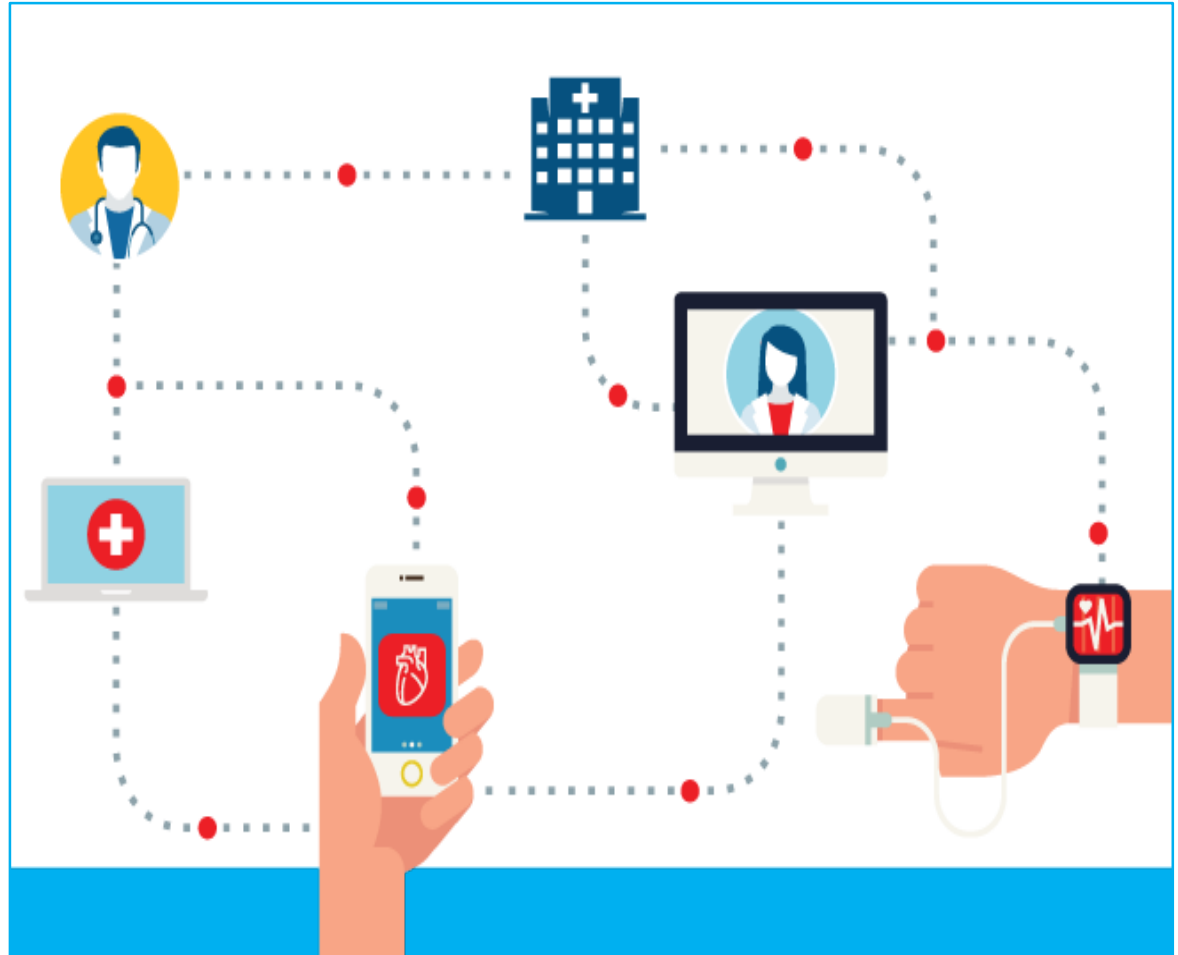


Key Considerations: HIPAA Security, Health IT, and the App Ecosystem

Linda Sanches

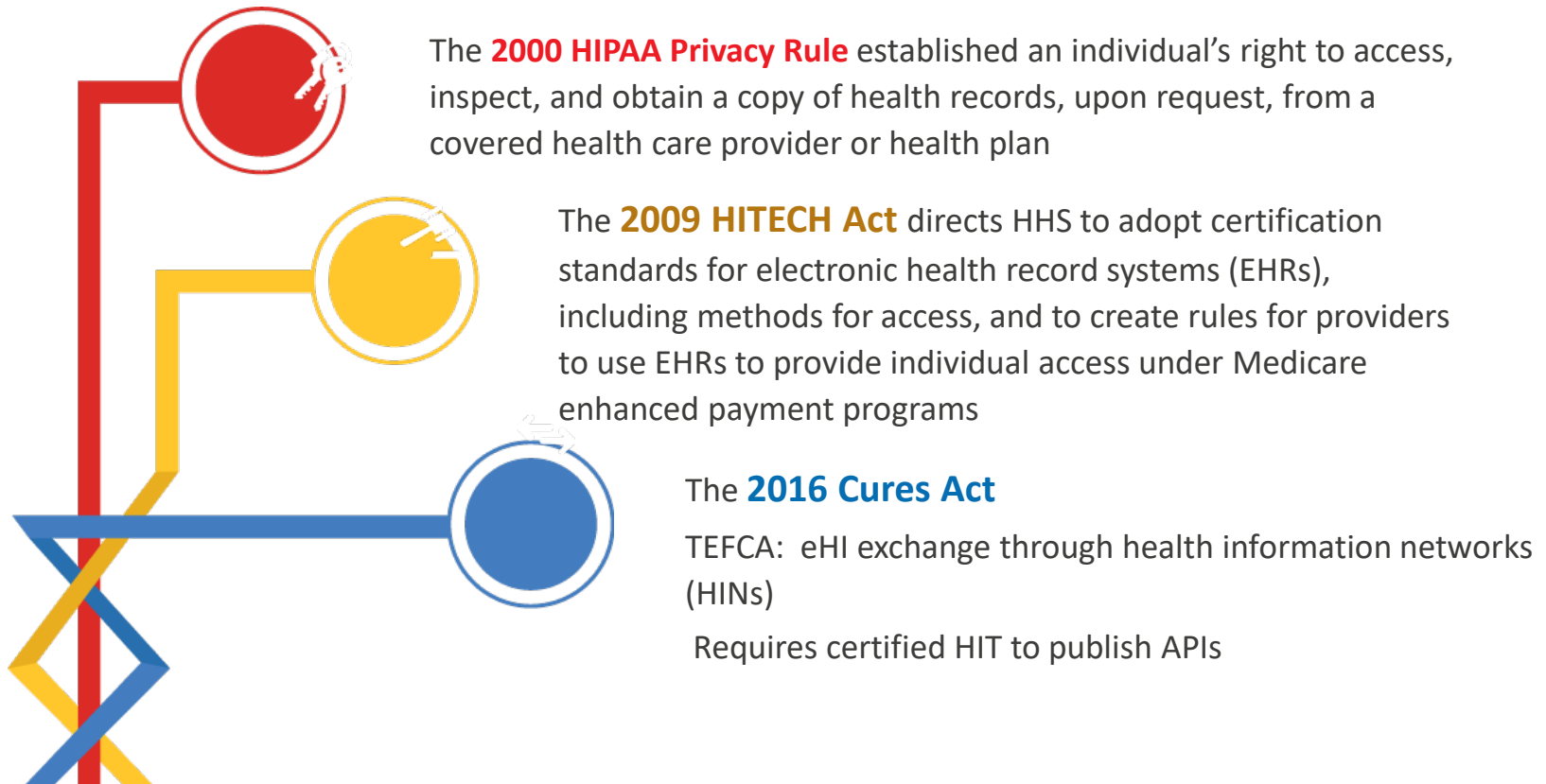
October 2019

Individual Access & Business Associates & Apps



Access, HIPAA & Electronic Health Information (eHI) Exchange

Recent laws work with existing HIPAA rights to simplify how health care providers can meet individual requests for access to electronic health information



Background: *HIPAA Access*

An individual has the right to request & receive a copy of medical, payment, and other records—Protected Health Information (PHI)—that providers and health plans use to make decisions about individuals

- Doesn't matter how old the PHI is, where it is kept, or where it originated
- Includes clinical lab test reports and underlying information



An individual has the right to receive the information electronically & in her preferred form and format if the entity has the ability to readily produce it

