Overview of ONC Notice of Proposed Rulemaking on the 21st Century Cures Act: **Interoperability, Information Blocking, and the ONC Health IT Certification Program**		
What is it?		On March 4, 2019, the Office of the National Coordinator for Health IT issued a 724-page Notice of Proposed Rulemaking on improving interoperability, prohibiting information blocking and revising the Health IT Certification Program. The comment period for this rule ends on May 3, 2019.
What are the highlights?		**New Acronym Alert: EHI** - Electronic Health Information - Defined as electronic protected health information that identifies the individual and is transmitted by or maintained in electronic media, that relates to the past, present, or future health or condition of an individual. - ONC proposed rules apply explicitly to health information in electronic form. **Regulated actors** are defined as: - Health Care Provider - Health IT Developer - Health Information Exchange - Health Information Network **One certification to rule them all:** Vendors take note! If you have one certified product, you have to comply with rules for ALL of your software products (i.e., can't have one narrow solution that is certified and claim all the other pieces aren't part of the certified solution). **Information Blocking is bad:** The proposed rule spends hundreds of pages covering the ways a failure to share EHI might NOT be considered information blocking by highlighting seven categories of exceptions: **Preventing harm:** Actor has a reasonable belief that the practice of not sharing EHI will directly and substantially reduce the likelihood of harm to a patient (e.g., mental health). **Promoting the privacy of electronic health information:** Actor may engage in practices that protect the privacy of EHI, based on sub-exceptions focused on scenarios that recognize existing privacy laws and privacy-protective practices (What CT laws could be impacted by this exception?) **Promoting the security of electronic health information:** The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI. A general prohibition is not acceptable. **Recovering costs reasonably incurred:** Actor may recover costs that reasonably incurred, in providing access, exchange, or use of EHI (cannot be arbitrary or discriminatory). **Responding to requests that are infeasible:** Actor may decline to provide access, exchange, or use of EHI if it imposes a substantial burden that is unreasonable (difficult to claim if using certified tech). **Licensing of interoperability elements on reasonable and non-discriminatory terms:** Technology licenses that are necessary to enable EHI access must be offered on reasonable and non-discriminatory terms.

Consent Policy Design Group

| | | **Maintaining and improving health IT performance:** Health IT can be made temporarily unavailable in order to perform maintenance or improvements to the health IT, but for no longer than necessary to achieve the maintenance or improvements. **Consent Management** The 2015 Certification Edition contained two "data segmentation for privacy" (DS4P) criteria, but were never required for certification or used in any HHS programs. Since that time, more work has been done on simplifying consent protocols and making them easier to implement in an API-driven environment. Consent2Share (C2S) is an open source application for data segmentation and consent management. C2S enables data segmentation and consent management for disclosure of several discrete categories of sensitive health data related to conditions and treatments including: alcohol, tobacco and substance use disorders (including opioid use disorder), behavioral health, HIV/AIDS, and sexuality and reproductive health. SAMHSA created a Consent Implementation Guide that describes how the Consent2Share application and associated access control solution uses the FHIR Consent resource to represent and persist patient consent for treatment, research, or disclosure. Note that the specification requires the use of FHIR Release 3, which is still a trial standard and not a balloted standard (all other certification requirements reference FHIR Release 2, a balloted standard). ONC is proposing to use this specification as a certification requirement. |
| **Where can I read more?** | | NPRM in the Federal Register: https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf

HealthIT.gov Information Page (including details on how to comment): https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health |