specialty pharmacy requirements for antiretroviral drugs for treatment.”

### **Implementation Strategies:**

#### **Short-Term:**

- **Encourage Medicaid Managed Care Pharmacy Benefit Programs to remove contractual barriers that prevent community pharmacies from dispensing HIV medications.**
- **Reimburse pharmacies for emergency ARV medication fills**
  - Grant pharmacists permission to override mail order requirement in cases when the patient is out of ARVs to guarantee reimbursement for an emergency supply.
- **Publish report listing all HIV medications on Pharmacy Benefit Manager contracts with terms and conditions for reimbursement which could restrict community pharmacy distribution.** Use of this resource could prevent failed prescription fill/refill attempts that lead to dangerous lapses in adherence. It may also prepare consumers who are restricted to certain pharmacies to make arrangements for mail order that are more conducive to their lifestyle (e.g., delivery to clinic instead of their house, arrange for specific delivery time)
  - Make this report a living document and promote as a resource for consumers and case managers.
- **Educate consumers about their right to choose whether or not to receive their medication in the mail.**

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<sup>7</sup> Hartocollis A. (2011, Dec 13). Mandatory-Mail-Order Pharmacy Plans Banned by New State Law. *The New York Times*.

**Long-Term:**

- **Remove any terms and conditions from Prescription Benefit Manager (PBM) contracts that prevent local pharmacies from receiving reimbursement for dispensing medications that are usually dispensed by mail order pharmacies.**
  - Remove extensive accreditation, documentation and storage requirements from contracts that are not proven to ensure the efficacy of the medication and the safety of how it is dispensed, or add clinical value to consumers.
- **Mandate that co-pays and prescription costs are the same whether consumers choose a network community pharmacy or mail order pharmacy.**

**Evidence:**

- Health plans are increasingly mandating the use of mail-order pharmacies for members with chronic health conditions. In a recent NYSDOH AIDS Institute survey of HIV positive consumers in New York, the third most common ARV medication access barrier respondents encountered was related to mail order pharmacy (out of 18 possible categories of access issues), leading to a significant lapse in medication adherence of three days or more.<sup>8</sup> Interviews with patients, patient advocates and doctors suggest that using mail order pharmacies presents significant barriers to medication access. There can be complex refill policies that require long phone calls, shipments that are delayed or erroneous, medications not kept at appropriate temperatures, and difficulty reaching a pharmacist or other representative.<sup>9</sup> Community-based pharmacists can talk to patients either face-to-face or on the phone, whereas mail order pharmacies rely solely on phone calls for communication.
- According to POZ (Positive Alliance), consumer complaints about mail-order pharmacies have been circulating for years and have recently been under greater scrutiny due to policies which ignore the basic premise of the 2011 AMMO law. Consumerwatchdog.org describes multiple PLWH who have seen changes in their policies that obligate them to receive their prescriptions in the mail.<sup>10</sup>
- Research and data on the impact of mail order pharmacies compared with community-based pharmacies on ARV adherence is limited.<sup>11</sup> Studies of non-ARV specific adherence have produced divided results; Duru et al. (2010), for example, found that the average adherence for diabetic patients using mail order was 84.7% compared with 76.9% for community pharmacy.<sup>12</sup>

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<sup>8</sup> Please note that this was a limited, non-randomized sample. Out of 2,101 patients given the survey, 149 reported issues accessing their HIV medication in the past year which had caused a lapse in adherence of three days or more. Of these 149 patients, 174 access issues were reported, of which 17 were related to mail order pharmacy, 24 were related to changing insurance plans, and 25 were related to prior authorization. Surveys were administered by providers, case managers and nurses to increase reporting accuracy.

<sup>9</sup> Thomas K & Pollack A. (2015). Specialty Pharmacies Proliferate, Along With Questions. *The New York Times*.

<sup>10</sup> Retrieved from: <http://www.consumerwatchdog.org/>

<sup>11</sup> Kibicho J, Owczarzak J & Pinkerton SD. (2012). Opinions of a Small Sample of Pharmacists About Pharmacy Setting and Patient Adherence to Antiretroviral Therapy. *JMCP Journal of Managed Care Pharmacy*, 18(6), 446-452.

<sup>12</sup> Duru OK, et al. (2010). Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications. *The American Journal of Managed Care*, 16(1). 33-40.

However, a cross-sectional study of PBM managed prescription benefit plans from 2008-2010 showed a higher, statistically significant medication possession ratio among patients who filled maintenance prescriptions at community pharmacies than those who used mail order.<sup>13</sup> As a result, it is important to enact policy that allows consumers to choose where to acquire their medications to align with their lifestyle and maximize the potential for full adherence.

- A major driver for the shift to mail order pharmacy was its potential for cost savings. Further research is needed to determine if mail order has indeed cut healthcare spending. However, a number of studies indicate otherwise [1-4]; a study of 2010 CMS data conducted by the Virginia Commonwealth University School of Pharmacy compared costs for prescriptions dispensed through mail order and retail pharmacies using a large random sample of patients enrolled in Medicare Part D. The results of this research indicated that mail order pharmacies did not result in savings for Medicare or third-party payers. Retail pharmacies had consistently lower costs regardless of whether medications were dispensed for comparable-days supplies or dispensed in larger quantities. While patients may have had less of the cost sharing responsibility, plans paid more [1].

### Context:

#### *Definition of Key Terms*

- **Mail Order Pharmacies:** developed by larger chain pharmacies and pharmacy benefits managers (PBMs). They were designed with the goal of maximizing efficiency and achieving cost-savings when processing prescriptions.
- **Specialty Pharmacies:** defined as the service created to manage the handling and service requirements of specialty pharmaceuticals. Specialty pharmaceuticals are typically used to treat chronic and/or rare diseases with high levels of consistent patient monitoring, and can be administered via injection, inhalation or orally. These drugs are expensive and require specialty handling. Specialty pharmaceuticals comprise the fastest growing component of the pharmaceutical market in the U.S.<sup>14</sup> Specialty pharmacies also perform functions such as dispensing, distributing, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases. The definition of specialty pharmacies continues to change as the marketplace develops.<sup>15</sup>
- **Community Pharmacies:** these pharmacies can exist in a variety of brick and mortar settings such as a grocery store or drug store. If the community pharmacy has more than four locations it is referred to as a chain community pharmacy. According to the World Health Organization (WHO) community pharmacists are more accessible to the public as they are able to have daily

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<sup>13</sup> Khandelwal N et al. (2012). Community Pharmacy and Mail Order Cost and Utilization for 90-Day Maintenance Medication Prescriptions. *Journal of Managed Care Pharmacy*, 18(3), 247-255.

<sup>14</sup> Steiber D & Erhardt D. (2006). *Specialty Pharmacy in Community Pharmacy: The Time Is Now – and How!* (White Paper). National Association of Chain Drug Stores. [http://www.nacds.org/pdfs/membership/white\\_paper\\_specialty\\_pharmacy.pdf](http://www.nacds.org/pdfs/membership/white_paper_specialty_pharmacy.pdf)

<sup>15</sup> Defining Specialty Pharmacy (2013) Retrieved from <http://www.drugchannels.net/2013/02/defining-specialty-pharmacy.html>

interactions. They supply consumers with a prescription or, when legally permitted, provide over the counter medications. Community pharmacists also perform duties such as counseling patients when dispensing medications, providing drug information to health professionals, patients and the general public, and participating in locally and federally sponsored health-promotion programs. Furthermore, they maintain links with other health professionals in primary health care.

- **Chain Pharmacies:** community pharmacies with more than four locations (see above).

#### *Relevant Legislation*

- **The Anti-Mandatory Mail Order (AMMO) Bill:** Governor Cuomo signed this bill into law in 2011. This legislation requires any policy which provides coverage for prescription medications to enable its insured individuals to fill any prescription that is eligible for mail order coverage, at the individual's own choosing, at an in-network pharmacy in their community. Additionally, co-payments for the same drug must remain the same, and health plans must pay the same amount, for a drug regardless of where it is filled. This law is not universal and does not apply to insurance coverage that is provided as a result of a union agreement.<sup>16</sup> The law took effect on January 11, 2012 and applied to new and amended contracts that began on or after that date.<sup>17</sup>

Calls for change have come from a number of pharmacy organizations and patient advocacy groups. Additionally, 38 associations representing approximately 70 separate groups throughout New York, including patient advocacy organizations, support the removal or contractual barriers for local pharmacy dispensing of specialty drugs.<sup>18</sup>

#### **Key References:**

- [1] Carroll, N. V., Brusilovsky, I., York, B., & Oscar, R. (2005). Comparison of costs of community and mail service pharmacy. *Journal of the American Pharmacists Association*, 45(3), 336–343.
- [2] Clark, B. E., Siracuse, M. V., & Garis, R. I. (2009). A comparison of mail-service and retail community pharmacy claims in 5 prescription benefit plans. *Research in Social and Administrative Pharmacy*, 5(2), 133–142.
- [3] Johnsrud, M., Lawson, K. A., & Shepherd, M. D. (2007). Comparison of Mail-Order With Community Pharmacy in Plan Sponsor Cost and Member Cost in Two Large Pharmacy Benefit Plans. *Journal of Managed Care Pharmacy*, 13(2), 122–134.

