June 3, 2019

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

RE: 21ST Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01)

We write on behalf of the Fenway Institute at Fenway Health and the 46 other undersigned health care providers and advocacy organizations across the U.S. focused on lesbian, gay, bisexual and transgender (LGBT) health issues and HIV prevention and care.

We have long shared ONC and HHS's vision about the promise of leveraging health IT to build a nationwide, interoperable, value-based, person-centered health system. Since 2012, we have worked with and advised ONC, the Centers for Medicare & Medicaid Services (CMS), HRSA, and HHS generally on issues related to the adoption and implementation of national sexual orientation and gender identity (SOGI) health IT standards. 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.[1] 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.[2] SOGI standards have achieved steadily increasing and high levels of maturity and adoption since 2015, as reflected in the 2019 edition of ONC's *Interoperability Standards Advisory*.[3]

To support nationwide interoperability, we agree with the need for a set of criteria which establishes a minimum baseline of data classes required to be exchangeable between certified health IT products. The proposed rule suggests the adoption of the United States Core Data for Interoperability (USCDI) as this standard. There is consensus that national SOGI interoperability

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[1] Office of the National Coordinator for Health Information Technology. (2015). 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. Final Rule. Available online at:
https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base
[2] Office of the National Coordinator for Health Information Technology. (2015). *2015 Interoperability Standards Advisory*. Page 7. Available online at:
https://www.healthit.gov/sites/default/files/2015interoperabilitystandardsadvisory01232015final_for_public_comment.pdf
[3] Office of the National Coordinator for Health Information Technology. (2019). *2019 Interoperability Standards Advisory*. Pages 20-22. Available online at: https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAReferenceEdition.pdf.

health IT standards are desirable.[4] In our 2015 comment to ONC signed by 105 organizations, we requested that SOGI be included in the Common Clinical data Set (CCDS) in order to "facilitate its exchange among providers during transitions of care and referrals, as well as its availability to patients and authorized representatives via view/download/transmit."[5] However, currently, USCDI does not include SOGI. We thus urge ONC to include existing, national SOGI standards from the "demographics" section of the 2015 Base EHR Definition in the "Patient Demographics" section of USCDI. Doing so 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 CCDS for USCDI in the service of fostering nationwide interoperability.[6] 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.

During the Stage 3 Meaningful Use (MU) rule-making process in 2015, CMS noted the importance of including SOGI standards in certified health IT. In the final rule, CMS stated:

> ONC is requiring that Health IT modules enable a user to record, change, and access SO/GI to be certified to the 2015 Edition "demographics" certification criterion. By doing so, SO/GI is now included in the 2015 Edition Base EHR definition, which is a part of the definition of CEHRT…CMS and ONC believe including SO/GI in the "demographics" criterion represents a crucial step forward to improving care for LGBT communities.[7]

Given the existence of mature, widely adopted, national SOGI standards and previous regulatory health IT guidance including SOGI data as demographic fields, USCDI should include SOGI in its "Patient Demographics" section. In addition to being of clinical value for patients, providers, and other users of health IT, the availability of structured SOGI demographic data will ease

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[4] Institute of Medicine. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, DC: National Academies Press, 2011, 9; Institute of Medicine (U.S.), Joe Alper, Monica N. Feit, and Jon Q. Sanders. *Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records: Workshop Summary*. Washington, D.C: The National Academies Press, 2013.

[5] The Fenway Institute and Center for American Progress. (2015). "Public Comment on 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications published March 30, 2015." Submitted to ONC. Avaialble online at: http://fenwayfocus.org/wp-content/uploads/2015/06/ONC-Health-IT-Certification-Criteria-rule-Fenway-CAP-public-comment-FINAL-052915.pdf?__hstc=185075638.95700bb649c0d9e3416b37ba4dfd1211.1540240778791.1556839763233.15586363 62962.7&__hssc=185075638.1.1558636362962&__hsfp=847861957

[6] Office of the National Coordinator for Health Information Technology. (2015). 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. Final Rule. Available online at: https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base

[7] 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.

processes of patient-matching and identity-proofing during transfers of care or instances of health information exchange.

In addition to the reasons described above for including SOGI in USCDI, increasing SOGI data collection has been a priority of the health care sector and the LGBT community[8] for many years. This is why the Institute of Medicine (IOM),[9] the Joint Commission,[10] and CMS[11] recommend asking questions about SOGI in clinical settings and including these data in EHR systems to improve quality of care. It is also why the Bureau of Primary Health Care at HRSA requires community health centers to report the SOGI of their 20 million adult patients.[12]

