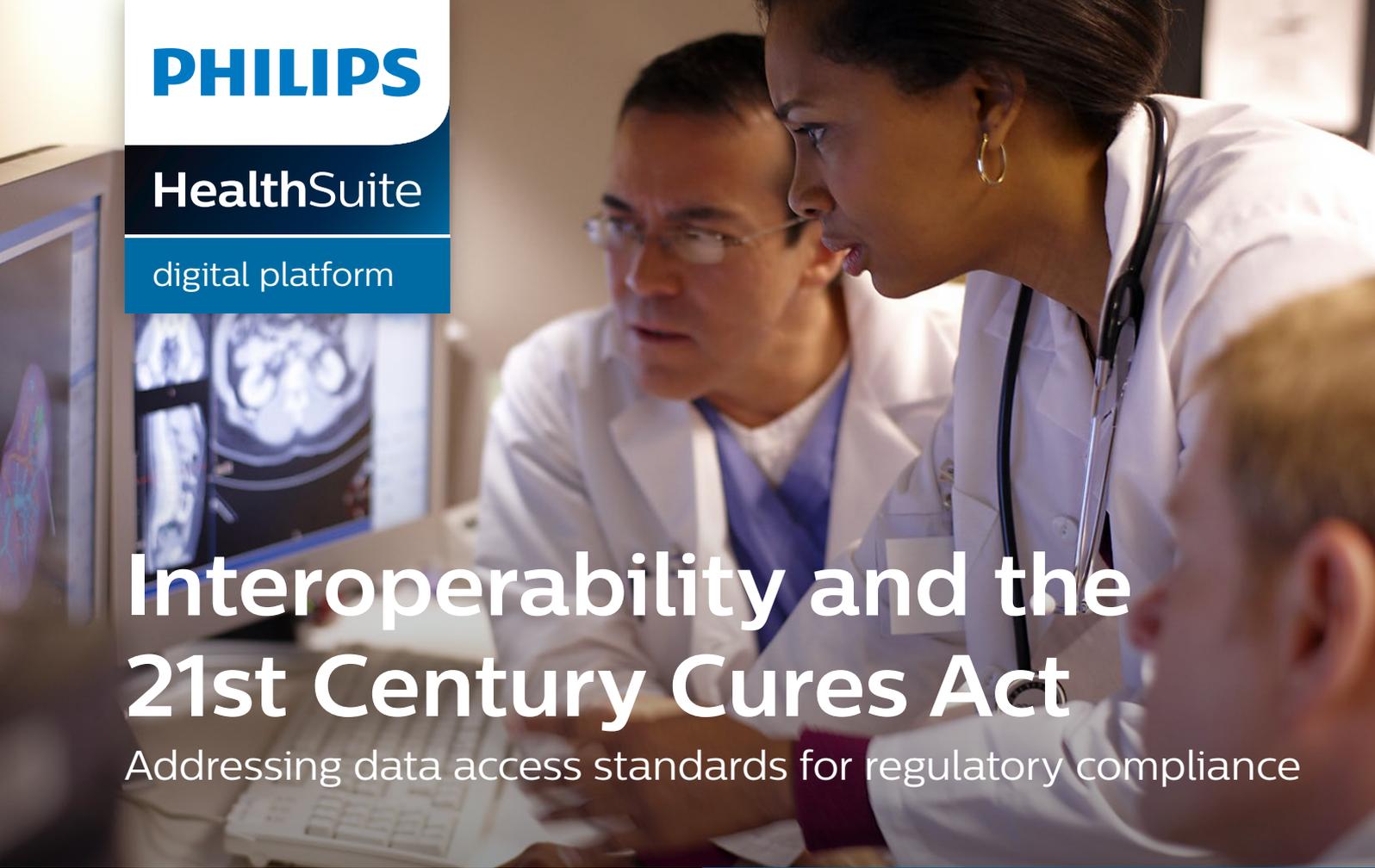




PHILIPS

HealthSuite

digital platform



Interoperability and the 21st Century Cures Act

Addressing data access standards for regulatory compliance

Today's savvy patients demand increased access to their personal health information (PHI). Health portal apps are being developed to make that a reality, providing individuals with a consolidated view of important health data. Yet achieving the transparency, accessibility, data convergence, and access control required for success, remains a challenge.

The 21st Century Cures Act of 2016 heightens this issue. According to the FDA, the act is “designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.” A critical provision of that legislation focuses on interoperability and secure data convergence, with severe consequences for information (data) blocking. These regulations are mandatory for a broad variety of healthcare providers and required adherence is imminent.

What can be done to confidently achieve interoperability?

The Philips HealthSuite digital platform (HSDP) provides a comprehensive set of tools and services designed to advance this process with the capability to connect devices, collect electronic health data, aggregate and store data securely, analyze data, and create solutions in a cloud environment. It provides outbound exchange and external access to data, as well as convergence among FHIR and HL7 formats to provide an API-driven connected care ecosystem.