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<sup>16</sup>An act to amend the insurance law, in relation to the purchase of prescription drugs, A5502B, 2011-2012 Regular Sessions (2011) [http://assembly.state.ny.us/leg/?default\\_fld=&bn=A05502&term=2011&Summary=Y&Actions=Y&Votes=Y&Memo=Y&Text=Y](http://assembly.state.ny.us/leg/?default_fld=&bn=A05502&term=2011&Summary=Y&Actions=Y&Votes=Y&Memo=Y&Text=Y)

<sup>17</sup> Tress T. (2012, January 25). The New Anti-Mandatory Mail Order Law. Retrieved from [http://www.nycps.org/myJSSImages/file/Anti-Mandatory Mail Order Law Implementation 01 25 12.pdf](http://www.nycps.org/myJSSImages/file/Anti-Mandatory%20Mail%20Order%20Law%20Implementation%2001%2025%2012.pdf)

<sup>18</sup> An act to amend the insurance law, in relation to the purchase of prescription drugs, S03995B, 2013-2014 Regular Sessions (2013) <http://www.pssny.org/general/custom.asp?page=LegislativeFailed>

- [4] Steiber, D. and Erhardt, D. (2006) *Specialty Pharmacy in Community Pharmacy: The Time Is Now – and How!* (White Paper). National Association of Chain Drug Stores. Retrieved from: [http://www.nacds.org/pdfs/membership/white\\_paper\\_specialty\\_pharmacy.pdf](http://www.nacds.org/pdfs/membership/white_paper_specialty_pharmacy.pdf)
- [5] Vail, R., & Brown, M. (2016, June). *2016 HIV Medication Access Survey*. Results presented at the Quality of Care Advisory Committee Meeting, NYSDOH AIDS Institute.
- [6] New York State Office of the Attorney General. (2013). *A.G. Schneiderman Sends Letters Urging 15 New York Health Insurance Plans To Implement Pharmacy Exemption Rules* (Press Release). Retrieved from <http://www.ag.ny.gov/press-release/ag-schneiderman-sends-letters-urging-15-new-york-health-insurance-plans-implement>

**Potential Key Collaborators:**

- NYS Office of Health Insurance Programs (OHIP)
- Pharmacists Society of the State of New York (PSSNY)
- National Community Pharmacists Association (NCPA)
- Chain Pharmacy Association of NYS
- NYS Chapter of American Society of Consultant Pharmacists (ASCP)
- New Yorkers for Accessible Health Coverage
- Gay Men’s Health Crisis
- Lupus Agencies of New York State (LANYS)
- Southern Tier Independence Center
- Latino Commission on Aids/Hispanic Health Network
- Treatment Action Group
- BOOM! Health
- Sage (Services and Advocacy for Gay, Lesbian, Bisexual and Transgender Elders)

### **Focus Area 3: Expand the Role of Pharmacists in HIV Medication Management**

It is well established that directly involving pharmacists in clinical care significantly facilitates the management of chronic medical conditions. New York State formally acknowledged this in 2011 by passing legislation to allow pharmacists to perform collaborative drug therapy management (CDTM) in teaching hospitals, and then expanding this practice to other clinical settings in 2015. Encouraging and supporting new collaborative practice agreements between pharmacists and providers is an important strategy to improve HIV management and reduce new infections. There is also significant evidence that pharmacist involvement in HIV care in community pharmacy settings impacts adherence and improves patient experiences. Effective models that bring pharmacists into team-based patient care have been tested nationwide and should be studied and applied to HIV healthcare settings in New York. As the final gate keepers between PLWH and their medication, pharmacists are in a unique position to ensure successful antiretroviral treatment. Facilitating medication synchronization and other strategies to improve community pharmacist involvement in HIV care is a second overall goal of this focus area. Additionally, this committee promotes implementation strategies which will expand clinical pharmacists' ability to work with PLWH in community pharmacy settings.

#### **Applicable Blueprint Goals/Sections:**

BP5: "Identifying additional actions related to pharmacy practice that will improve ongoing access to medication."

BP6: "Empowering patients and providers with joint access to electronic medical records (EMRs), pharmacy, and laboratory data"

BP7: "Use client-level data to identify and assist patients lost to care or not virally suppressed."

CR9: improve VLS rates, by creating "standards of care for pharmacy access" to ensure uninterrupted access to medication.

#### **Implementation Strategies:**

##### ***Short-term***

- **Revise Medicaid policy to encourage/mandate medication synchronization.**
  - Allow pharmacists to dispense partial fills so as to synchronize multiple medications to be filled on the same date. This would enhance the likelihood of patients receiving all of their medications each month and eliminate a medication access barrier for PLWH.
- **Ensure reimbursement for partial (re)fills for NYS Medicaid Managed Care beneficiaries.**
- **Expand HIV-specific educational resources for pharmacists in NYS**
  - Develop tools to encourage all pharmacists in NYS to take HIV-related Continued Pharmacy Education (CPE) credits [see **Appendix A**].
- **Develop protocols to enhance provider-pharmacist communication, for example:**
  - Share secure email addresses
  - Monthly client medication profile updates to medical care team
  - Web-based platform to share filling records with providers, re-order prescriptions, confirm prescriptions are filled as ordered
  - Utilize existing tools to have pharmacists communicate late refills to medical care team

- **Encourage Managed Care Organizations (MCOs) to conduct trainings and/or provide updated educational materials to help pharmacists navigate insurance coverage systems.** As more PLWH are directed to MCOs, pharmacists can help resolve and prevent medication access issues rooted in insurance coverage for these clients.
  - These trainings/materials would, at least at first, only need to cover HIV-related treatment, including ARVs, medication for common HIV comorbidities, and related service coverage.
- **Pilot collaborative/comprehensive medication management models in New York pharmacies**
  - Consider combining this initiative with pilots for HIV testing and PrEP/PEP

### **Long-term**

- **Encourage manufacturers of ARV medication to package medication in one-week supply bottles/containers** to accommodate pharmacists dispensing partial refills without opening sealed packaging. This will facilitate medication synchronization, be cost effective and minimize waste of partially used bottles.
- **Grant pharmacists with collaborative practice agreements access to real-time patient data**, allowing them to assess the patient's clinical status and see progress toward treatment goals.
- **Authorize qualified pharmacists to note therapeutic changes, measures and follow-up within the record.** This would allow for measurement and reporting as well as improved communication for care coordination with other members of the clinical team.
- **Expand the definition of Medication Therapy Management (MTM) in Medicare Part D**, allowing pharmacists to more easily get reimbursed for collaborative services.
- **Change MTM eligibility criteria for Medicare Part D** to include PLWH and/or patients on medications that require strict adherence to maintain drug efficacy.

### **Evidence:**

In 2011, NYS commissioned a demonstration project which aimed to evaluate the effects of CDTM on care outcomes among patients with six common chronic health conditions: anticoagulation, diabetes, heart failure, cancer, asthma and HIV. Results of the project, which were submitted to the NYS Legislature in 2014, showed that adoption of CDTM was associated with significant improvement in medication compliance and quality of life for patients across all conditions. Participating pharmacists optimized patient safety and treatment plans by providing comprehensive medication reconciliation and recommending treatment initiation, and facilitated ARV adherence by working directly with patients to create accommodative regimens. Among PLWH in particular, results indicated that CDTM improved adherence, with a majority of participating patients agreeing that pharmacists played an integral role in their care, helped them better understand the indications and side effects of their medication, and assisted them in avoiding missed doses [18].

Furthermore, studies have shown that increasing pharmacist collaboration in patient care is both cost containing and cost effective [19]. Allowing pharmacists to participate in CDTM in multiple clinical settings was a great leap forward for New York healthcare, and supports efforts to include pharmacists on multidisciplinary care teams in community-based clinical settings as well [see *Relevant Legislation*].

