

September 24, 2019

HRSA Information Collection Clearance Office
Room 14N136B
5600 Fishers Lane
Rockville MD 20857

Submitted to paperwork@hrsa.gov

Re: Information Collection Request Title: Health Resources and Services Administration Uniform Data System, OMB No., 0915-0193—Revision

The Fenway Institute at Fenway Health submits the following comment regarding the Information Collection Request related to the health center program's Uniform Data System. The Fenway Institute is the research, education and training, and policy arm of Fenway Health, a federally qualified health center in Boston, MA. We provide care to about 32,000 patients every year. Half of our patients are lesbian, gay, bisexual and transgender (LGBT). About 2,200 of our patients are people living with HIV. We are a Ryan White Part C clinic. Currently we have 3,200 patients receiving pre-exposure prophylaxis for HIV prevention, and have prescribed PrEP to 4,700 patients since it became available earlier this decade. We have been providing HIV care since the early 1980s, and conducting HIV prevention research since 1985.

We wish to comment on four elements of the UDS Information Collection Request:

Revising the HIV linkage to care measure from 90 days from diagnosis to being seen for follow-up treatment to 30 days

Effective and timely linkage to care after HIV diagnosis is critical to the health of the newly diagnosed individual and to achieving the goals of the Ending the HIV Epidemic Initiative. According to the Centers for Disease Control and Prevention's Diagnosis-Based HIV Care Continuum, 74% of people living with HIV are receiving care, 58% are retained in care, and 62% are virally suppressed.¹ Cohen et al. found that earlier treatment decreases HIV transmission, so connecting newly diagnosed individuals to care in a more timely manner will likely save costs by decreasing HIV incidence.² Connecting newly diagnosed individuals more quickly to HIV care will also help achieve Strategy 2 of the Ending the HIV Epidemic Initiative, "Treat HIV rapidly after diagnosis, and effectively, in all people with HIV to help them get and stay virally suppressed." Fenway Health is confident that, with the help of high acuity case managers and an integrated approach to care that addresses behavioral health and the non-medical support service needs of the patient, that newly diagnosed individuals can be quickly linked to and retained in care and virally suppressed.

¹ CDC, Understanding the HIV Continuum, July 2019, <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>

² Cohen S, Van Handel M, Branson B et al. Vital Signs: HIV Prevention Through Care and Treatment—United States. *Morbidity and Mortality Weekly Report*. December 2, 2011 / 60(47);1618-1623. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6047a4.htm>. Accessed August 14, 2012.

Adding CMS349v2 HIV Screening

The Information Collection Request states that, “The addition of the CMS HIV screening measure will contribute to concerted efforts to better identify priority geographies, assist high risk groups among health center patients, and more effectively deploy interventions and resources in support of the ‘Ending the HIV Epidemic’ Initiative.”

According to the Centers for Medicare and Medicaid Services’s eCQI Resource Center, “This measure evaluates the proportion of patients aged 15 to 65 at the start of the measurement period who have documentation of having received an HIV test at least once on or after their 15th birthday and before their 66th birthday.”³ Fenway Health supports universal screening for HIV. Because health centers serve a broad and diverse swath of the U.S. population, it is especially important that all health center patients in this age group be screened for HIV.

Adding Prescription for Pre-Exposure Prophylaxis (PrEP) International Classification of Diseases (ICD) 10 Codes and Current Procedural Terminology (CPT) codes

The Information Collection Request states that, “The addition of the PrEP ICD-10 and CPT codes will allow for the collection of this HIV prescription prevention data in health centers and further supports the ‘Ending the HIV Epidemic’ Initiative.” The Fenway Institute at Fenway Health was involved in the first PrEP study to demonstrate efficacy—the iPrEx Study—and has been involved with a number of PrEP clinical trials since iPrEx, including studies of injectable PrEP and other modalities. We also conduct studies of microbicides and antibody infusion for HIV prevention. As noted above, we have prescribed PrEP to thousands of patients at risk of HIV infection. We think that PrEP is an important prevention approach that will help our country achieve the goals of the Ending the HIV Epidemic Initiative and keep thousands of vulnerable individuals HIV-negative. We strongly support this move, which will enable more efficient prescribing of PrEP for HIV prevention.

The ICD-10 diagnostic codes that are currently proposed can also be used for non-PrEP clinical assessments. Therefore, this may result in an over count of patients prescribed PrEP. We propose that instead UDS use a measure that would include patients who are HIV uninfected and have an ART prescription greater than 30 days. The greater than 30 days criteria would eliminate patients who were prescribe ART for nPEP (non-occupational Post-Exposure Prophylaxis), which is typically a 30-day prescription. Given this, initially this measure may be better suited for the “Other Data Elements Section” rather than Table 6A.

The current description of the measure is also confusing in that it describes reporting data on those prescribed PrEP as well as those who may be PrEP candidates:

“Table 6A will be modified to capture data on patients prescribed tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) (brand name Truvada®) during the reporting year for PrEP. The following ICD codes are recommended to help identify patients at risk for HIV and potentially candidates for PrEP”.

³ CMS eCQI Resource Center. HIV Screening. <https://ecqi.healthit.gov/ecqm/ep/2020/cms349v2>

We recommend that the measure should report those who were prescribed PrEP—either new or ongoing—during the reporting period. Identifying patients who might be good candidates for PrEP requires more data variables beyond ICD-10 codes.

Adding CMS125v8 Breast Cancer Screening

Breast cancer is a major concern for lesbian and bisexual women. Transgender men are also at risk for breast cancer, even if they have had breast removal through top surgery. Because lesbian and bisexual women have higher rates of certain risk factors for breast cancer, such as nulliparity, they may be at elevated risk for breast cancer. Behavioral Risk Factor Surveillance System data⁴ and health center data⁵ indicate that lesbians and bisexual women and transgender people are less likely to access breast cancer screening. There are also striking racial and ethnic disparities in breast cancer screening. Adding the CMS measure will help achieve higher screening rates, better treatment outcomes, and could help reduce disparities affecting sexual and gender minority patients and Black and Latina/o/x patients. While the current CMS measure is critical to include, the measure is not inclusive of all genders who may have breasts, such as transgender masculine people. In order for the breast screening measure to be effective, the inclusion criteria must be expanded to include all patients who currently have or have had breasts.

Thank you for the opportunity to comment on this Information Collection Request. Should you have any questions, please contact Sean Cahill, PhD, Director of Health Policy Research, at scahill@fenwayhealth.org or 617-927-6016.

Sincerely,

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⁴ Cochran SD, Mays VM, Bowen D, et al. Cancer related risk indicators and preventive screening behaviors among lesbians and bisexual women. *Am J Public Health*. Apr 2001;91(4):591-597.

⁵ Bazzi A, Whorms D, King D, Potter J. Adherence to mammography screening guidelines among transgender persons and sexual minority women. *Am J Public Health* Nov 2015;105(11):2356-8.

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