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The Office of the National Coordinator for Health Information Technology (ONC)

Information technology (IT), or the use of devices like computers for the handling of electronic data, has existed for decades, but has only recently become accessible to many Americans in a health care context. The federal government has tasked the Office of the National Coordinator for Health Information Technology (ONC) with developing a framework for and implementing widespread adoption of information technology in health care to create an interoperable, equitable, and accessible system for all Americans. ONC's mission is to systemically improve the American people's health "through the access, exchange, and use of data." ONC is a staff division within the Office of the Secretary for the Department of Health and Human Services (HHS).

Organization and Programs

All of ONC's organizational efforts are unified by two objectives. First, ONC endeavors to "[a]dvanc[e] the development and use of health IT capabilities." Second, ONC strives to "[e]stablish ... expectations for data sharing." ONC comprises four offices: the Immediate Office of the National Coordinator (Immediate Office), the Office of the Chief Operating Officer, the Office of Policy, and the Office of Technology. The Immediate Office and the Office of the Chief Operating Officer lead agency-wide support through leadership, management, and advisory activities. The Office of Policy is responsible for developing policies in accordance with pertinent statutes and executive orders. The Office of Technology provides coordination, and technical and program support.

Focus Areas

ONC offices broadly conduct activities related to health IT standards, certification, and exchange. Across these ONC efforts, there are multiple ongoing key activities:

Interoperability. Advancing interoperability is at the core of many of ONC's activities. According to the Healthcare Information and Management Systems Society, interoperability is defined as the "ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals." Interoperability in health care presents myriad potential benefits, including increasing clinical safety, promoting health equity, and speeding public health emergency responses. ONC organizes interoperability efforts nationwide.

Trusted Exchange. In January 2022, ONC published the first versions of its Trusted Exchange Framework and Common Agreement (TEFCA), documents meant to establish minimum acceptable interoperability standards. Specifically, the Common Agreement delineates infrastructure and governing approaches for basic information sharing across all health networks. In turn, the Trusted Exchange Framework enumerates aspirational principles for trust policies and practices across health information networks.

United States Core Data for Interoperability (USCDI). The USCDI is "a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange." Required data include clinical notes, allergies and intolerances, laboratory results, and medications. Adhering to the USCDI is a mandatory condition for health IT stakeholders seeking certification under the ONC Health IT Certification Program. The third version of the USCDI was released in July of 2022, with a fourth version expected in July 2023.

ONC Health IT Certification Program (Certification Program). Begun in 2010, the Certification Program is an initiative under which health IT developers may voluntarily obtain health IT certification. The Certification Program incentivizes baseline conformity across electronic health record (EHR) systems through a combination of evolving standards, implementation specifications, and certification criteria issued by the HHS Secretary. This conformity is meant to promote interoperability through access, exchange, and use of electronic health information (EHI), especially through the use of open application programming interfaces (APIs).

Information Blocking. The expectation in health care is that EHI be shared amongst authorized parties. When an actor engages in activities that interfere with, or are likely to interfere with, the access, exchange, or use of EHI, this is considered information blocking under the Final Rule promulgated under the 21st Century Cures Act (Cures Act; P.L. 114-255). Per this rule, actors, including health care providers, health information networks or health information exchanges, and health IT developers of certified health IT, are forbidden from practices constituting information blocking. ONC has, however, identified eight exceptions to the information blocking prohibition. Regulated actors who violate the information blocking rule may be subject to civil monetary penalties.

Health Information Exchange (HIE). Through its standards work, ONC promotes electronic HIE, allowing

for the secure exchange of appropriate health information between individuals, caregivers, and clinicians. HIE is vital to interoperability and can reduce medical errors and costs related to readmissions, incorrect prescriptions, misdiagnoses, and duplicative testing. There are presently three primary modes of HIE: directed, query-based, and consumer mediated.

Health Information Technology Advisory Committee (HITAC). Established by the Cures Act and subject to the Federal Advisory Committee Act, HITAC is an ONC advisory body that recommends policies, standards, implementation specifications, and certification criteria to the National Coordinator for Health Information Technology. HITAC concentrates its efforts on design and use of technologies that advance health equity and support public health, interoperability, privacy and security, and patient access to information. HITAC has contained numerous task forces and workgroups, organized as subcommittees, since its inception. HITAC builds upon, and has replaced, two committees that existed prior to the enactment of the Cures Act.

Authorities

The position of National Coordinator for Health Information Technology within the HHS Office of the Secretary was created by President George W. Bush via Executive Order 13335. The Office of the National Coordinator for Health Information Technology (originally ONCHIT) was then legislatively mandated under the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act; P.L. 111-5) to promote the creation of a national health information technology infrastructure capable of electronic data use and exchange. Much of ONC's duties and related authorities are outlined under Title XXX of the Public Health Service Act (PHSA, as amended) [42 U.S.C. §300jj et. seq.], as originally added by the HITECH Act.

ONC's duties were further augmented and amended by the Medicare Access and CHIP Reauthorization Act (MACRA; P.L. 114-10) in 2015 and the Cures Act in 2016. Under MACRA, ONC was delegated the task of promoting EHR system interoperability. Under the Cures Act, key ONC initiatives and powers were authorized, including conditions of maintenance and certification for the HIT certification program, the creation of TEFCA, the formation of HITAC, and identifying reasonable and necessary activities not constituting information blocking. Most recently, in response to the COVID-19 pandemic, ONC was charged under President Joseph R. Biden Jr.'s Executive Order 13994, published on January 21, 2021, with advising the HHS Secretary on gaps in public health information systems.

Regulations

ONC administers many regulations, sometimes in conjunction with the Centers for Medicare & Medicaid Services (CMS). Most of ONC's regulations address topics including meaningful use, interoperability, information blocking, and the Certification Program. Among the primary regulations ONC enforces are its Cures Act Final Rule (85 *Federal Register* 25642, 2020), as well as CMS's

Interoperability and Patient Access Final Rule (85 *Federal Register* 25510, 2020). Notably, under the Cures Act Final Rule, ONC implemented information blocking provisions and specified eight exceptions to information blocking. In turn, under CMS's final rule, ONC is responsible for aiding CMS in the implementation of foundational interoperability standards to better protect patient privacy and security.

Funding

From FY2009 through FY2023, ONC has been funded by the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, either via annual discretionary appropriations or directed transfers. (In FY2020 and FY2021, ONC received additional funds from the Coronavirus Aid, Relief, and Economic Security Act [CARES Act; P.L. 116-136], American Rescue Plan Act [P.L. 117-7], and Consolidated Appropriations Act [CAA], 2021 [P.L. 116-260].) Annual funding for ONC between FY2014 and FY2023 has ranged between roughly \$60 million and \$66 million per year. In FY2024, the President's budget request for ONC is \$104 million. This proposed increase is to enable ONC to build upon previous digital advancements and focus on continued progress in policy development, standards, certification, and interoperability.

Select Policy Considerations

Determination of Information Blocking Practices

What precisely constitutes information blocking is often difficult to discern; in guidance, ONC has stated it will approach events on a case-by-case basis. In its FY2023 budget materials, ONC requested HHS authorize the creation of an *advisory opinion process* capable of issuing binding opinions to requestors about whether a specific practice may violate information blocking provisions.

Balancing Access with Safety

The information blocking rule has created controversy amongst stakeholders regarding rapid patient access to potentially distressing health information without contextual and interpretive information. Some physicians argue that exceptions to the rule are too narrow, and that doctors may be required to divulge test results before being able to provide context to patients. Conversely, HHS counters that instant access to test results empowers patients.

Interoperability Shortcomings and COVID-19

COVID-19 highlighted the importance of rapid information exchange between public health entities and clinics. It also revealed current gaps in interoperability. ONC has been working with the Centers for Disease Control and Prevention (CDC) to advance public health data interoperability through the Data Modernization Initiative, among other efforts. Congress has encouraged ONC to collaborate with state-based health data utilities to better prepare for future public health threats (H.Rept. 117-96).

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