Research also indicates that pharmacist involvement can be taken a step further; it does not have to be limited to clinical settings. There is a growing body of evidence that clinical collaboration in community



pharmacies increases medication adherence, prevents drug-drug interactions, facilitates coordination of care, improves health outcomes, and cuts costs [10]. When used for PLWH, the resulting positive effects are amplified [15]. Research of this strain presents a strong case that pharmacists possess sufficient clinical expertise to participate in advanced collaborative medication management. However, this committee acknowledges that such an expansion in pharmacist scope of practice is a long-term goal. It is thus critical in the short term to create and improve processes which enable community pharmacists to aid in disease management without requiring formal collaborative practice agreements. One effective example is medication synchronization. The simple process of aligning a patient's refills so they can pick up all their prescriptions in one visit has been shown to improve adherence [4,5]. Research suggests that medication synchronization programs, which often include monthly pharmacist appointments and reminder communication, have an even stronger impact on patients living with chronic conditions [2,3,6]. Additionally, all pharmacists can help clients maintain an accurate and updated medication list, enhance safety, and identify more cost effective drugs or therapies. Even at this basic level, pharmacist medication management improves adherence and access to medications.<sup>19</sup>

### **Context:**

#### *Definition of Key Terms*

- **Clinical Pharmacist:** Clinical pharmacists are trained and work in healthcare facilities such as medical centers, clinics and hospitals. They “practice in health care settings where they have frequent and regular interactions with physicians and other health professionals, contributing to better coordination of care. This specialized knowledge and clinical experience is usually gained through residency training and specialist board certification.”<sup>20</sup>
- **Community Pharmacist:** also known as “retail” pharmacists. For the purposes of this document, a community pharmacist is defined as a licensed pharmacist who has not completed the residency training required of a clinical pharmacist.<sup>21</sup> These pharmacists are still highly qualified with training in pharmacology, pharmaceutical care and drug information/education for patients, promoting public health and basic elements of clinical care.<sup>22</sup>
- **Medication Synchronization:** A pharmacy service that “allows patients to pick up all of their ongoing prescription refills at the pharmacy on a single, convenient day each month and work closely with the pharmacist on sticking to their medication regimen. The once a month appointment day facilitates increased pharmacist-patient dialogue and allows time for

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<sup>19</sup> McInnis T. “Medication Underuse: The Most Underappreciated Quality of Care Gap.” Pharmacy Times March 2015

<sup>20</sup> American College of Clinical Pharmacy (ACCP). About Clinical Pharmacists. Retrieved from <https://www.accp.com/about/clinicalpharmacists.aspx>

<sup>21</sup> Please note that there are many clinical pharmacists who work in community settings and would identify as a “community pharmacists”. However, in this document, they will be referred to solely as clinical pharmacists.

<sup>22</sup> American Association of Colleges of Pharmacy. Doctor of Pharmacy (Pharm.D.) Degree. Retrieved from <http://www.aacp.org/resources/student/pharmacyforyou/documents/pharmd.pdf>

additional patient care services.”<sup>23</sup> Organizing all medications for a client reduces missed doses, enhances consistency, and improves adherence.

- **Medication Therapy Management (MTM):** At their most basic level, MTM services require knowledge of currently prescribed medications. The goals: Ensure an accurate and updated medication list, enhance safety, and improve adherence and access to those medications. This involves checking for drug-drug interactions, duplicative therapies and medications that may be less costly or easier to take; it may also involve answering patient questions on the use of medications [10]. In contrast to CDTM (see below), MTM services do not require the development of formal practice agreements between pharmacist and physician, and MTM services may be provided by other ancillary health care personnel. In addition, individual state pharmacy practice laws do not establish the scope of MTM services that may be offered unlike CDTM requirements.
  - The distinction between CDTM and MTM programs in New York State is important given that formalized agreements between physicians and pharmacists are not required for MTM and the scope of services provided under CDTM is typically broader than those for MTM.
- **Collaborative Drug Therapy Management (CDTM):** “a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy. In this role, pharmacists augment the physician, applying their specific drug therapy knowledge, skills and abilities to complement other types of care provided by collaborating professionals.”<sup>24</sup> CDTM, as opposed to MTM, allows pharmacists to adjust doses of prescribed medication in accordance with protocols without direct conferral with a prescribing physician.

#### *Relevant Legislation*

- **The Medicare Modernization Act of 2003:** requires Medicare Part D plans to include MTM services to clients with multiple qualifying chronic conditions (diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure), at least \$3,000 in drug costs, *and* on a minimum threshold of prescription medications. HIV is not a qualifying chronic condition under this law.
- **2011 CDTM Bill** (Chapter 21): authorized certain pharmacists to engage in CDTM within New York's teaching hospitals and affiliated clinics.
- **2015 Expanded CDTM Bill** (S04857-A Lavelle/A5805-A McDonald): expanded CDTM to all hospitals, nursing homes, diagnostic centers and hospital outpatient departments.<sup>25</sup>
- **Medication Synchronization Bill** (S2809 Lanza/A4036-A Quart): This bill has not been passed by the NYS Senate, despite passing the Assembly twice since 2015. It would modify NYS insurance law to mandate insurers to cover partial medication fills (e.g., 15-day supply for a 30-day

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<sup>23</sup> National Community Pharmacy Association (NCPA). Medication Synchronization. Retrieved from <http://www.ncpanet.org/solutions/adherence-simplify-my-meds/simplify-my-meds/preview-of-simplify-my-meds/medication-synchronization>

<sup>24</sup> Academy of Managed Care Pharmacy (AMCP). (February 2012). Practice Advisory on Collaborative Drug Therapy Management. Retrieved from <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=14710>

<sup>25</sup> See Bill details at the New York State Senate Website: <https://www.nysenate.gov/legislation/bills/2015/A5805>

prescription), pay the full dispensing fee for the partial fill (because it usually costs the pharmacy the same amount to dispense 15 vs. 30 pills of the same medication), and pro-rate the co-payment (e.g., if patient is only getting 15-day supply for a 30-day prescription with a \$20 co-pay, the co-pay would be reduced to \$10).<sup>26</sup>

### *Current Landscape for Pharmacist Medication Management in New York State*

Reimbursement guidelines for collaborative medication management (CMM) services provided by clinical pharmacists are highly variable, and depend on the source and model of payment [Appendix B]. As few payers currently recognize CMM as an approved service of clinical pharmacists, reimbursements for CMM are generally indirect and/or partial. Broader endorsement of the utility of collaborative medication management and the integral role played by clinical pharmacists in the sustainability of this care model will be required to streamline future reimbursement guidelines and encourage widespread implementation.<sup>1</sup>

In 2015, 97% of New York pharmacies were already set for electronic prescribing (ePrescribing), while 94% were EPCS-ready. Nationally, more than 80%, or 54,000, of all pharmacies are certified for ePrescribing of controlled substances (EPCS).<sup>27</sup> This means that web-based platforms for communication between providers and community pharmacies already exist, and could be used to facilitate collaborative HIV management.

In 2010, NYS Medicaid conducted an MTM pilot program with beneficiaries in the Bronx. The goal of the project was to use pharmacy MTM to improve therapeutic outcomes by optimizing responses to medication, managing treatment-related interactions or complications, and improving adherence to drug therapy. Unfortunately, there was low patient enrollment and program development was discontinued in consideration of NY State's overall strategy to move fee-for-service Medicaid beneficiaries into managed care.<sup>28</sup>

The new NYS legislation that allows pharmacists to participate in CDTM should not discourage efforts to help pharmacists manage medication outside of collaborative practice agreements. The NYSDOH can take lessons learned from the MTM pilot program, for example, to launch improved initiatives to reimburse pharmacists for basic medication management services such as medication synchronization.

The Centers for Medicare & Medicaid Services (CMS) recently announced an initiative to enhance the MTM program within Medicare Part D, testing a model to accelerate the development and testing of new payment and service delivery in 11 states.<sup>29</sup> New York is not one of these states, but could imitate this model of medication management expansion.

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<sup>26</sup> See Bill details at the New York State Senate Website: <https://www.nysenate.gov/legislation/bills/2013/a8975>

<sup>27</sup> Soble-Lernor, M., Helping Physicians Take Full Advantage of EPCS, DrFirst, September 21, 2015.

