

# The Wonders of 340B for Viral Hepatitis and Drug User Health

**Implementing  
Strategic Visions to  
End the Epidemics**

# Welcome

- In 2019, the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs indicated that, in addition to STD programs, HIV and viral hepatitis prevention CDC grantees and subgrantees, authorized under Section 318 of the US Public Health Services Act, may qualify to participate in the 340B Drug Pricing Program and much progress has been made by viral hepatitis and drug user health programs to interpret, maximize and continue to leverage the 340B Drug Pricing Program.
- This session will provide a space for the NYC Department of Health and for START Treatment & Recovery Centers to speak to their achievements and all the work that allowed for them to be conferred 340B eligibility. Session moderators will guide the discussion to highlight opportunities and challenges navigating the 340B Drug Pricing Program as well as patient impacts and outcomes centering on a syndemic approach while advancing health equity.

# 340B Partnership

- **Partnership elements:**
  - There is a financial relationship
    - Direct funding and/or in-kind contributions
  - Understands the 340B Drug Pricing Program and its requirements
  - Has an established relationship with patients, maintains medical records
  - Provides services, or range of services, consistent with the scope of the grant to patients

# 340B Partnership

- HCV prevalence among PWID is estimated at 40% globally, with IDU accounting for 23% of new HCV infections (CDC)
- Rapid increases in HCV is associated with the opioid epidemic
- Opioid treatment programs (OTPs) are well positioned to provide HCV treatment
  - Culturally competent, trauma-responsive
  - Onsite medical staff
  - See their patients regularly
  - Increased federal funding to address OUD

# 340B Partnership

- START Treatment & Recovery Centers and New York City Department of Mental Hygiene
- Evolution of the partnership from 2019 to 2022
  - Subgrantee of Care Cascades Funding
    - HCV testing and program staff
  - Continued work through in-kind contributions
- Desire to maintain services despite billing limitations and low reimbursement rate

340B to the Rescue!!!!

# 340B Partnership

- Technical assistance from NASTAD HepTAC
- Formalizing the partnership
  - Internal negotiations
  - Memorandum of Understanding (MOU)
  - Sharing data elements
- Conferring eligibility
- Time investment

# Administrative Barriers – 340B ESP

- Gilead now requires all 340B covered entities to register with 340B ESP and upload claims level data for prescriptions of their hepatitis C treatment regimens
  - Merk and Abbvie also have CLD requirements in place for all their outpatient medications dispensed via 340B contract pharmacy arrangements with hospitals, including DAAs & ARVs
- Covered entities that provide the requested CLD will be able to continue to use the contract pharmacies of their choice. Covered entities with on-site pharmacies that opt not to provide the requested CLD will no longer be eligible to place “ship to/bill to” replenishment orders for these DAAs dispensed through any of their 340B contract pharmacies
- Covered entities without on-site pharmacies that opt not to provide the requested CLD will have the option to select a single contract pharmacy location for dispensing these products
- 340B covered entities with contract pharmacies that exclusively serve uninsured patients can submit an attestation form indicating they do not serve clients with any form of insurance, such as Medicaid, Medicare Part D, or a commercial plan

