March 18, 2020

Don Rucker, M.D., National Coordinator for Health IT
Steven Posnack, M.S., M.H.S., Deputy National Coordinator for Health IT
Office of the National Coordinator for Health Information Technology
Office of the Secretary, United States Department of Health and Human Services

Re: Request for Public Comment, 2020-2025 Federal Health IT Strategic Plan

Submitted electronically to https://www.healthit.gov/topic/2020-2025-federal-health-it-strategic-plan

Dear Dr. Rucker and Mr. Posnack,

The Fenway Institute at Fenway Health submits the following comment regarding ONC's draft 2020-2025 Federal Health IT Strategic Plan. 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 (LGBTQIA+). About 2,300 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 share ONC's vision about the promise of leveraging health IT to build a nationwide, interoperable, value-based, person-centered health system. The Fenway Institute has engaged with ONC since 2012 on issues related to the adoption and implementation of national sexual orientation and gender identity (SOGI) health IT standards. We appreciate your responsiveness to our priorities. In 2015, ONC adopted SOGI standards as required fields in the "demographics" section of the 2015 Edition Base Electronic Health Record (EHR) Definition certification criteria, making SOGI part of all Certified Electronic Health Record Technology (CEHRT) products. Further, in addition to being required fields for EHR certification, SOGI have also been included in the Interoperability Standards Advisory since it was first published in 2015. SOGI standards have achieved steadily increasing and high levels of maturity and adoption since 2015, as reflected in the 2020 reference edition of ONC's Interoperability Standards Advisory. We welcome the opportunity to comment on ONC's draft Federal Health IT Strategic Plan for 2020-2025.

We agree, as the draft Strategic Plan states in Objective 1c (page 14), that capturing and integrating social determinants of health data into EHRs assists in decision support, integration of medical and social care, and addressing health disparities. In addition to collecting and tracking demographic data such as the patient's sex, age, race, ethnicity, socioeconomic status, nativity (foreign or native born), geography, and language(s) spoken and understood, knowing a patient's sexual orientation and gender identity (SOGI) and their family structure (e.g. whether they have a cohabiting same-sex spouse or partner) are important pieces of information for health care providers and public health researchers to know.

Knowing a patient's current gender identity and sex assigned at birth, as well as their anatomical inventory, is important for informing clinical decision support. There are striking disparities in accessing preventive services that correlate with sexual orientation and gender identity, as well as race/ethnicity and other factors. For example, lesbian and bisexual women are less likely to access cervical cancer screening and mammograms. This is also true of Black and Latina women. Lesbian and bisexual women may also be at elevated risk of breast and ovarian cancer related to nulliparity.

Objective 2a speaks to "establish[ing] identity solutions that improve patient matching across data systems." Collecting SOGI data on patients could assist with patient matching. This objective also speaks to "customiz[ing] care through precision medicine to assist in the diagnosis of disease and targeting of treatment to individual patients through the use of data in real-time." Collecting SOGI data, and conducting an anatomical inventory on patients, especially transgender patients, allows providers to better know the life experiences of patients, and could also inform decision support and preventive screenings. Furthermore, the name the patient uses and the sex listed on documentation (i.e., insurance, driver's license) may differ, therefore causing issues in patient matching. It is imperative that patient matching algorithms consider these differences.

Objective 2c calls for "harmoniz[ing] provider data collection and reporting requirements across federal agencies." We agree with ONC and the Centers for Medicare and Medicaid Services, which wrote in the Stage 3 Meaningful Use final rule in 2015:

> CMS and ONC believe including SO/GI in the "demographics" criterion represents a crucial step forward to improving care for LGBT communities.[1]

We also agree with Healthy People 2020, CMS's Equity Plan for Medicare Beneficiaries, and other federal policy initiatives that have promoted SOGI data collection in health care settings and their use in Electronic Health Records. We also note that we have assisted the Bureau of Primary Health Care (BPHC) as well as many Federally Qualified Health Centers (FQHCs) with implementing SOGI data collection as required elements in their annual Uniform Data System (UDS) reports. We encourage ONC to take concrete steps in the 5-year strategic plan to standardize SOGI data collection and reporting requirements across federal agencies. For example, we believe that SOGI should be included in the next release of FHIR standards.

We agree, as ONC states in objective 3a, that "harmonization of data elements and standards by creating a common vocabulary set" will benefit quality of care and public health research on health disparities affecting sexual and gender minority (SGM) populations. It can also "enable population health planning, analysis of quality and patient outcomes across care settings and programs, and clinical research." It is especially important that SOGI data collection and use be standardized and, at a minimum, encouraged, and even better, incentivized or required, so that

[1] Federal Register Volume 80, Number 200 (Friday, October 16, 2015). Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017. A Rule by the Centers for Medicare and Medicaid Services on 10/16/2015. https://www.federalregister.gov/documents/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications.

we can increase our understanding of SGM health disparities with high quality clinical data. It is also important to cross tabulate SOGI data with other demographic data to understand the intersection of SGM disparities with those affecting members of racial and ethnic minority groups, people with disabilities, immigrants and non-English speakers, people living in rural areas, and any other disparity populations.

Objective 3b "support[s]research and analysis using health IT and data at the individual and population levels." Collecting and using SOGI data to better understand patient and population health can inform more effective, quality care and help us develop strategies to reduce and eliminate health disparities affecting SGM populations. Health Information Technology, in particular EHRs, will need to need to have expanded value sets for sexual orientation, gender identity, administrative sex, sex assigned at birth.