<sup>28</sup> [https://www.health.ny.gov/health\\_care/medicaid/program/mtm/](https://www.health.ny.gov/health_care/medicaid/program/mtm/)

<sup>29</sup> <https://innovation.cms.gov/initiatives/enhancedmtm/>

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#### Potential Key Collaborators:

- American College of Clinical Pharmacy (ACCP)
- Academy of Managed Care Pharmacy (AMCP)
- Board of Pharmacy Specialties
- National Community Pharmacy Association (NCPA)
- Food and Drug Administration (FDA)

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<sup>30</sup> Data from pharmacist provided medication management services provided to 9,068 patients and documented in electronic therapeutic records were retrospectively analyzed over the 10-year period from September 1998 to September 2008 in one health system with 48 primary care clinics.

## **Focus Area 4: In-Pharmacy HIV Testing**

Currently HIV testing is only available in health departments, physician’s offices and official HIV testing sites, which can require booking an appointment and significant travel time. Pharmacies are ubiquitous, often easily accessible with flexible hours, and staffed with professionals who have at least a basic knowledge of HIV and antiretroviral drugs. Some people also consider them to be less stigmatizing than traditional testing sites. Additionally, in light of the fact that they are already authorized to deliver immunizations, adding HIV testing to pharmacists’ scope of practice is a realistic goal. As instrumental actors in the field of public health, pharmacists should be involved with HIV testing initiatives by recommending and providing HIV testing, counseling on HIV tests, and linking those who test positive to care.

There are over 5,400 licensed pharmacies in New York State, making them key points of contact for diagnosis and linkage to care.<sup>31</sup> Offering on-site HIV testing in pharmacies would be an effective and cost-efficient way to realize the ETE goal to identify undiagnosed persons with HIV. Since New York State law already requires counseling and follow-up for rapid HIV testing, pharmacists also become the natural agents to connect PLWH to care.

### **Applicable Blueprint Goals/Sections**

One of the three stated goals of the Ending the Epidemic initiative is to identify persons with HIV who remain undiagnosed and link them to health care.

BP1: Make routine HIV testing truly routine

- “Additional settings for routine testing should be permitted, such as dental offices, **pharmacies**, and mental health facilities, and additional changes to the law should be considered for New York to adopt a truly opt-out testing model” [CR1]

BP2: Expand targeted testing

- “determine strategies to engage those within the population most likely to be at risk of infection.” Among others, expanding testing to “community based settings” are listed as “strategies for consideration.”

### **Implementation Strategies:**

#### ***Short Term***

- **Conduct a follow-up pilot study in community pharmacies in highly affected areas of New York City**, testing a model that may be more sustainable, where pharmacists and pharmacy staff conduct HIV testing and counseling and community-based organizations or case managers from partnered hospitals provide linkage to care and retention in care services.
- **NY Links and NY Knows to partner with community pharmacies during HIV testing initiatives.**
- **Encourage community pharmacists to stock over-the-counter HIV testing kits** and be able to educate individuals about the proper method for administering the test and interpreting the results and to take action on both reactive and nonreactive test results.

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<sup>31</sup> University of the State of New York – New York State Education Department. (2016, July 25). License Statistics. Retrieved from <http://www.op.nysed.gov/prof/pharm/pharmcounts.htm>

- **Encourage pharmacists to familiarize themselves with evolving HIV testing diagnostics;** CDC maintains a website of HIV-testing recommendations.<sup>32</sup> ([www.cdc.gov/hiv/guidelines/testing.html](http://www.cdc.gov/hiv/guidelines/testing.html)).

### **Long Term**

- **Include HIV testing in pharmacist scope of practice.**
  - Allow pharmacists with the appropriate training to oversee quality assurance programs for HIV rapid testing in their own pharmacies rather than requiring the direct, in-person involvement of a medical provider.
- **Make the reimbursement of HIV testing a pharmacy benefit as well as a medical benefit.**

### **Evidence:**

Qualitative research shows that support for in-pharmacy HIV testing is high among pharmacy staff [1], and patient-centered pharmacy services can help patients take greater responsibility for self-managing their HIV infections [3]. Efforts to use alternative, community based sites for HIV testing have been particularly successful in NYC in recent years. Starting in 2008, the New York City Department of Health and Mental Hygiene (NYSDOHMH) partnered with 78 community agencies (representing more than 140 testing sites) to launch *The Bronx Knows* initiative to test the estimated 250,000 Bronx residents who had never been tested for HIV. This initiative has now expanded to all five boroughs as *New York Knows*. As of March 2016, *New York Knows* partners have conducted over 2,770,000 tests, identified over 20,500 HIV positive individuals, and linked almost 13,000 of them to care. Of those, 6,942 individuals were reported to be newly diagnosed and more than three-quarters of them were linked to care [4].<sup>33</sup>

In a 2009 study that introduced rapid counselor-based HIV testing in five community pharmacies in the Bronx and Manhattan, 2,030 out of 2,805 (72.8%) eligible clients were tested over a period of 294 days. In addition to this high acceptance rate for testing, an overwhelming majority of subjects (98.6%) felt that HIV testing with PHAs in pharmacies was easy. These data strongly suggest that members of the highly affected community under study were open to and supportive of HIV testing in pharmacy venues. Furthermore, there was a high linkage to care rate (83%), indicating that testing and counseling in pharmacies with immediate linkage can bring a larger proportion of newly diagnosed HIV patients into HIV specialist care [1].

This year, *New York Knows* has taken their initiative one step further by collaborating with a major chain pharmacy in Manhattan. Starting on March 11, 2016, *Manhattan Knows* partnered with Duane Reade/Walgreens to pilot HIV testing at their pharmacies in two Manhattan neighborhoods. After little

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<sup>32</sup> See Center for Disease Control website at [www.cdc.gov/hiv/guidelines/testing.html](http://www.cdc.gov/hiv/guidelines/testing.html)

<sup>33</sup> For *The Bronx Knows* and *Brooklyn Knows* initiatives, partners provide only aggregate data. These data include the number of tests conducted, the number of confirmed positive tests, the number of confirmed positive individuals successfully linked to care (ever), the number of newly diagnosed positives (by self-report), and the number of newly diagnosed confirmed positives successfully linked to care (ever). Partners do not provide BHIV with data on clients with preliminary positive results, clients interviewed for partner services, or clients referred to prevention services. Also, because not all partners can report on new positives (some report confirmed positives only), numbers reported here are likely an underestimate of new diagnoses.

over three months (as of June 24, 2016), 78 individuals had been tested for HIV through their program [5].<sup>34</sup>

These New York based programs show significant success on in-pharmacy testing, but data tend to be recent, small scale, and preliminary. However there is no lack of established evidence outside of the state and country. A large scale study in Spain, for example, examined three Spanish pharmacy programs comprising 110 pharmacies. The researchers aimed to discover whether these programs effectively diagnosed new individuals generally as well as individuals in important subgroups. The programs, which were partnerships between the Regional Ministries of Health and the Councils of Professional Associations of Pharmacists, were rolled out with a large amount of publicity and advertising. The authors found that the programs discovered 10% of new diagnoses and meaningfully reached and diagnosed priority populations like MSM. Finally, they found that the pharmacy programs seemed to work well outside of large cities [2].

In the US, Weidle et al. conducted a pilot project which developed and tested a model for implementing confidential HIV counseling and testing services at 21 community pharmacies and retail clinics. 106 staff members were trained and conducted 1,540 rapid, point-of-care HIV tests. Pretest counseling and consent took a median of 4 minutes, posttest counseling took a median of 3 minutes, and wait time for test results was a median of 23 minutes. These results suggest that confidential HIV testing services can be administered by existing staff at community pharmacies and retail clinics and successfully integrated into a busy work environment with a modest amount of staff-patient interaction time [8].

#### **Context:**

##### *Definition of Key Terms*

- **Rapid HIV tests:** The rapid test is an immunoassay used for screening, and it produces quick results, in 30 minutes or less. Rapid tests use blood or oral fluid to look for antibodies to HIV. If an immunoassay (lab test or rapid test) is conducted during the window period (i.e., the period after exposure but before the test can find antibodies), the test may not find antibodies and may give a false-negative result. All immunoassays that are positive need a follow-up test to confirm the result.<sup>35</sup>
  - Follow-up diagnostic testing is performed if the first immunoassay result is positive. Follow-up tests include: an antibody differentiation test, which distinguishes HIV-1 from HIV-2; an HIV-1 nucleic acid test, which looks for the virus directly, or the Western blot or indirect immunofluorescence assay, which detect antibodies.

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<sup>34</sup> This very small pilot program includes only eight agencies based in two Duane Reade/Walgreens locations. We are looking to expand this initiative to other locations in Manhattan, as well as to Brooklyn and Queens. The number of tests can vary based on whether an agency brings outreach workers; due to capacity limitations, sometimes agencies are able to send only one staff member, which can present a challenge to outreach and testing efforts. We do not widely promote this pilot in terms of advertisement buys, but as we continue to expand there is potential to utilize social media platforms.

<sup>35</sup> HIV Test Types. *AIDS.gov* (2015). Available at: <https://www.aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/>.



### *Current Landscape for HIV Testing in NYS Pharmacies*

Any organization that performs a rapid HIV test to provide results to patients is considered a laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In New York State, all laboratories must register with the NYS Clinical Laboratory Evaluation Program (CLEP) and comply with public health law and regulations. New York State is one of the few states that requires a written HIV test order from a licensed medical professional to carry out rapid testing in pharmacies. Additionally, if a pharmacy wants to become a certified laboratory, they must establish and maintain a quality assurance program with a medical provider as Laboratory Director.<sup>36</sup> This process requires time and resources that many pharmacies do not have or are not incentivized to allocate. As a result, few New York pharmacies offer HIV testing.

Even though rapid tests are relatively simple to use, things can go wrong. To help find and prevent problems, CLEP requires the basic elements of a Quality Assurance (QA) program to be in place before offering testing. It is important to ensure high quality HIV testing and reliable results. However, medical providers are not the only healthcare professionals who are capable of overseeing quality programs and monitoring HIV testing in limited service laboratory settings. Pharmacists should be allowed to take on this responsibility.

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<sup>36</sup> <http://www.health.ny.gov/diseases/aids/providers/testing/rapid/workbook.htm>

**Potential Key Collaborators:**

- NYCDOHMH *New York Knows*
- NYSDOH *NY Links*
- Duane Reade/Walgreens Inc.
- Pharmacists Society of the State of New York
- NY State Board of Pharmacy (NYSED)
- Pharmaceutical Care Management Association (PCMA) [represents US PBMs]
- National Community Pharmacists Association (NCPA) [Committee on Emerging Models]

## **Focus Area 5: PEP/PrEP Access and Care in Pharmacies**

Post-exposure and pre-exposure prophylaxis make prevention of HIV transmission not only possible, but entirely practical. With these incredible advances in medicine, there is no need for anyone who is willing to take 1-3 pills a day to contract HIV. Yet seroconversion rates remain high; one major explanation is that many people simply do not know about HIV prevention measures. It is important to take advantage of pharmacies as a key point of contact with individuals at high risk of infection, especially those who do not regularly see a primary care physician. Pharmacists should be educated about PEP and PrEP and be prepared to provide counseling and referrals. Another barrier is the complex and often lengthy process required to get a prescription written and filled for PrEP and PEP. Pharmacists have a unique opportunity to simplify and shorten this process, increasing access, improving care and lowering HIV transmission rates.

### **Applicable Blueprint Goals/Sections:**

One of the three main goals of the Blueprint to End the Epidemic is to “provide access to PrEP for high-risk persons to keep them HIV-negative”

BP11: Undertake a statewide education campaign on PrEP and nPEP

- “Considerable education must be done with...those who should be prescribing PrEP and nPEP and those who should be taking it.” [this would include pharmacists]

BP12: Include a variety of statewide programs for distribution and increased access to PrEP and nPEP

### **Implementation Strategies:**

#### ***Short-term***

- **Raise awareness about and encourage provider registration for the NYS PrEP/PEP Provider Directory** which is a public list of providers who prescribe HIV PrEP [3].
- **Explore options to disseminate information about PrEP and PEP in pharmacies**
  - Create educational materials targeted at high risk populations i.e., youth
  - Encourage pharmacies to place PrEP/PEP educational materials in the area/aisle where condoms are shelved.
- **Support pharmacy stocking of PEP and PrEP medications**
  - Encourage manufacturers of PEP medication to package medication in 7 and 21 tablet bottles to accommodate pharmacists dispensing the maximum of 7 days’ worth of medication and then dispensing the appropriate amounts of medication to complete the 28 day treatment. This will be cost effective and minimize waste of partially used bottles.
  - Encourage all pharmacies to carry adequate stock of PrEP and PEP medication to assure immediate availability.
- **Expand pharmacist role in helping uninsured individuals access PEP/PrEP through Medication Assistance Programs**

- **Provide pharmacy continuing education credits (CPEs) for pharmacists regarding PEP and PrEP**
  - Consider ways to encourage pharmacists to take these CPEs
  - Explore the possibility of making PEP/PrEP specific CPEs a requirement for all NYS pharmacists [see Appendix A].
- **Promote the role of pharmacists in educating and supporting patients on PrEP**
  - Share/modify PrEP information that is developed for medical providers and consumers for pharmacist education and distribution to patients
  - Provide adherence counseling when appropriate
- **Promote innovative pilot projects to demonstrate the use of pharmacies as key access points for PrEP**
  - Consider merging pilot projects to provide PrEP in pharmacies with HIV testing pilots (see Focus Area 4).
  - Consider projects such as Kelley-Ross' pharmacy-based PrEP program, One-Step PrEP™ (see key references).

### **Long-term**

- **Link the approval of pharmacists to offer HIV testing with education regarding PrEP;** If someone self identifies as being at-risk for HIV and is requesting an HIV test, PrEP should be discussed as one method to prevent HIV infection in individuals with on-going risk.
- **Establish grant program to train pharmacists to provide counseling and referral to drug treatment for PEP and PrEP**
  - Qualifying pharmacies could apply to the grant program to be reimbursed for the cost of sending pharmacy assistants to be trained by the AIDS Institute or an AI grantee. The relevant training curriculum already exists and costs associated would be aimed at educating pharmacy providers on the program and training for relevant staff.

### **Context:**

- To increase access to PEP, the NYS Legislature recently passed a bill that allows pharmacists to dispense up to a one week supply of PEP medication to appropriate patients under a non-patient specific order written by a physician or nurse practitioner.<sup>37</sup> This provides an extremely important safety net of access to treatment for NYS residents. Ideally PEP is started within two hours of a potential exposure to HIV and having access through pharmacies will ensure timely and geographic availability across all parts of the state.
- There is a similar need for access to pre-exposure prophylaxis (PrEP) and pharmacists may be able to increase availability of PrEP in a same manner. However, current legislation does not allow pharmacists in NYS to dispense PrEP. Individuals who want to protect themselves from exposure are required to go through a two to three week process before being able to start PrEP, which then takes at least seven days to reach high levels of protection in the body. They have to make an appointment with a primary care physician, who may or may not be familiar with PrEP, wait for labs, and navigate insurance and/or state-funded medical coverage.

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<sup>37</sup> See Bills A10724/S8129 at: <https://www.nysenate.gov/legislation/bills/2015/a10724/amendment/original>

Allowing pharmacists to counsel for and dispense PrEP would significantly reduce the wait time during which candidates for this preventative medication remain in danger of contracting and spreading HIV.

#### Evidence:

- The 2014 US Public Health Service clinical practice guideline on the use of PrEP for HIV prevention states that, “Using a broad array of a health care professionals (e.g., physicians, nurses, case-managers, physician assistants, **clinic-based and community pharmacists**) that work together on a health care team to influence and reinforce adherence instructions significantly improves medication adherence and may alleviate the time constraints of providers.”<sup>38</sup>
- **One-Stop PrEP Pilot Program:** This pilot took place in a pharmacist-run PrEP clinic set in Kelley-Ross Pharmacy, a community pharmacy in Seattle, Washington. The goal was to investigate PrEP service implementation and feasibility in the pharmacy setting. The project launched in March 2015 and preliminary findings were announced at the National HIV Prevention Conference in December 2015.<sup>39</sup>

**Method:** Established under physician oversight with a collaborative drug therapy agreement (CDTA), One-Step PrEP allows for a single patient encounter to provide access to PrEP. Pharmacists meet with patients individually, make a risk assessment, provide counseling and testing, evaluate results, prescribe and dispense PrEP when appropriate, and provide follow-up care as outlined by CDC guidelines.

**Cost and Resource Predictions:** Using a prediction model, Kelley-Ross estimated that during the first year of operation with a patient panel of 100, profitability would be at 6%, marketing costs and equipment costs at 43% and 18% respectively, and training costs are the lowest at 1%.

**Pharmacist Training:** Phlebotomy training was the most time consuming, requiring 24 hours of pharmacist time over 5 weeks and an additional 5 weeks for licensure.