# Leveraging 340B for the Expansion of Viral Hepatitis Services in Opioid Treatment Programs

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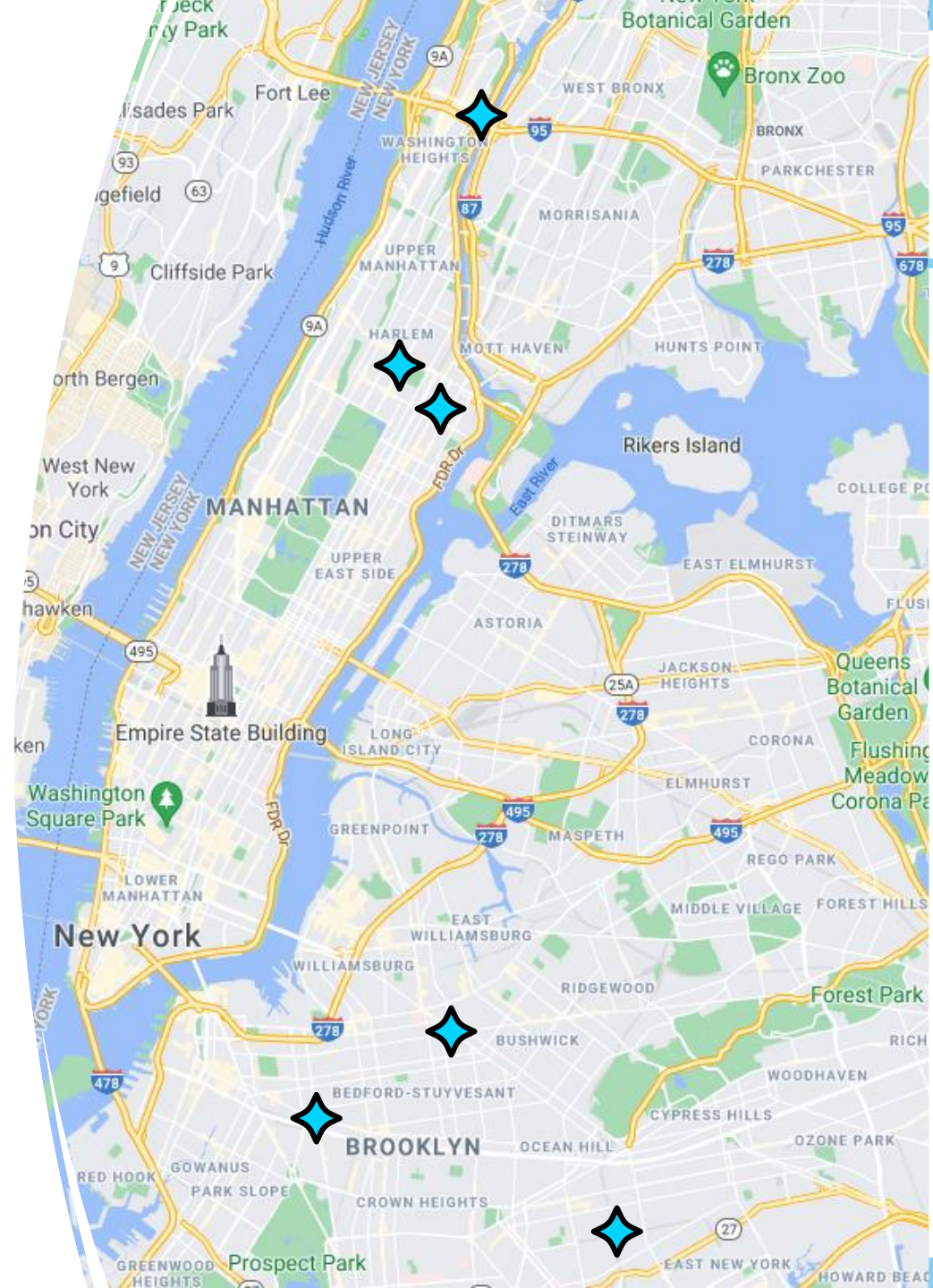


# START

TREATMENT & RECOVERY CENTERS

*The right way to treat people.®*

- Founded in 1969
- 7 NYS OASAS-certified, opioid treatment programs (OTPs)
- Article 28 licensure: onsite primary care services
- Adult mental health program - Reach
- Adolescent mental health program - Teen START



# Hep C Treatment Gaps among Persons who Inject Drugs (PWID)

- Despite willingness to start treatment among a large percentage (~70%) of PWID who are diagnosed with chronic Hep C infection, treatment gaps remain
  - Stigma related to both injection drug use and infectious disease
  - Limited success with referrals to treatment
  - Limited availability of screening and treatment at OTPs where patients could benefit most

*Sources: CDC, 2020; NYC DOHMH, Hep A, B, and C in NYC: 2019 Annual Report; Talal, 2021.*

# OTP Screening & Treatment Services

- Ideal sites for viral hepatitis prevention, screening and treatment
  - Non-judgmental and non-stigmatizing social context
  - Increase patient awareness and decrease barriers that limit patient access to and engagement in care
  - Integrated care for the treatment of infectious diseases and opioid use disorders (OUDs)
- Recent study found that patients enrolled in OTPs
  - Reported comfort with and sense of support engaging in treatment at OTPs
  - Reported trust in OTP providers and care staff

*Sources: NYC DOHMH, Hep A, B, and C in NYC: 2019 Annual Report; Talal, 2021.*

# NYC Department of Health Viral Hepatitis Program (January 2020 – April 2021)

- CDC Care Cascades Funding
- Goal: Build capacity at START to deliver hepatitis C treatment onsite, via telemedicine and by referral

## **Viral Hepatitis Program, NYC DOHMH**

- Nadine Kela-Murphy, MPH
- Umaima Khatun, MPH
- Versalle Shelton, MPH

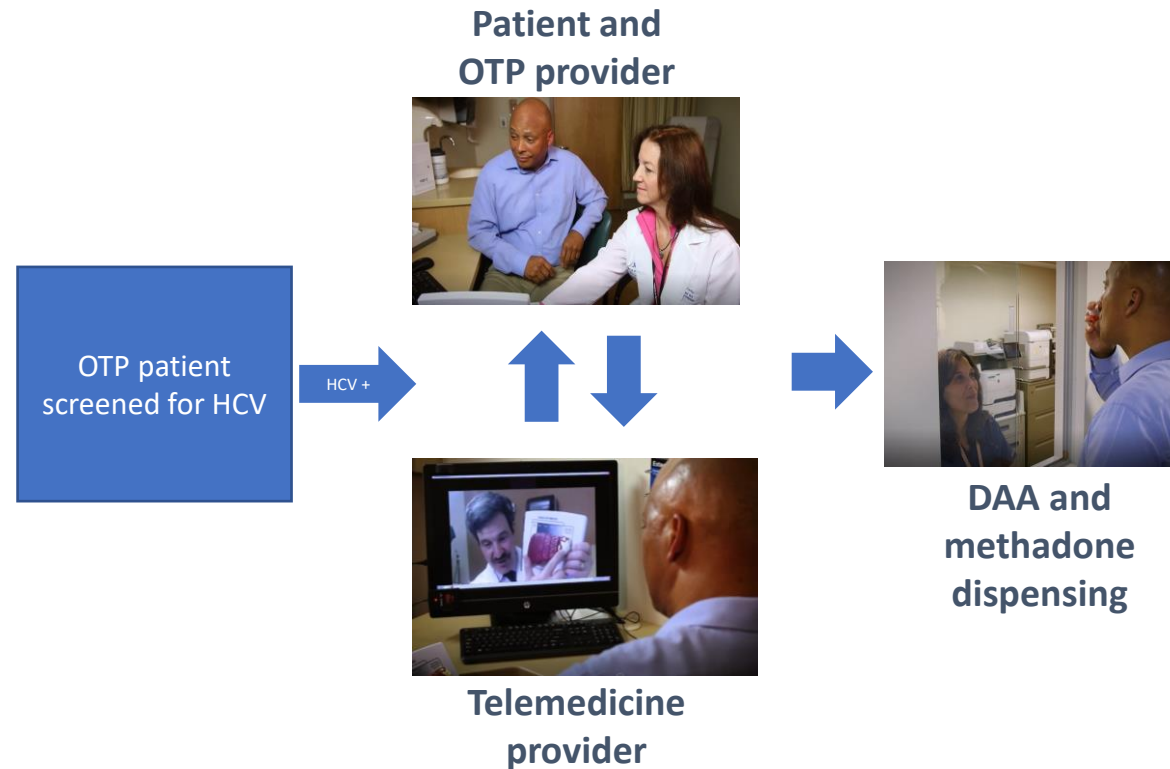




# Project Collaborators

- NYC DOH Viral Hepatitis Program – Data to Care Clinical Practice Facilitation Program
  - Surveillance data – hepatitis C patient lists
  - Electronic health record query tools
  - Training and technical assistance
- Empire Liver Foundation – NY State Network of liver specialists, funded by NYC Council to deliver clinical education
  - Supported NY Hepatitis Telehealth Workgroup start-up and meetings
  - Trained START clinical providers in hepatitis C treatment
  - Supported Peer-to-Peer mentoring
- Hep Free NYC – NYC-based community coalition
  - Supported NY Hepatitis Telehealth Workgroup recruitment, resource and information dissemination
  - Website, email list, social media, contact management system (PHPC/SalesForce)