45 CFR 164.524

www.HHS.gov/HIPAA

HITECH Reinforced Individual Right of Access to ePHI

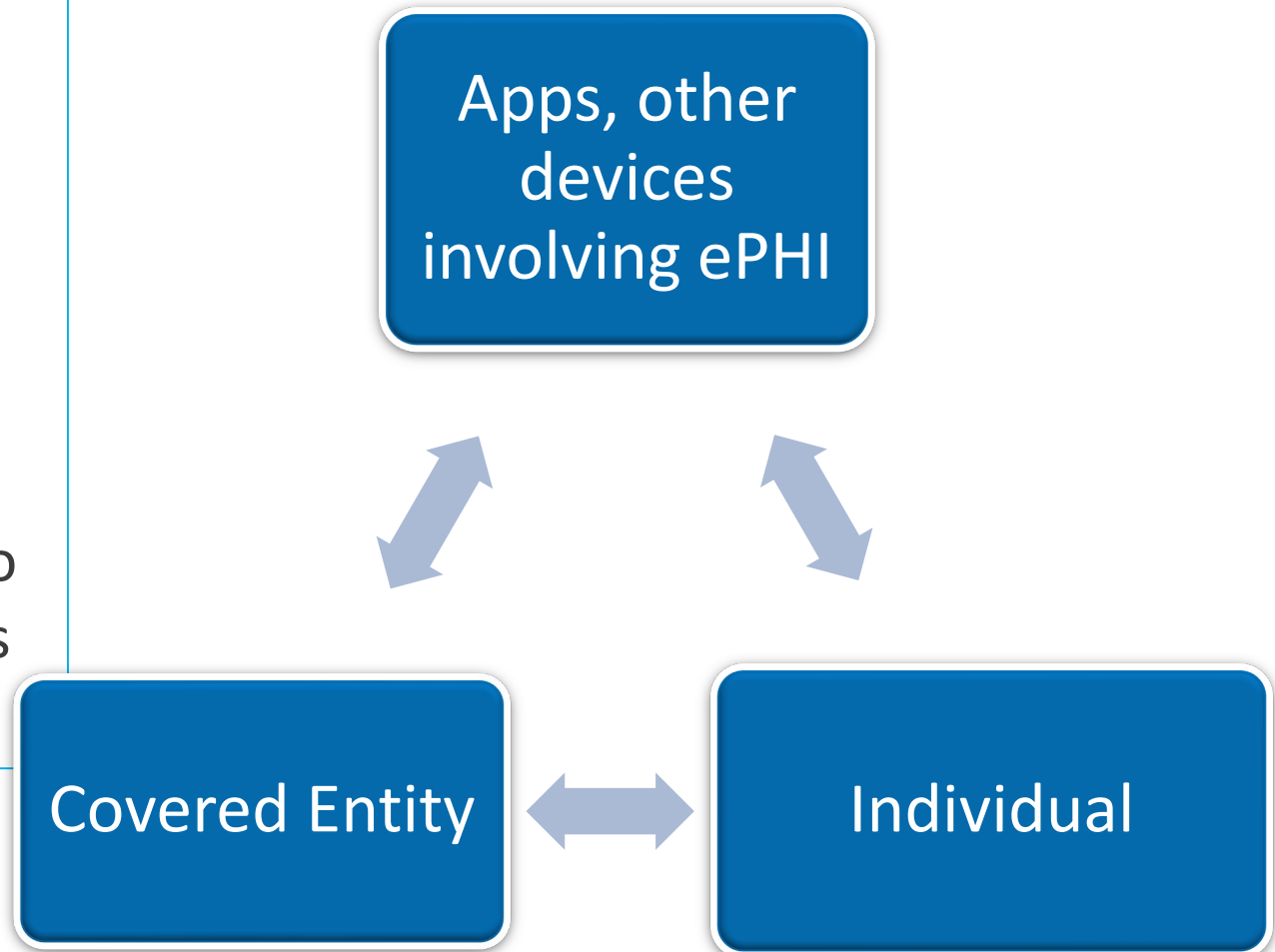
If a covered health care provider or health plan uses an EHR that holds an Individual's PHI:

- The individual has a right to obtain a copy of that PHI in an electronic format and
- To direct the provider or plan to transmit the copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific

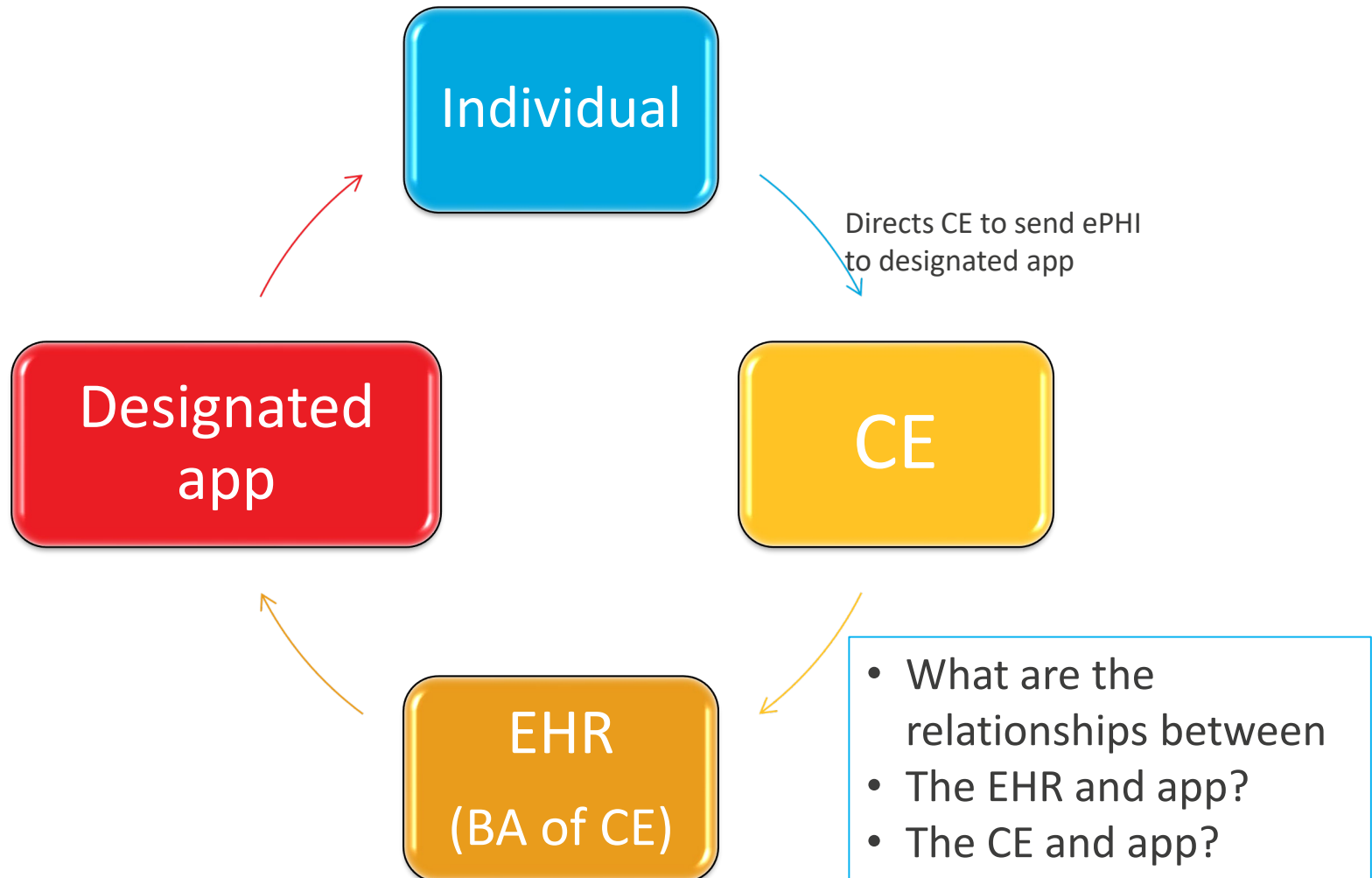
See HITECH 13405(e)

HIPAA Security Requirements & PHI Transmitted Between Entities

- What is the relationship between the CE and health IT developer?
- Does the CE contract with app/other tech to provide functions for CE?



CE, EHR and App



HIPAA Access Right, APIs & Health Apps

- 5 FAQs posted on OCR HIPAA website
April, 2019
- Supplement the *Health App Use Scenarios* document

<https://www.hhs.gov/hipaa/for-professionals/faq/health-information-technology/index.html>

