

HIPAA Summit

More Data Please!

What is “HIPAA” without a little AI?

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Agenda

What is AI?

When does an AI Vendor becomes a Business Associate?

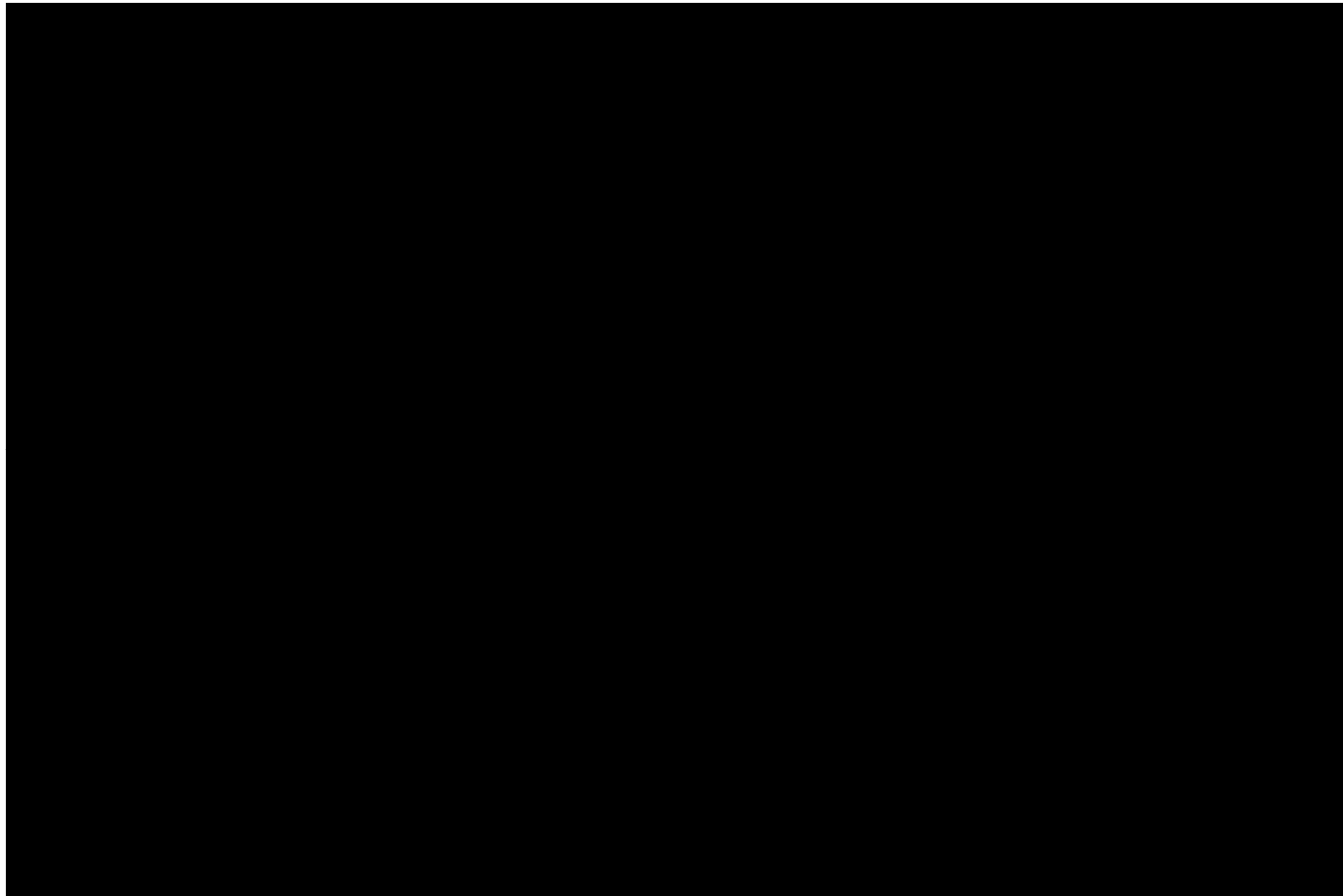
How Does HIPAA Apply to AI?

What is AI?



- Ability of a computer system to deal with ambiguity
- By making predictions using previously gathered data and
- Learning from errors in those predictions
- To generate newer, more accurate predictions about how to behave in the future

Our Vision of AI



AI in Health Care

Voice-activated personal assistants

Chat bots

Clinical decision support

Safety checklists

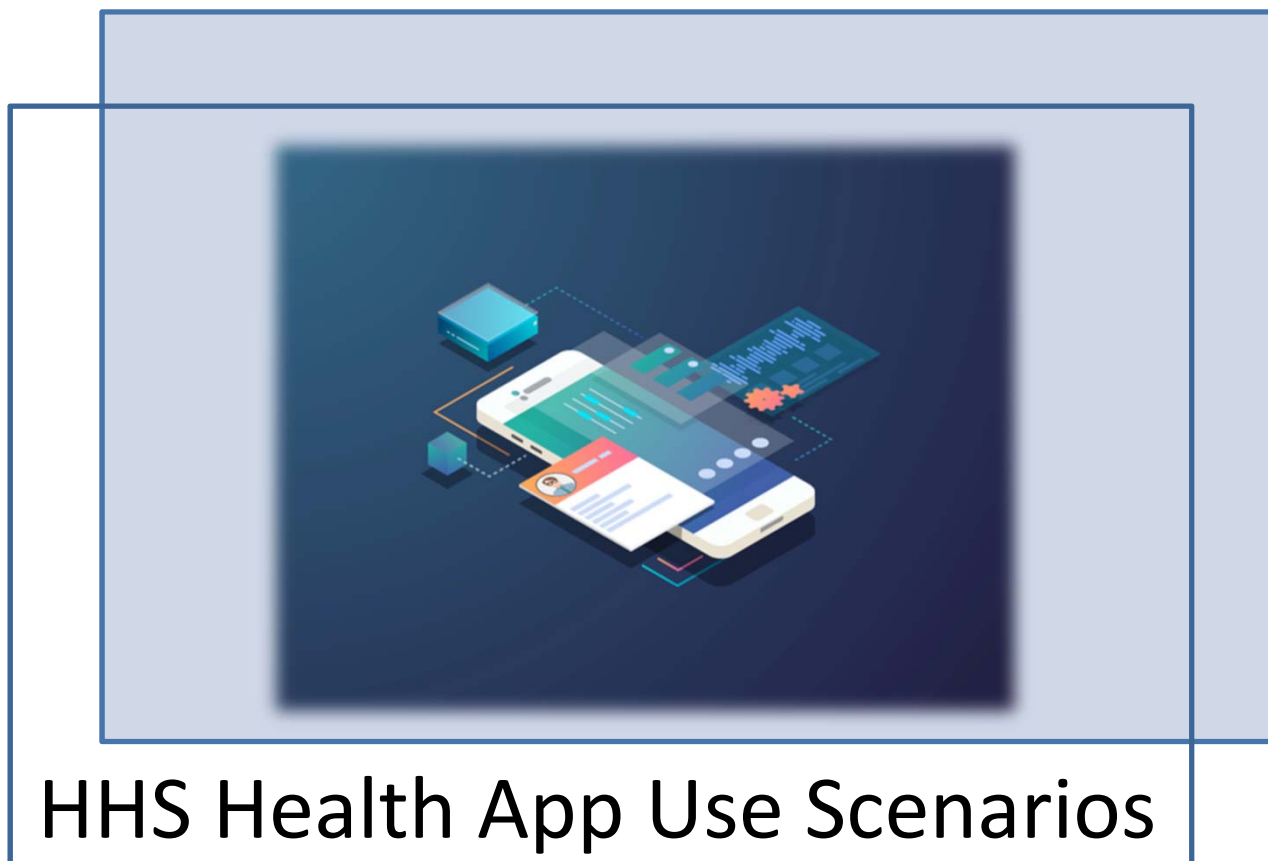
Discharge Instructions

Radiology, MRI, Imaging

Guard against cyber attacks



HIPAA and Health Apps



Developers



Consumer-provided information

Device tracks activity levels
Consumer enters own health information (e.g., weight, BP, glucose levels)

HIPAA does not apply

Patient: not restricted by HIPAA

Developer: not creating, receiving, maintaining, or transmitting PHI on behalf of a covered entity or business associate



Consumer downloads Doctor's information

Information from Doctor's EHR downloaded through a patient portal to consumer's computer and App

HIPAA does not apply to

Patient or Developer
(Doctor must comply with HIPAA)

HIPAA for Developers



Doctor recommends an App to patient. Patient downloads app information to smartphone and sends information to Doctor

HIPAA does not apply to Patient or Developer

(HIPAA applies to Doctor)

- Doctor instructs patient to download an App
- Doctor contracts with Developer for patient management services – remote health care counseling, monitoring of patient’s diet and exercise
- Information inputted by patient automatically becomes part of the Doctor’s EHR

HIPAA applies

Developer is business associate of Doctor

Both Doctor and Developer are covered by HIPAA

HIPAA does not apply to Patient



Determining HIPAA Applicability to AI



Who?



What?



How?



Why?

Who?

Is a Covered Entity or Business Associate Involved?

- Covered Entities
- Business Associates
- Subcontractor Business Associates
- Verify Hybrid Entity Status
- As opposed to only consumers



What?

Is Protected Health Information (PHI) Involved?

- PHI:
 - Individually identifiable
 - In any media
 - Includes demographic information when tied to health care

versus

- De-identified information
- or
- Non-PHI



How?

Use of PHI

What is a “Use” under HIPAA?

Comment: One commenter observed that the definition [of “use”] could encompass the **processing of data by computers** to execute queries. It was argued that this would be highly problematic because computers are routinely used to identify subsets of data sets. It was explained that in performing this function, computers examine each record in the data set and return only those records in the data set that meet specific criteria.



How?

Use of PHI

What is a “Use” under HIPAA?

Comment (cont’d): Consequently, a human being will see only the subset of data that the computer returns. Thus, the commenter stated that it is only this subset that could be used or disclosed.

Response: We interpret “**use**” to **mean** only the **uses of the product of the computer processing, not the internal computer processing that generates the product.**

Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,629 (Dec. 2000).



How?

Disclosure of PHI

But ...

In a ransomware attack, a breach has occurred because the ePHI encrypted by the ransomware was acquired (i.e., unauthorized individuals have taken possession or control of the information), and thus is a “disclosure” not permitted under the HIPAA Privacy Rule.



How?

Use and Disclosure of PHI



Even if AI processing is not a “use,” most AI projects involve some human review of data:

- Initial categorization (e.g., initial identification of whether image includes a tumor, from which the AI will learn).
- Quality control of AI’s output

Why?

Finding a Permissible Purpose

- HIPAA is a Stop Sign
- No use or disclosure of PHI
- Unless specifically permitted or required



Why?

Purpose of Use or Disclosure

Treatment

- Examples: AI assistance with
 - Diagnosis
 - Capturing treatment notes
 - Discharge/maintenance support



Payment

- Examples: AI assistance with
 - Coding
 - Making payments



Why?

Purpose of Use or Disclosure

Health care operations

- Example: AI assistance with analysis of patient population for quality improvement



Research

- Example: Examining how AI can improve health outcomes



Why?

Potential Permissions under HIPAA

Health care operations vs. Research



- “Health care operations” includes “[c]onducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose ...”
- “Research” is: “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Bottom line: Is the primary purpose to contribute to “generalizable knowledge”?

But: What about product development but not publication?

Why?

Health Care Operations v. Research



Follow the money:

- Covered entity $\xrightarrow{\$}$ AI developer
 - Supports that AI developer is supporting CE's health care operations
- AI developer $\xleftrightarrow{\$0}$ Covered entity
 - Harder to claim that the AI developer's primary purpose is the CE's health care operations
- Covered entity $\xleftarrow{\$}$ AI developer
 - Suggests developer is focused on developing the AI (and its intellectual property) and could raise sale-of-PHI implications

If HIPAA Applies...

- Include AI as part of risk analysis/risk management
- AI vendor likely is a business associate
 - New to HIPAA?
 - Jump through HIPAA Loops
- Business associate agreement, other contract
- Don't forget about other business associates (such as Cloud Service Providers)



On the Horizon

- Executive Order on AI
- NIST to set “appropriate technical standards” for AI
- 5 Principles – The U.S. must:
 - Drive technological breakthroughs in AI
 - Drive standards & reduce barriers
 - