INTEGRATION OF CARE COMMITTEE

God's Love We Deliver
166 Avenue of the Americas
July 6, 2016, 9:40am-11:45pm

DRAFT MINUTES

Members Present: Christopher Joseph (Co-Chair) , Lisa Zullig (Co-Chair), Amber Casey (for Graham Harriman), Joan Edwards, Deborah Greene, Zach Hennessey, Peter Laqueur, Julie Lehane, PhD, Jan Carl Park, John Schoepp, Claire Simon, Brenda Starks-Ross

Members Absent: Peter Campanelli, PsyD, Christopher Cunningham, Michael Ealy, Dorothy Farley, Janet Goldberg, Terry Hamilton, Gina Quattrochi, David Price, Bobby Rallakis

Staff Present: David Klotz, Eric Rude (NYC DOHMH)

Public Health Solutions Staff Present: Bettina Carroll

Agenda Item #1: Welcome/Introductions/Moment of Silence/Minutes

Mr. Joseph and *Ms. Zullig* opened the meeting followed by introductions and a moment of silence. The minutes from the meeting on June 22nd were accepted with no changes. The meeting packet was reviewed.

Agenda Item #2: Overview: Hepatitis C in NYC

Mr. Park noted that the IOC is following up on a recommendation from the Needs Assessment Committee (NAC) to expand access to Hepatitis C direct acting antiviral medications for Ryan White Part A eligible HIV/HCV co-infected clients by establishing a Local Pharmaceutical Assistance Program (LPAP). The timeline is short, given that a request would have to be put into the FY 2017 grant application, and input is needed from additional parties, such as LPAPs in other jurisdictions.

Mr. Rude gave an overview of hepatitis C in NYC and the NYC DOHMH Viral Hepatitis Program (VHP). The VHP does surveillance and applied research, program evaluation, provider education, direct services (screening, linkage to care, and treatment access to the most impacted and highest at-risk for HCV infection delivered through contracted partners), community organizing and public awareness, and policy work.

He described the hep C treatment cascade from estimated infected (149,500) to status known (73,250), referral to clinical evaluation (58,600), treatment eligibility (31,050), treatment (19,255) and sustained virological response (9,630) – which is only 10% of those infected (note: this is total hep C cases, not HIV/HCV co-infected). In 2015, there were 7,313 newly reported cases of HCV infection (from 170,000 tests conducted). Most were males in the "baby boomer" age cohort. The Bronx had the highest infection rate, with Blacks and Hispanics the majority of cases. Hep C has overtaken HIV in the number of fatalities per year. HCV and liver cancer rates and mortality are concentrated in areas with highest levels of poverty.

VHP also conducts in-depth analysis of program evaluation data and quality management work (modeled on the State's HIVQual program). A group of NYC hospital "champions" was formed for peer-to-peer learning. All NYC acute care hospitals have been visited covering all boroughs. VHP also funds Project INSPIRE, a model of service delivery and payment (based on the Part A Care Coordination model) that can reduce morbidity and mortality from chronic illness and reduce costs associated with its complications. The model moved clients from enrollment to cure, but does not pay for the medications. 1,887 clients have been enrolled, with 416 cured. Also, City Council is funding patient navigation programs in clinics and syringe exchange programs that have enrolled 638 clients with 94 cured so far (and rising) and many more referred to hep C medical care.

Mr. Rude discussed the VHP's public awareness and community organizing efforts, as well as major policy issues for NYC: advocate to City Council for increased viral hepatitis services; consider changes to the City Health Code for mandatory rapid Hep C test reporting; eliminate Medicaid/Managed Care restrictions on DAA prescribing; ensure insurance coverage of Hep C patient navigation; Health Homes, DSRIP, ACO, etc.; remove ban on use of syringe exchange funds (eased this year); Eliminate Medicaid restrictions on DAA prescribing; and the high cost of DAAs.

Strategies for combatting the high cost of hep C drugs include advocacy, legislative pressure, threat of legal action and encouraging competition. It was noted that most Ryan White clients are Medicaid eligible and fee-for-service Medicaid covers DAAs, but there are restrictions, such as not treating active drug users or not having HIV viral load suppression (although people with HIV-HCV coinfection are being priorities within Medicaid). Also, Medicaid Managed Care plans are still a barrier.

The following is a summary of the ensuing discussion:

- There is no data on approval rates at patient assistance programs.
- The City treats people on Rikers Island and there are new funds for HCV on Rikers, but the barrier is connecting people who leave the island to care, as stays can be short.
- Merck's drug is considered as good as Gilead's Harvoni, but it is not clear whi it is not being prescribed more. A new pan-genotypic drug has just been released by Gilead and the next generation of drugs will be similar.
- State ADAP formularies are decided by local committees that considers multiple criteria. NYS ADAP Director Christine Rivera says that the NYS ADAP formulary committee is currently considering adding non-Gilead drugs.
- The State has more leverage than the City in negotiating discounts.
- The biggest barriers in the fall-off in the hep C treatment cascade are clinicians not testing for HCV, doctors and patients not knowing about treatment, linkage, care coordination and

eligibility. Also, for HIV patients taking ARVs that contain tenofovir, there are contraindications with DAAs that would mean changing regimens that have often been successful for many years.