Objective 4a calls for adoption and advancement of "nationally endorsed standards, implementation specifications, and certification criteria through continued collaboration across public and private sectors." Last June, in our comment on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01), we urged ONC to include existing, national SOGI standards from the "demographics" section of the 2015 Base EHR Definition in the "Patient Demographics" section of the United States Core Data for Interoperability (USCDI). We stated that this would provide both regulatory and technical continuity between existing health IT certification requirements and USCDI, thus advancing the overall goal of nationwide interoperability and the goal of modestly expanding the Common Clinical Data Set for USCDI in the service of fostering nationwide interoperability. SOGI standards have achieved much higher levels of maturity and adoption since their inclusion in the demographics section of the 2015 Base EHR Definition, and are thus ideal candidates for USCDI.

Objective 4d of the draft ONC strategic plan calls for the promotion of "secure health information that protects patient privacy." This is important for SGM patients, especially those who are particularly vulnerable: children, adolescents, older adults, and people with disabilities. As the health IT ecosystem develops and becomes increasingly interoperable, it is important to give patients control over how their electronic health information is exchanged, especially for sensitive health data. This will help to build a patient-centered healthcare system. ONC supports the use of consent management mechanisms and guidelines to obtain consent from patients before the disclosure of several discrete categories of sensitive health information. For example, ONC collaborated with the Substance Abuse and Mental Health Services Administration (SAMHSA) to create Consent2Share (C2S), on open source application for data segmentation and consent management, to address specific privacy protections for patients. SAMHSA created a Fast Healthcare Interoperability Resources (FHIR) implementation guide, called the "Consent Implementation Guide." The 2019 proposed interoperability rule described how C2S can be used to "capture a record of a health care consumer's privacy preferences." The rule proposed to adopt the Consent Implementation Guide, and also outlined specific use cases for C2S, including consent management for disclosure of "alcohol, tobacco and substance use disorders, behavioral health, HIV/AIDS, and sexuality and reproductive health." We recommended last year to ONC that SOGI should fall under "sexuality and reproductive health," and that ONC continue to support the development of tools such as C2S and other data segmentation and consent

management technologies in the future that give patients the ability to control the exchange of their health data. If patients are educated about their ability to consent or refuse to consent to the exchange of their electronic health information, the development of these tools will give patients greater control over their health and healthcare decisions. We believe that it is useful for health care providers to collect, track and use a patient's SOGI, name and pronouns used. Patients should be able to consent, or not, before this information is shared.

We have a few other suggestions for inclusion in the ONC 2020-2025 strategic plan. Electronic Clinical Quality Measures should be based on anatomy, not sex. Mechanisms to collect and document anatomical inventory should be mandated in all EHR systems. An anatomical inventory allows documentation of sex organs into a patient's electronic health record and does not make assumptions based on an individual's sex or gender. Rather, it eliminates assumptions and provides a structured format to document organs that are present or absent. The anatomical inventory should include the following organs: Breasts/Chest, Uterus, Ovaries, Cervix, Vagina, Penis, Urethra, Testes, and Prostate. Ideally, each of these conditions or surgeries will be associated with an International Statistical Classification of Diseases and Related Health Problems (ICD) code. Since ICD is a standardized system, this enables a comprehensive, systematized, and widely understood documentation method. Using standardized value sets as part of this process contributes to standardization and high-quality clinical practice.

Ideally, these data are captured in discreet data fields that are stored in problem lists and surgical histories. The benefit of data stored in problem lists is that these data can be used in clinical decision support tools and for billing or coding purposes. Using these data in billing claims can justify why a procedure was or was not done for a patient. Using these data in clinical decision support allows more accurate recommendations of procedures a patient is due for. All individuals with a cervix should be screened for cervical cancer. This includes cisgender women as well as most transgender men and gender nonbinary individuals who were female assigned at birth. There are frequent billing and claims issues with transgender and gender diverse patients, whose gender identity does not match their "insurance sex." By promoting national standards and guidelines for collecting and using data regarding gender identity, sex, and anatomical inventory, ONC could play a key role in helping to resolve these issues for providers serving transgender and gender diverse patients. Also, given the rapidly changing terminology in the field of SGM health, we encourage ONC to allow for future expansion of response options regarding sexual orientation and gender identity.

An increasing number of states are changing policies allowing residents to mark a gender other than male or female on birth certificates and other legal documentation, such as driver licenses. While some of the legal protections have reduced barriers to care, the process of filing and obtaining reimbursement for services continues to be significant impediment for transgender people. The Centers for Medicare and Medicaid Services (CMS) Health Insurance Claim form (CMS-1500) is the health insurance claim form used to bill Medicare and Medicaid for reimbursement. While the form is created and used by CMS, CMS-1500 has been adopted as the industry standard form used by all insurance carriers. The form is used by clinicians and healthcare organizations to submit claims for reimbursement of services; therefore, completing CMS-1500 thoroughly and correctly is essential for getting reimbursed. CMS-1500 is a comprehensive form which includes several required fields (i.e., patient's name on the insurance

card, sex, ICD-10, CPT codes, etc.) which have limited number of response categories for certain fields, such as the sex field that only has two options: male or female. In several states and cities, legal documentation now allows for sex options other than male or female, rendering the claim form and EHR systems incompatible with legal documentation categories. This invalidates an individual's sex and creates obstacles for reimbursement and care. A claim form inclusive of an additional sex category would provide alignment with an individual's sex as well as state and city policies. EHR value sets will need to be expanded to allow for additional sex categories.

Thank you for the opportunity to comment on ONC's 2020-2025 Federal Health IT Strategic Plan. 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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