Any proposed product, solution or application subject to the blocking regulation must be compliant with the terms of the 21st Century Cures Act's ONC certification program – a process which can be complicated and costly!

Incorporating accessibility

Healthcare providers must open up their data sources to health information exchanges and networks to assure improved accessibility. Proprietary communication schemes are obsolete, and disparate data sources must employ common data transfer standards (e.g. FHIR, IHE, HL7, Continua, DICOM) to drive health data exchange and comply with the data blocking regulation.

Today, healthcare systems find complying to value-based care models necessitates interoperability and data normalization to achieve their strategic and financial goals. In fact, hospital inpatient incentives are increasingly tied to interoperability capabilities. The 'companion' CMS rule, issued along with the data blocking regulation, requires payers doing business with CMS to share payer data with patients, and requires hospitals to share ADT (admit, discharge, transfer) information with a patient's provider network – a clear example of interoperability.

What does Information Blocking compliance look like?

Central to the concept of interoperability and accessibility is the definition of information (data) blocking. The Information Blocking requirements (section 4004) of the 21st Century Cures Act are exacting – defining what must be shared and what need not be shared.

Who is an information blocker? Any ‘actor’ regulated by the information blocking provision who is involved with electronic health information (EHI), and who is likely to interfere with access, exchange, or use of EHI². In addition to certified health IT vendors, the list includes entities from hospitals to pharmacists to blood draw centers and more.



Health Care Providers

Who are they?

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- rural health clinic
- ambulatory surgical center
- provider operated by, or under contact with, the Indian Health Services or by an Indian tribe, tribal organization, or urban Indian organization
- ‘covered entity’ under certain statutory provisions
- therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

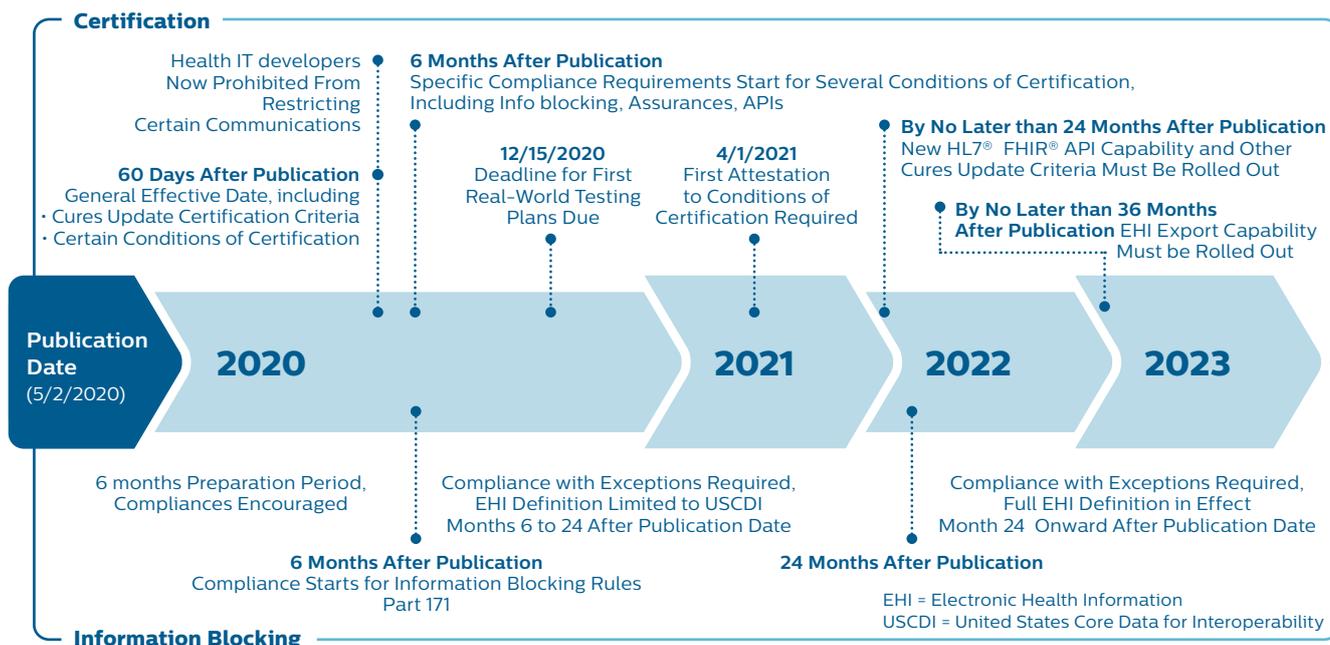
What information must be shared? The Information Blocking provision requires providers to share data in a manner consistent with the framework of the HIPAA Privacy Rule and other laws providing privacy rights for patients. Exemptions too are linked to HIPAA. Sets of data classes include:

- Assessment and plan of treatment
- Care team members
- Clinical notes
- Patient goals
- Health concerns
- Immunizations
- Laboratory data
- Medications
- Patient demographics
- Procedures
- Provenance
- Vital signs
- and more...