Ms. Casey then presented on what an LPAP is and how it would function. HRSA national monitoring standards say that LPAPs are a supplement to State ADAP programs for states where the ADAP program has a restricted formulary or eligibility criteria. The New York EMA has never had an LPAP because our ADAP formulary is robust and eligibility criteria generous. Most LPAPs are in the South, where state governments have restrictive eligibility and may only cover one ARV (the minimum required). LPAPs are for proving medications using a drug distribution system that has: a client enrollment and eligibility determination process that includes screening for eligibility with rescreening every six months; an LPAP advisory board; uniform benefits for all enrolled clients throughout the EMA; a drug formulary approved by the local advisory committee/board; and recordkeeping system for distributed medications.

The Council's role is to establish the need (with an estimated number of those not served by ADAP), and to develop a directive and allocate the funds. The needs assessment must determine: how many people are affected; what are the barriers/restrictions to access; what other resources are available; how does an LPAP address these barriers. The Grantee implements the LPAP, starting with establishing an advisory committee (which has HRSA rules on membership), which would set the formulary, eligibility and a cost containment plan (for waiting lists if there is not enough money. Cost containment could also include eligibility restrictions (e.g., more advanced stage of disease, not allowing people who fail their regimen due to non-adherence to return). The grantee would then determine the administrative mechanism and drug distribution systems (e.g., contract with a pharmacy benefits manager). The EMA cannot set up an LPAP without asking for it in the annual grant application (which requires detailed justification and data).

The LPAP advisory committee is established by the Grantee to oversee the LPAP. The LPAP Advisory Committee can be a subcommittee of the Planning Council, however the grantee must insure that there is no conflict of interest in this situation and that the grantee is responsible for appropriate administration of the LPAP. The LPAP Advisory Committee is responsible for developing written policies and procedures in the following areas: purpose, structure, financing, eligibility criteria, formulary, quality assurance, and quality management.

Ryan White funds cannot be used to pay for services that can reasonably be expected to be covered by another payer. For an LPAP, that includes: ADAP, Medicaid, Medicare Part D, and private insurance. People eligible to enroll must be: HIV+, resident of the EMA, meet Ryan White income eligibility, be un- or under-insured. In the event of a waitlist, additional eligibility criteria may have to be established by the LPAP advisory board as a cost-containment strategy. Steps for a client accessing an LPAP are: 1) Assessment of Eligibility (must be assessed/reassessed every 6 months); 2) Ensure Payer of Last Resort (Is the person eligible based on insurance status); 3) Waitlist and/or Cost Containments (any ADAP or LPAPs that have waitlists must establish cost-containment strategies including restricted eligibility or medical criteria). This is not a fast track. POLR requirements include assessing insurance coverage, denials by insurers and patient assistance programs, etc. An LPAP could pay for a prohibitive co-pay. Ms. Casey estimated that the earliest an LPAP could begin enrolment is summer 2017. If ADAP adds a DAA to the formulary, then any funds allocated to an LPAP would be unspent and would need to be reprogrammed. Given that

ADAP is not always able to take money late in the year, that risks high under-spending of the grant. While an LPAP can add new HIV drugs in the pipeline (e.g., gene therapy), the NYS ADAP program has a strong history of adding HIV therapies to the formulary quickly, thus it is impossible to predict spending. Also, unreimbursed cancer drugs are usually covered by hospital charity care.

Possible mechanisms for medication dispensing include: NYS HIV Uninsured Care Program (ADAP) as a Pharmacy Benefits Manager (PBM) (separate from our ADAP activities and would cost 10% for admin); a PBM company; there are several that specialize in ADAPs/LPAPs; working with a single/several pharmacy(ies) to distribute medications (least likely option as it unnecessarily restricts access). ADAP currently takes no administrative funds, which allows the grantee to give all other Part A providers a 12% administrative cap. If ADAP starts charging an administrative fee, that would be lowered to 10%, which might prove too burdensome, especially to small providers, who may decide to discontinue taking Part A funds.

A summary of the ensuing discussion follows:

- LPAPs only distribute medication and do not address all the other barriers to HCV care.
- There is way to do a cost/benefit analysis of long-term savings from treatment, the way insurers do by considering hospital visits, transplants and other things that would not have to be paid for.
- Many other steps would be required before drug dispensing, including advertising that the LPAP even exists.
- It may be better to use funds to address the earlier steps that address barriers on the HCV treatment cascade.
- HCV has been a high priority for the NYC DOHMH HIV Bureau's Care and Treatment Program, which has concluded that the biggest impact can be in screening, testing and follow up (e.g., RNA testing). Only half of all people who have been tested HCV positive in Ryan White Care Coordination programs have had follow up.
- Health promotion, assistance with the prior approval process, training staff to help with appeals of denials, etc. would address many barriers to care.
- Most Ryan White clients have Medicaid and can access the DAAs. The LPAP pool would be from existing ADAP clients.
- Many agencies give Gilead access to clients and should leverage that to pressure them on prices.

Agenda Item #3: Public Comment

A. Gaudino: Gilead is pricing their newest, pangenomic drug lower than Harvoni and have no incentive to lower the price of Harvoni. An LPAP could cover newer drugs for those who have failed other treatments.

M. Brown: Gilead has good P.R., which other drug companies can emulate. Also, we need more advocacy to put pressure on them.

There being no further business, the meeting was adjourned.