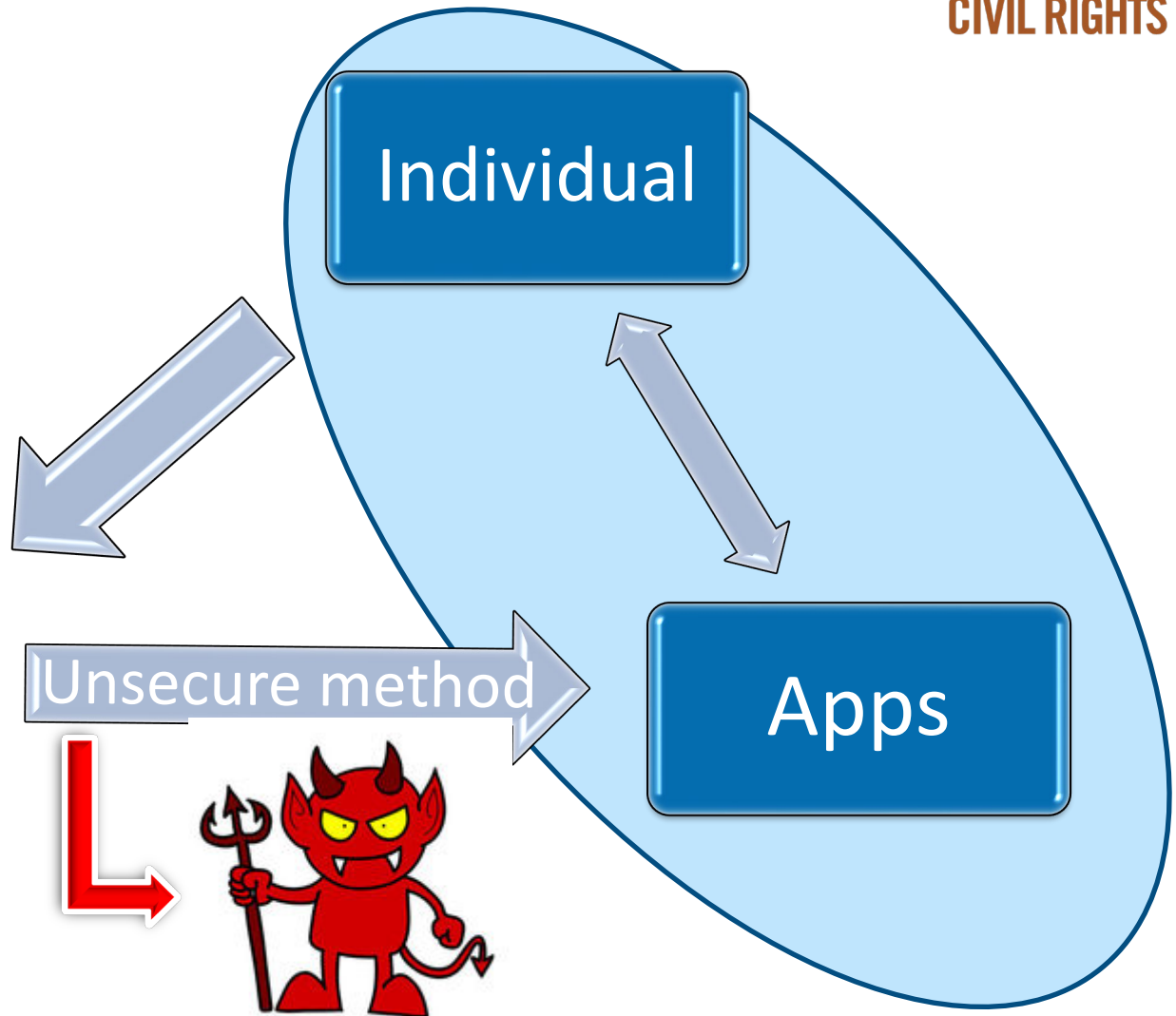
FAQ 3010 Covered Entity Liability for Insecure Transmission

- What liability does a covered entity face if it fulfills an individual's request to send their ePHI using an insecure method to an app?

FAQ 3010

- Individual directs Covered Entity to send ePHI to health app of her choice using an unsecure method.
- Is CE liable for unauthorized access while in transmission?

Provider/
Health Plan



The Upshot: Health Apps, Individual Access & Business Associates

If requested by an individual, a health care provider or health plan must transmit an individual's PHI directly to another person or entity designated by the individual—e.g., a health app



App developer acting only on behalf of the individual *is not* subject to HIPAA Rules regarding the health information it creates, maintains, receives from or transmits to a covered entity

App developer creating, receiving, maintaining or transmitting protected health information (PHI) *on behalf of a covered entity* or another business associate is itself a business associate



App developer that is a business associate *is subject* to HIPAA Rules, and must have a business associate agreement with covered entity (or business associate)

Mobile Health Apps Interactive Tool



Produced in cooperation with the U.S. Department of Health & Human Services (HHS): the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the Food and Drug Administration (FDA)



The Office of the National Coordinator for
Health Information Technology

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Health app developers, what are your questions about HIPAA?

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HIPAA Health Information Privacy, Security and Breach Notification Rules

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Health App Use Scenarios & HIPAA

Guidance on HIPAA & Cloud Computing

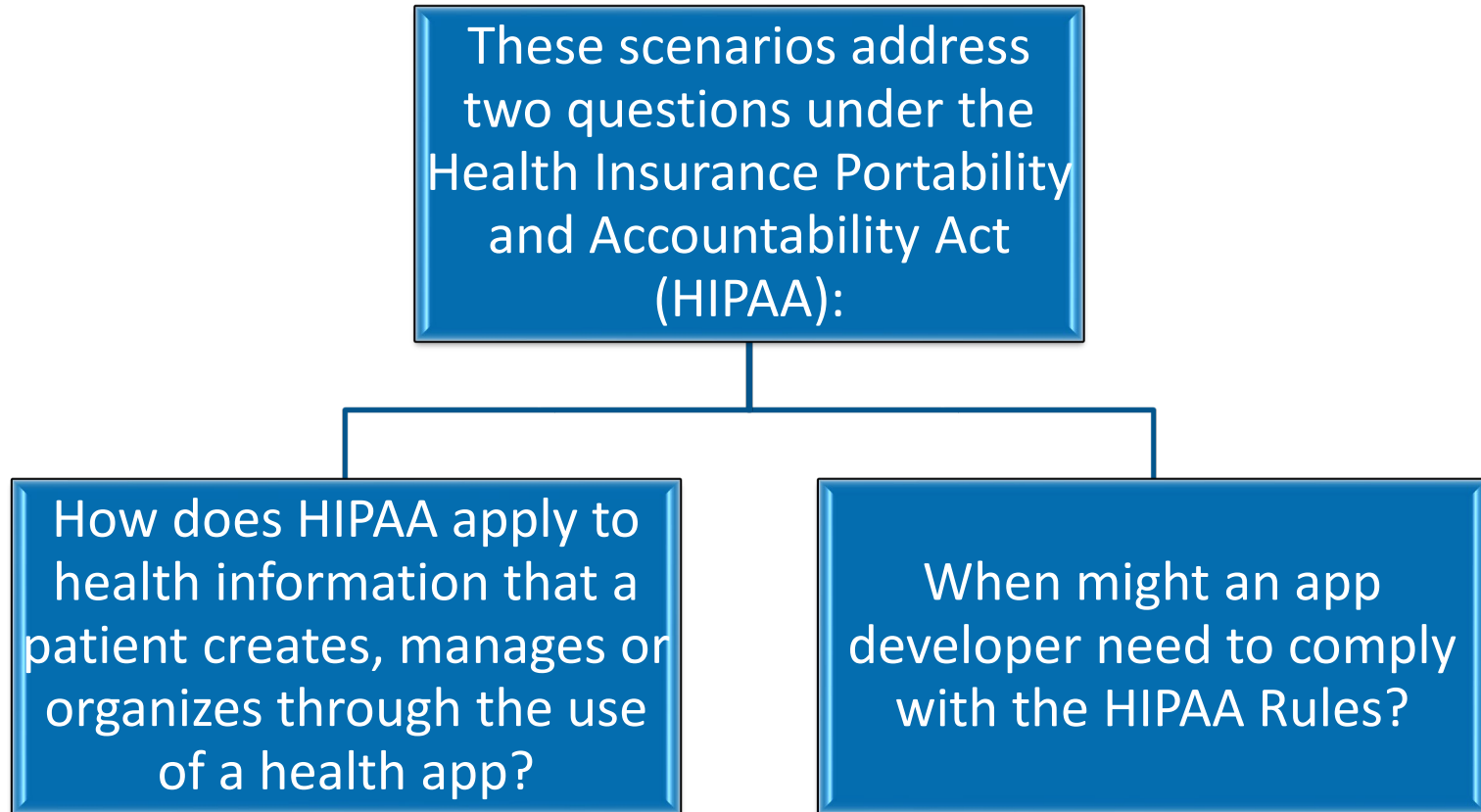
Engage with OCR on issues & concerns related to protecting health information privacy in mHealth design and development

Submit & View Questions

<http://hipaaQsportal.hhs.gov/>

About

Health App Use Scenarios & HIPAA



Questions?

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