As with many other classes of health data that could be considered "sensitive," there may be concerns that inclusion of SOGI in the USCDI will mandate that SOGI data be exchanged during transfers of care, and that if providers decline to exchange this data, they may face accusations of information blocking. In a fact sheet produced by ONC titled, "Seven Exceptions to the Information Blocking Provision,"[13] ONC explains seven categories of reasonable and necessary activities that do not constitute information blocking under the proposed rule. One such category includes actions that promote the privacy of electronic health information (EHI). ONC states that "an actor may engage in practices that protect the privacy of EHI" and that such action would be an exception to the information blocking provision of the proposed rule. ONC also elaborates on four specific privacy-protective practices that are recognized under this proposed exception to the information blocking provision. One recognized privacy-protective practice is "respecting an individual's request not to share information."[14] We believe that this exception should apply to situations where providers choose not to share a patient's SOGI data to protect the patient's privacy, especially in circumstances where the patient requests that the information not be shared. We recommend that providers' declining to exchange SOGI data, along with other classes of sensitive health data, not be considered information blocking under the promoting privacy of EHI exception, if this is not already the case.

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[8] Fenway Institute, the Center for American Progress, and 103 other health care, research, professional, and patient advocacy organizations Public Comment on Stage 3 Meaningful Use proposed rule CMS-3310-P, published March 30, 2015 http://fenwayfocus.org/wp-content/uploads/2015/06/CMS-Stage-3-final-rule-Fenway-CAP-public-comment-FINAL-052915.pdf?__hstc=185075638.6686f8fd6b32eae6ae1236aae7cbc54b.1524150030434.1554840164748.1554912352313.53&__hssc=185075638.1.1554912352313&__hsfp=420343025

[9] Institute of Medicine. Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities; Board on the Health of Select Populations; Institute of Medicine. *The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People: Building a Foundation for Better Understanding*, Washington, DC: National Academies Press, 2011. http://www.nap.edu/catalog.php?record_id=13128. Accessed November 24, 2015.

[10] The Joint Commission. *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals.* Oakbrook Terrace, IL: The Joint Commission, 2010, page 11.

[11] Centers for Medicare and Medicaid Services (2015). *Equity Plan for Medicare Beneficiaries.* https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf

[12] Cahill S (2018). Legal and policy issues for LGBT patients with cancer or at elevated risk of cancer. *Seminars in Oncology Nursing*. 34(1):90-98.

[13] ONC. Seven Exceptions to the Information Blocking Provision. Available online at: https://www.healthit.gov/sites/default/files/nprm/ONCCuresNPRMInfoBlocking.pdf

[14] ONC. Information Blocking Exception for Privacy-Protective Practices. Available online at: https://www.healthit.gov/sites/default/files/nprm/InfoBlockingExceptionPrivacy.pdf

We do believe that as the health IT ecosystem develops and becomes increasingly interoperable, it will be important to prioritize giving 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 proposes 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 proposed rule describes how C2S can be used to "capture a record of a health care consumer's privacy preferences." The rule proposes to adopt the Consent Implementation Guide, and also outlines 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 recommend 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. The development of these tools will give patients greater control over their health and healthcare decisions. ONC should also take steps to ensure that patients are educated about their ability to consent or refuse to consent to the exchange of their electronic health information.

The Fenway Institute works to make life healthier for those who are LGBT, people living with HIV, and the larger community. We do this through research and evaluation, education and training, and policy analysis. We are the research division of Fenway Health, a federally qualified health center (FQHC) and Ryan White Part C grantee through the Health Services and Resources Administration (HRSA) in Boston, MA that serves 32,000 patients each year

Thank you for the opportunity to provide comment. If you have any questions please feel free to reach out to Sean Cahill, PhD at scahill@fenwayhealth.org or Tim Wang, MPH at twang@fenwayhealth.org.

Sincerely,

The Fenway Institute
African American Health Alliance
AIDS Action Baltimore
AIDS Alabama
AIDS Foundation of Chicago
AIDS United
American Atheists
Boston Public Health Commission
Cascade AIDS Project & Prism Health
Callen-Lorde Community Health Center
Center for Transgender Medicine & Surgery
CenterLink: The Community of LGBT Centers

Equality California
Equality North Carolina
FORGE, Inc.
Gender Spectrum
GLBTQ Legal Advocates & Defenders
HIV Dental Alliance
Howard Brown Health Center
Human Rights Campaign
John Snow, Inc.
Keshet
Latino Commission on AIDS
Los Angeles LGBT Center
Massachusetts General Hospital Transgender Health Program
Mazzoni Center
Modern Military Association of America
Mount Sinai Hospital
Nashville CARES
National Coalition of STD Directors
National Center for Transgender Equality
National LGBT Cancer Network
National LGBTQ Task Force
National Partnership for Women & Families
National Transgender Bar Association
New England Association for HIV over Fifty
Positive Women's Network - USA
Silver State Equality
The AIDS Institute
The LGBT Bar Association of New York
The Trevor Project
The Williams Institute
Treatment Action Group
Two-Spirit Journal
University of Minnesota HIV/STI Intervention & Prevention Studies
Vanderbilt University School of Medicine
Whitman-Walker Health