# Facilitated Hepatitis C Treatment via Telemedicine Integrated into an OTP



PI: Andrew Talal, MD, SUNY Research Foundation

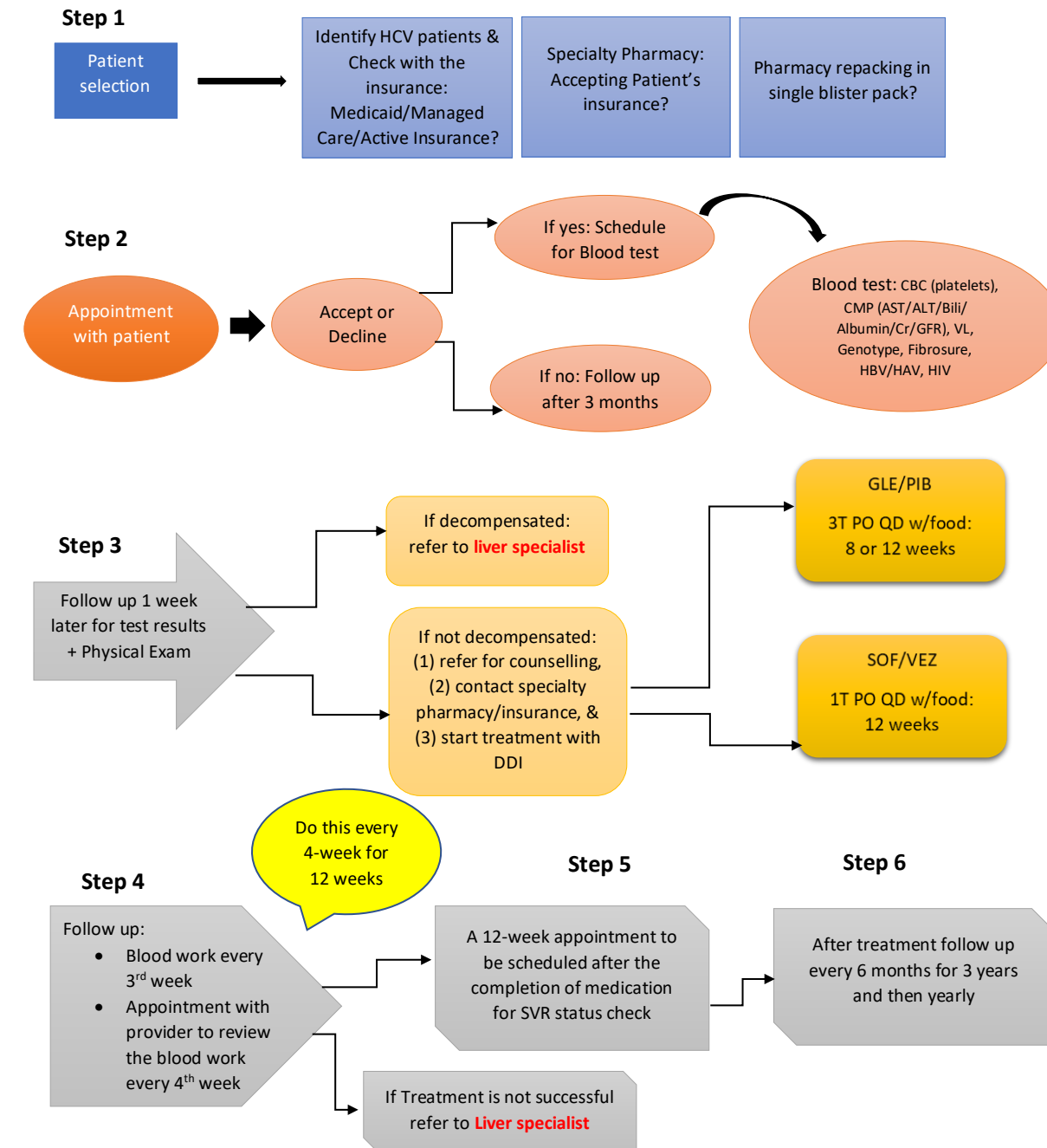
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# Viral Hepatitis Program Implementation at START

- Screening: part of usual care model at time of admission and during annual physical exams
- Electronic medical record review
  - Reviewed screening rates, number of antibody tests and subsequent RNA tests as indicated
  - Developed a list of hepatitis C RNA positive patients in need of treatment (362 patients at the time)
- Patient navigation to engage and educate patients about treatment options
- Clinical treatment workflow with OTP clinicians

# START Hepatitis C Clinical Workflow



Patient without insurance will go in separate list



# Hep C Treatment Summary

## As of April 30, 2022

	Approached	Enrolled	Refer to PCP	Discharged/ Insurance Issue	Started DAA therapy	HCV RNA Undetected @ Week 8	12- Week SVR	% SVR
Phase 1	30	22	8	4 <sup>a</sup>	18	16	16	89%
Phase 2	30	26	4	4 <sup>a</sup>	22	20	15	68%
Total	60	48	12	8	40	36	31	78%

Note: SVR – sustained virologic response. Follow-up monitoring is ongoing.

# 340B Program – Facilitate Scale Up

- Sustain and scale treatment services
  - 362 active patients in 2020, 238 active patients today
  - 34% reduction in active patients from 2020-2022
- Cost analysis conducted by Biomatrix using claim records estimates a 340B discount of nearly \$4,000 per treated patient
- Clinical workflow not complex, but requires multidisciplinary team (clinical and nonclinical staff)
  - In addition to the Medical and Nursing staff, leadership, behavioral health, finance, regulatory, HR, research & evaluation worked collaboratively
- START's micro-elimination goal: Treat existing patients by 2024

# Patient Navigation: Treatment Education and Counseling

- What to expect during the treatment (Tx) process
- How HCV Tx has evolved to differentiate from earlier treatment, like interferon
- Tx effectiveness → cure
- Tx safety and what to expect in terms of side effects
- What to expect during the health coverage authorization process, highlighting not cost prohibitive
- Address misconceptions about who is appropriate for and/or deserving of Tx (current IDU and Tx eligibility)
- Importance of adherence
- What to expect during the monitoring and follow up Tx process
- Minimizing risk of reinfection

# Patient Navigation: Addressing Barriers to Treatment

- Patient hesitancy in starting treatment, particularly given misconceptions about treatment and eligibility
- Financial and time constraints
- Empower OTP providers to be well-versed in Hep C treatment and to gain a sense of self-efficacy in treating their patients
- Liaison work with specialty pharmacy to reduce burden on patients and clinic staff
  - After initial set up of onsite treatment, the authorization process is completed and medications are delivered in just a few days

# Patient Navigation: Adherence Support

- Directly observed therapy was helpful and convenient to some patients, especially when combined with medication for opioid use disorders
- Flexibility with medication dispensing was needed throughout the COVID pandemic to minimize in-person contact
  - Take homes of DAA were provided similar to procedures and eligibility criteria for methadone dispensing for use at home
- For many, seeing changes in viral load with updated lab results served to motivate

# Supports for START's Model: It takes a village to raise a 340B Program

## Ecosystem for success

- NYC Department of Health and Mental Hygiene - Bureau of Hepatitis, HIV, & STI
- NASTAD
- NYS Office of Addiction Services and Supports (OASAS)
- NYS Department of Health, Bureau of Hepatitis Health Care, AIDS Institute
- NYS Medicaid Office
- Specialty pharmacy: Biomatrix
- PVP: Apexus
- START Leadership, Chief Financial Officer, General Counsel

# Acknowledgements

## Viral Hepatitis Program, NYC DOHMH

- Nadine Kela-Murphy, MPH
- Umaima Khatun, MPH
- Versalle Shelton, MPH

## NASTAD

- Rita Isabel Lechuga, MD, MPH
- Erin Fratto, MS, CHES

## NYS OASAS

- Kelly S. Ramsey, MD, MPH, MA, FACP, DFASAM, Chief of Medical Services

## NYS DOH, Bureau of Hepatitis Health Care, AIDS Institute

- Colleen Flanigan, RN, MS, Director

## START Treatment & Recovery Centers

- Anthony McLeod, Lead Implementation Coordinator and Manager
- Alvin Chu, MA, MPH, EdD, Associate, Director of Funded Projects

## Biomatrix

- Sabine Enright, PharmD, Director, 340B Services

## Specialists

- Andrew Talal, MD
- Jesi Ramone, MD
- Alan Stein, MD
- Pete Pecoraro, 340B, Verity Solutions

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# Questions & Discussion



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# Resources

- [340B for Viral Hepatitis Programs](#), NASTAD
- [340B Drug Pricing Program](#), HRSA
- [340B Prime Vendor](#), Apexus
- [Update on 340B Eligibility for Programs Authorized Under Section 318 of the US Public Health Service Act](#), NASTAD/NCSD
- [Your Guide to Integrating HCV Services into Opioid Treatment Programs](#), Addiction Technology Transfer Center Network (ATTC)