The average health system can have up to a dozen different EHRs to manage in addition to ancillary data sources, all of which must be translated to a readable shareable record for mobility inside and outside the organization. Solutions must have open APIs and connectors for FHIR and HL7 standards, to be successful. And vendors/providers must be ready to accommodate these provisions before the end of 2020.

Blocking final rule

Highlighted Regulatory Dates



Time is short and the penalties for blocking data access are significant. For developers of certified health IT, health information networks, and health information exchanges, civil monetary penalties (CMPs) of up to \$1 million per violation can be levied. For healthcare providers, ‘appropriate disincentives’ will be enacted.

Why choose Philips to help?

The Philips HealthSuite digital platform is the culmination of years of technological leadership. Philips has a long history of supporting interoperability, a commitment formalized in a letter to the U.S. Administration in 2016. HSDP is designed to normalize, federate and securely exchange data from multiple sources across healthcare delivery to increase patient access.

Philips' effort to define an open, vendor neutral/patient centric ecosystem has developed over the course of several years. In 2013 Philips began work on a cloud-based, vendor agnostic platform designed to share data not only between Philips applications, but with any third party or consumer of that data – even to patient consent capabilities built into the APIs. Today the HealthSuite digital platform has been recognized by Forrester as one of the preeminent enterprise health cloud solutions of 2019. Philips received the top score in the data interoperability criterion, and received the highest score possible in the AI and Machine Learning, and Security criteria.

Philips is committed to advancing interoperability and open standards through participation in organizations such as the CommonWell Health Alliance and eHealth Exchange. Philips has also joined Carequality, part of the recognized coordinating entity consortium working to define the 'rules of the road' for the federal government's upcoming Trusted Exchange Framework and Common Agreement (TEFCA) initiative – the single national network structure.

A recent, tangible example of a Philips interoperability solution at work is the creation a COVID-19 patient data portal to address the need to pass on the longitudinal patient record upon moving a patient from one hospital to another to make the best of available ICU and care staff capacities. Specific information, such as a patient's radiology images, reports, and patient summary, is shared via the portal. The information is then available to the receiving hospital, provided that the originating hospital and the patient have given their explicit consent.

HSDP – tools to address the challenges

HealthSuite digital platform offers a diverse set of capabilities for ingesting data from multiple data sources – EHRs, RIS, consumer devices, medical devices, imaging modalities, genomics, digital pathology, patient monitors, and more. That data can then be stored, shared, and analyzed in a highly secure cloud environment conducive to algorithm and predictive model development. Critically important for information blocking is HSDP's

ability for consent based access control. Identity and Access Management (IAM) provides secure centralized mechanisms to manage identities, authentication and authorization of users, services and devices. Building a patient portal that allows healthcare institutions to share data via organized consent is an important step in allowing patients to access their health records.

The FHIR API supports different access control mechanisms based on the following access types:

- Institutional access using Organization based Access Control for caregivers and other staff to access and manage health records of patients managed by the healthcare organization
- Patient Portal access using Consent based Access Control for patients accessing their data within the healthcare organization
- Personal Health Record access for patients managing their personal health data
- Personal Health Record access for Healthcare providers to access personal health data of patients using Consent based Access Control

HSDP's Clinical Data Repository (FHIR server) provides a range of storage services to match data types and the requirements of customer applications. The services acquire, store and archive data in different types of cloud-hosted repositories. The clinical data repository (CDR) aggregates data from users and clinical systems to create a longitudinal patient record. It assures multi-tenancy so data from different organizations is stored separately and securely in different instances. It uses the open FHIR standard to provide REST APIs for standardized data access and representation of clinical data. And it encrypts data at rest and in transit.

A logical choice

HealthSuite digital platform gives healthcare and life science organizations the cloud expertise and capabilities to connect devices, collect electronic health data, aggregate and store data securely, analyze data, and create solutions in the cloud. HSDP provides developers with the technical tools and services for creation of regulatory compliant cloud-based solutions supported with industry leading interoperability. Healthcare providers can circumvent the need to assign scarce IT resources by employing HSDP to achieve their goals in a rapid and cost-effective manner.

¹ https://www.healthit.gov/sites/default/files/cures/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf

² Anthony, Elise Sweeney, JD, Lipinski, Michael, JD, Knee, Mark, JD, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, The Office of the National Coordinator for Health Information Technology, accessed online June 4, 2020. <https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingFinalRuleWebinar.pdf>

About the Philips HealthSuite digital platform (HSDP)

HealthSuite digital platform gives healthcare and life science organizations the cloud expertise and capabilities to connect devices, collect electronic health data, aggregate and store data securely, analyze data, and create solutions in the cloud.

For more information visit: www.usa.philips.com/healthcare/innovation/about-health-suite