**Other Barriers:** Screening and monitoring for HIV/STI and medication toxicity.

**Lessons Learned:** A pharmacist-run HIV PrEP clinic in a community pharmacy is feasible and prediction models prove it to be financially sustainable. Additional revenue may be generated from administration of routine immunizations in high-risk populations. The clinic has been operational since March 2015. A majority of One-Step PrEP patients do not have primary care providers. Equipment and technology are currently available on the market place for successful implementation of the program. Phlebotomy training and licensing are the most time-consuming barriers but are technically and intellectually manageable for pharmacists.<sup>40</sup>

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<sup>38</sup> US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014: A clinical practice guideline. May 14, 2014. (<http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>)

<sup>39</sup> One-Step PrEP™: Kelley-Ross Pharmacy’s Our Program, One-Step PrEP at <https://www.krrph.com/our-services/medications/prep/program-one-step-prep/> or watch YouTube video at: [https://www.youtube.com/watch?v=iQV\\_3mhF1Us&feature=youtu.be](https://www.youtube.com/watch?v=iQV_3mhF1Us&feature=youtu.be)

<sup>40</sup> Guzman A. (2016, July). *Current Topics in PEP/PrEP in New York State Pharmacies*. PowerPoint presented at the Pharmacy Committee Meeting, NYSDOH AIDS Institute.

**Key References:**

- [1] Daskalakis D, et al. (2015). *Accelerating the implementation of antiretroviral medications to prevent HIV infection in New York City*. National HIV Prevention Conference, abstract 1419.
- [2] Tung E, et al. (2015). *One-Step PrEP: A Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic in a Community Pharmacy Setting*. National HIV Prevention Conference, abstract 2091.
- [3] Eligible providers can register for the [NYS PrEP/PEP Provider Directory](http://www.surveymonkey.com/s/S329ZK5) at the following link:  
[www.surveymonkey.com/s/S329ZK5](http://www.surveymonkey.com/s/S329ZK5)

**Potential Key Collaborators:**

- NYCDOHMH
- Clinical Education Initiative
- National Institutes of Health Adolescent Medicine Trials Network for HIV/AIDS Interventions
- Hetrick-Martin Institute
- NY State Board of Pharmacy
- Community Health Care Association of New York

## **Focus Area 6: Increase Access to Naloxone and Buprenorphine**

Tremendous success has already been seen in reducing new HIV infections among persons who inject drugs, and pharmacists have played a key role in this through the Expanded Syringe Access Program (ESAP). However, the recent rise in misuse of prescription opioids, heroin use, and associated opioid overdoses across New York State suggests that continued efforts are needed to address the evolving needs of persons who use drugs statewide to maintain these gains and to reduce the spread of HIV.

### **Applicable Blueprint Goals/Sections:**

BP15: Increase momentum in promoting the health of people who use drugs

GTZ23: Enact Reforms to improve drug user health

### **Implementation Strategies:**

- **Promote pharmacy dispensing of naloxone** – this can be done in the following ways:
  - **Pharmacies can register as an opioid overdose prevention program;**
  - **Pharmacies can work with another registered program,** and request approval to have their prescriber issue a standing order to the pharmacy. Registered programs currently offering this option to pharmacies include: NYCDOHMH for the five boroughs of NYC; Erie County DOH for 8 counties in the western region of NYS; Albany County DOH for Albany County and the Harm Reduction Coalition for the rest of the state and for chains spanning more than one region.
  - **Pharmacy continued education (CPE) can be promoted** to allow more pharmacists to have the authority to dispense naloxone; collaborate with Clinical Education Initiative (CEI)
  - **A decal can be developed to be placed on pharmacy doors** to show that their pharmacies are dispensing naloxone.
- **Expand access to sterile syringes**
  - **Promote the provision of education and referrals to patients purchasing syringes;** effective in the 16/State Budget, pharmacies may offer education and referral to patients who are purchasing syringes.
    - NYSDOH AIDS Institute will work with the Harm Reduction Coalition to develop a CPE on the Expanded Syringe Access Program and the role the pharmacist can play in providing education and referrals;
    - Materials will be developed to be shared with pharmacies so they can provide additional information when syringes are purchased including access to referrals.
- **Expand access to evidence based treatment**
  - **Promote the role pharmacists can play in educating patients on buprenorphine**
    - Develop a CPE for pharmacists on buprenorphine;
    - Share buprenorphine fact sheets that are being developed for medical providers and patients/consumers for pharmacist education and distribution to patients

**Evidence:**

Approximately 4 million syringes are sold annually by around 3,000 pharmacies that have registered for ESAP. To date, close to 2,000 pharmacies have either registered as overdose prevention pharmacies or have received/requested standing orders from registered programs - prior to the legislation requiring chain pharmacies to do so [5,6]. Both of these activities are vital in preventing transmission of HIV & HCV as well as preventing opioid overdose deaths. New York State DOH has funding to increase access to buprenorphine.

This is evidence that pharmacists in NYS are willing and able to be major partners in promoting the health of people who use drugs. This role can be supported and expanded through training and education.

Research in the implementation phase of the Expanded Syringe Access Program found that training and education of pharmacists increased the likelihood that they would sell syringes and decreased negative opinions of people who inject drugs. As injection drug use spreads in NYS the education of pharmacists in selling syringes must be expanded to include pharmacists with less experience with people who inject drugs.

The American Public Health Association and the National Association of Boards of Pharmacy have recognized the role of the pharmacist in overdose training and furnishing naloxone; pharmacy provision has been increasing across the US. This is being scaled up rapidly and may also serve alongside ESAP to open the door to education about treatment and referrals.

Recent work has found that increased knowledge of and materials on substance use disorders enhanced the likelihood that pharmacists would provide information on addiction services. Providing education and materials on buprenorphine can help pharmacists expand their role in decreasing morbidity and mortality NYS is seeing with opioid substance use disorders [3,4,7].

**Context:***Relevant Legislation*

- **16/17 State budget** - All chain pharmacies with 20 or more stores will be required to dispense naloxone. Independent pharmacies also have the authority to request approval to dispense naloxone.
- **Comprehensive Addiction Recovery Act (CARA)**
- **Standing orders**
- **Medicaid covering a formulation**

*Background on naloxone and buprenorphine*

**Naloxone** is safe, effective, inexpensive, and relatively easy to administer via intramuscular injection or nasal spray. Naloxone reverses the deleterious action of excess opiates, and has no psychoactive effects.



Furthermore, there is no potential for abuse of naloxone. Adverse reactions are rare, and researchers attribute those that do occur to the effects of the overdose itself.<sup>41</sup>

The effectiveness of bystander naloxone administration in conjunction with overdose education programs has been demonstrated in several studies and meta-analyses and has been associated with increased odds of recovery.<sup>42</sup>

**Buprenorphine** is referred to as an “opioid partial agonist.” Evidence clearly shows that buprenorphine maintenance treatment (BMT), compared to placebo, improves both retention in treatment and reduces illicit opioid use.<sup>43</sup> Furthermore, a study conducted in 2015 evaluated a six month change in quality of life scores among patients on buprenorphine and noted improvements in all areas: physical, psychological, environmental and social.<sup>44</sup> Randomized clinical trials demonstrate that side effects related to buprenorphine are reported to be significantly lower and more tolerable compared to methadone. Additionally, buprenorphine has a lower risk of overdose when compared to methadone.<sup>45</sup>

An analysis of buprenorphine use in New York City indicated that over 50% of participants of syringe exchange programs had used illicit buprenorphine to self-treat their opiate dependence, and 80% of those individuals indicated that they would agree to BMT with specialized buprenorphine if doctors were available to prescribe it.<sup>46</sup> Individuals also indicated that the reason for their illicit use of buprenorphine was due to the lack of doctors prescribing buprenorphine and/or that they were not aware of where they could go to receive BMT in NYC.

#### Key References:

- [1] Fuller CM, Galea S, Caceres W, et al. (2007). Multilevel community-based intervention to increase access to sterile syringes among injection drug users through pharmacy sales in New York City. *Am J Public Health, 97*, 117-124.
- [2] Green TC, Dauria EF, Bratberg J, et al. (2015). Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduction Journal, 12*(25).

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<sup>41</sup> Bazzazi AR, Zaller ND, Fu JJ & Rich JD. (2010). Preventing Opiate Overdose Deaths: Examining Objections to Take-Home Naloxone. *J Health Care Poor Underserved, 21*(4), 1108-1113.

<sup>42</sup> Edelman EJ, et al. (2014). The impact of buprenorphine/naloxone treatment on HIV risk behaviors among HIV-infected, opioid-dependent patients. *Drug and Alcohol Dependence, 139*, 79-85.

<sup>43</sup> Fox AD, Chamberlain A, Sohler NL, Frost T & Cunningham CO. (2015). Illicit buprenorphine use, interest in and access to buprenorphine treatment among syringe exchange participants. *Journal of Substance Abuse Treatment, 48*(1), 112-116.

<sup>44</sup> Giglio RE, Li G & DiMaggio CJ. (2015). Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis. *Inj. Epidemiol, 2*(1).

<sup>45</sup> Mitchell SG, et al. (2015). Changes in Quality of Life following Buprenorphine Treatment: Relationship with Treatment Retention and Illicit Opioid Use. *Journal of Psychoactive Drugs, 47*(2), 149-157.

<sup>46</sup> Thomas, C. P. et al., (2015). Medication-Assisted Treatment with Buprenorphine: Assessing the Evidence. *FOC, 13*(3), 363-376.

- [3] Hagemeyer NE, Alamian A, Murawski MM & Pack RP. (2015) Factors associated with provision of addiction treatment information by community pharmacists. *J Subst Abuse Treat*, 52, 67-72.
- [4] Hammett TM, Phan S, Gaggin J, et al. (2014). Pharmacies as providers of expanded health services for people who inject drugs: a review of laws, policies, and barriers in six countries. *BMC Health Serv Res*, 14, 261.
- [5] Jones CM Lurie PG & Compton WM. (2016). Increase in Naloxone Prescriptions Dispensed in US Retail Pharmacies Since 2013. *Am J Public Health*, 106(4), 689–690.
- [6] Lim JK, Bratberg JP, Davis CS, Green TC, Walley AY. (2016). Prescribe to Prevent: Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists. *J Addict Med*.
- [7] Watson T & Hughes C. (2012). Pharmacists and harm reduction: a review of current practices and attitudes. *Can Pharm J*, 145, 124–127.

**Potential Key Collaborators:**

- Harm Reduction Coalition
- PSSNY
- Chain Pharmacy Association of NYS
- Injection Drug Users Health Alliance and syringe exchanges outside NYC
- ESAP Pharmacies
- NY Society of Addiction Medicine
- OASAS
- NYS Association of Family Practice
- Clinical Education Initiative

## **Focus Area 7: Reduce ARV Medication Diversion**

Due to the well-documented difficulty of collecting accurate information on illicit activities, reliable data on the ARV black market are limited. However, multiple incidents of major Medicaid fraud, as well as a multitude of anecdotal reports from consumers and providers, indicate that the illegal sale and consumption of antiretroviral medication is a serious problem in New York [1-5]. Furthermore, studies have indicated that ARV drug diversion significantly reduces adherence rates, causing viral load suppression to drop and the epidemic to spread [6].

It is critical that efforts to reduce ARV medication diversion do not cast PLWH in a negative light. Trusting and open relationships between pharmacists and their patients is of the utmost importance. PLWH are already socially vulnerable in the face of high rates of poverty, comorbidity, substance dependence and mental illness [7]. Practices should *not* be put in place that make HIV positive individuals, who are already so often burdened by stigma in public settings, feel uncomfortable in the place they go to pick up their life-saving medications. Therefore, rather than focus on incriminating patients who sell their ARVs, this advisory group suggests strategies that will deter pharmacists from illegally buying back medications and encourage practices that track adherence and enable follow-up on patients who are not filling or taking their medications.

### **Applicable Blueprint Goals/Sections:**

BP7: Use client-level data to identify and assist patients lost to care or not virally suppressed

### **Implementation Strategies:**

- **Explore ways to give providers access to pharmacy data on ARV prescription fills and refills.**  
This would allow providers to see if their patients are picking up their medication, enabling them to open a dialogue with patients who are filling their ARVs and are virally unsuppressed.
  - One possibility is to record ARV medication in the Prescription Monitoring Program (PMP) Registry. This would enable both prescribers and pharmacists to view dispensed ARV prescription histories, flag unusual refill patterns, and follow up with patients who are picking up ARV medication and are not virally suppressed.
  - Many independent pharmacies currently have no way to follow up on a patient who has stopped refilling their ARVs. They cannot tell if that patient is simply filling at a different pharmacy or is no longer filling their prescription at all. Access to a database that tracks patient specific refills for ARVs would allow pharmacists to follow up on patients who have not refilled their ARVs and contact the patient and/or their provider.
  - Pharmacists are not required to consult the PMP Registry, but could be encouraged to do so.
- **Educate HIV providers about the importance of reporting medication diversion.**
  - Promote iSTOP program
- **Give providers access to Medicaid claims data**, which can also be compared to patient viral load (for patients on Medicaid) and improve care coordination.
- **Develop channels for providers to report suspected incidences of medication buy-back in pharmacies that do not link directly back to their patients.**
- **Establish a community web-based platform for reporting medication buybacks.**
- **Explore options to reward the reporting of medication buy-back**

**Context:***Key Terms and Definitions*

- **ARV medication diversion:** the illegal transmission of antiretroviral medication from a legitimate source - such as an individual with a prescription - to the illicit market.
- **Medication buy-back:** when pharmacists offer patients who have a legitimate prescription the option to sell their medication back to the pharmacy. For example, when a patient comes to pick up their ARVs, the pharmacist might put a \$100 bill on the counter next to the medication and tell the patient they can choose to take one or the other. This illegal practice allows pharmacies to submit claims for medication that was not actually dispensed and get reimbursed for more medication than they bought.

**Key References:**

- [1] New York Field Office. (2012). *Manhattan U.S. Attorney Announces Charges Against 48 Individuals in Massive Medicaid Fraud Scheme Involving the Diversion and Trafficking of Prescription Drugs* (Press Release). Federal Bureau of Investigation. Retrieved from <https://archives.fbi.gov/archives/newyork/press-releases/2012>
- [2] New York State Office of the Attorney General. (2003). *Owners of Brooklyn Pharmacy and Clinic* (Press Release). Retrieved from <https://www.fbi.gov/>
- [3] New York State Office of the Attorney General. (2006). *Charges Announced In \$70 Million Drug Diversion Case* (Press Release). Retrieved from <http://www.ag.ny.gov/press-release/charges-announced-70-million-drug-diversion-case>
- [4] New York State Office of the Attorney General. (2013). *NYC Pharmacy and Clinic-Based Criminal Enterprise Charged with \$16 Million Theft and Fraud Perpetrated on Medicaid* (Press Release). Retrieved from <http://www.ag.ny.gov/press-release/nyc-pharmacy-and-clinic-based-criminal-enterprise-charged-16-million-theft-and-fraud>
- [5] New York State Office of the Attorney General. (2016). *A.G. Schneiderman Announces Trial Conviction Of Pharmacist Who Illegally Sold Black Market HIV Medications* (Press Release). Retrieved from <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-trial-conviction-pharmacist-who-illegally-sold-black-market>
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**Potential Key Collaborators:**

- Office of the Medicaid Inspector General (OMIG)
- Centers for Medicaid and Medicare Services (CMS)



**APPENDIX A****Pharmacy Courses Update (Revised 9/13/2016)****Instructions to view current list of CE approved CEI courses**

1. Visit [www.ceitraining.org](http://www.ceitraining.org)
2. Select “request onsite training” on the lower right side of web page
3. Select “click here to check the existing courses for onsite training” and a list should appear
4. Select each course of interest to see the learning objectives and credit hours awarded

**Current CPE credit approved conferences/courses (LIVE)**

- 2nd Annual New York State STD Conference (6.5 hours)
- 3rd Annual New York State STD Conference (6.5 hours)\*
- Antiretroviral Therapy (1 hour)
- Building an Inclusive Practice: Transgender Health and HIV (1 hour)
- Building an Inclusive Practice: Transgender Health and HIV (1.5 hours)
- Drug-Drug Interactions Seen in Treatment for Hepatitis C (1 hour)
- Hepatitis C and HIV Co-Infection (1 hour)
- HIV Medication Errors (1 hour)
- HIV Screening and Diagnosis in New York State (1 hour)
- HIV Screening and Diagnosis in New York State (1 hour)
- HIV Screening and Diagnosis in New York State (1.5 hour)
- HIV Screening and Diagnosis in New York State (1.5 hours)
- HIV-STD Inter-relationship (1 hour)
- New York State 2016 Clinical Conference on HIV and HCV: Advancing Care through Knowledge, Policy, and Implementation (6 hours)
- New York State 2016 HIV Cure Symposium: Connecting Research to Clinical Practice (7 hours)
- New York State 2017 Clinical Conference on HIV and HCV (6 hours)\*
- Naloxone: Preventing Opioid Overdose in the Community (1 hour)\*
- Post-Exposure Prophylaxis (1 hour)
- Pre-Exposure Prophylaxis (1 hour)
- Pre-Exposure Prophylaxis (1.5 hours)
- PrEP Implementation Workshop: Challenges and Solutions in Clinical Practice (4 hours)
- Smoking Cessation in the HIV-Infected Patient (1 hour)\*
- Testing, Treatment, and Prevention: The Clinician’s Role in Ending the AIDS Epidemic in New York State (3 hours)
- Testing, Treatment, and Prevention: The Clinician’s Role in Ending the AIDS Epidemic in New York State (5.5 hours)
- Transgender Health and HIV Conference (6 hours)\*
- Treatment for Hepatitis C: New Tests, New Drugs, and New Recommendations (1 hour)
- Treatment for Hepatitis C: New Tests, New Drugs, and New Recommendations (1.5 hours)

\*Curricula in development and expected to be approved before July 2017

**Current CPE credit approved conferences/courses (HOMESTUDY)<sup>‡</sup>**

- 2nd Annual New York State STD Conference (6.5 hours)
- 3rd Annual New York State STD Conference (6.5 hours)\*
- Antiretroviral Therapy (1 hour)
- Building an Inclusive Practice: Transgender Health and HIV (1 hour)
- Common STD Syndromes (1 hour)\*
- Drug-Drug Interactions Seen in Treatment for Hepatitis C (1 hour)
- Genital Herpes Simplex Virus Infection (1 hour)\*
- Gonococcal and Chlamydial Infections (1 hour)\*
- Hepatitis C and HIV Co-Infection (1 hour)
- HIV Medication Errors (1 hour)
- HIV Screening and Diagnosis in New York State (1 hour)
- HIV-STD Inter-relationship (1 hour)
- Introduction to the Clinical Management of STDs (1 hour)\*
- New York State 2016 Clinical Conference on HIV and HCV: Advancing Care through Knowledge, Policy, and Implementation (6 hours)
- New York State 2016 HIV Cure Symposium: Connecting Research to Clinical Practice (7 hours)
- New York State 2017 Clinical Conference on HIV and HCV (6 hours)\*
- Naloxone: Preventing Opioid Overdose in the Community (1 hour)\*
- Post-Exposure Prophylaxis (1 hour)
- Pre-Exposure Prophylaxis (1 hour)
- PrEP Implementation Workshop: Challenges and Solutions in Clinical Practice (4 hours)\*
- Smoking Cessation in the HIV-Infected Patient (1 hour)\*
- STD Overview for Clinicians (1 hour)\*
- STD Update for Clinicians (1 hour)\*
- STD/HIV Risks and Screening for Black Men Who have Sex with Men (1 hour)\*
- Syphilis (1 hour)\*
- Testing, Treatment, and Prevention: The Clinician's Role in Ending the AIDS Epidemic in New York State (3 hours)
- Testing, Treatment, and Prevention: The Clinician's Role in Ending the AIDS Epidemic in New York State (5.5 hour)
- The Clinical Diagnosis and Treatment of Gonorrhea, Chlamydia and Genital Herpes (1 hour)
- Transgender Health and HIV Conference (6 hours)\*
- Treatment for Hepatitis C: New Tests, New Drugs, and New Recommendations (1 hour)
- Vaginitis (1 hour)

**Contact Information**

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<sup>‡</sup> Tentative launch date for homestudy CPE material on CEI website is early 2017

\*Curricula in development and expected to be approved before July 2017

**APPENDIX B****Reimbursement guidelines for clinical pharmacists' services, by payment source**

Source of payment	Guidelines
Third-party Direct  Indirect	Payment is made directly to the pharmacists or pharmacies for approved services, including MTM.  In physician clinics, payment is made directly to the physician with whom a pharmacist is either (1) employed as a member of the practice, or (2) has a collaborative practice agreement. In hospital-based clinics, pharmacist services are generally billed under the heading of "technical/facility fee" and payment is made directly to the hospital.
Medicare	Payment is made directly or indirectly to pharmacists for medical therapy management services under Medicare Part D. At present, services provided by pharmacists are not covered by Medicare Part B.
Medicaid	In New York State, Medicaid beneficiaries receive prescription drug coverage through Medicare Part D. As a result, payment for medication therapy management services may be made to pharmacists or pharmacies directly or indirectly depending on the context of care.

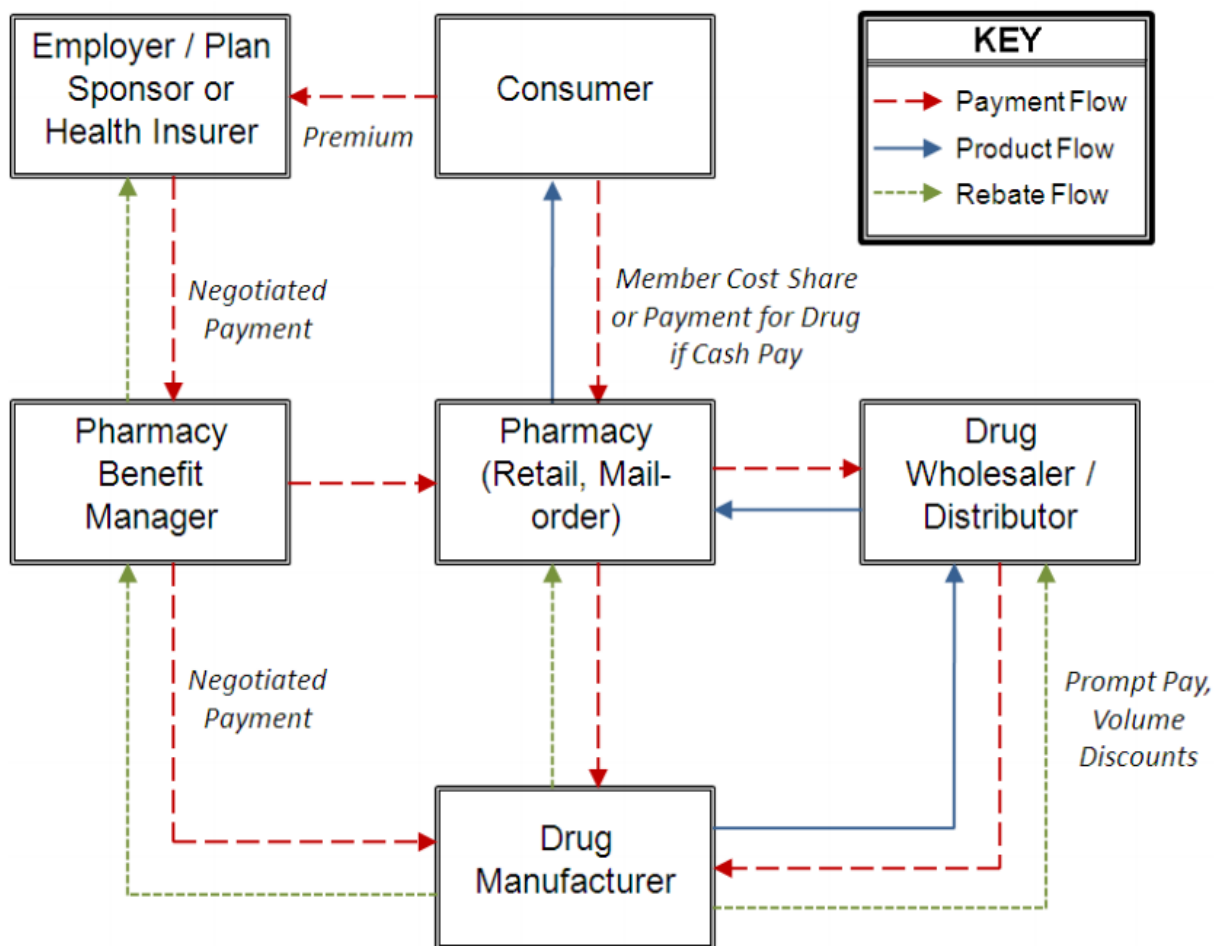
**Source:** McBane S.E., et al. (2015). Collaborative Drug Therapy Management and Comprehensive Medication Management—2015. *Pharmacotherapy*, 35(4), e39-e50.



## APPENDIX C

The following chart illustrates the business relationships in which PBMs play a role<sup>47</sup>

### Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain



Source: The Health Strategies Consultancy LLC

<sup>47</sup> Texas Department of Insurance. (2010). *Pharmacy Benefit Managers: A Study of Prescription Drug Management Practices and Policies*. Texas. Retrieved from <http://www.tdi.texas.gov/reports/life/documents/pbmstudy.pdf>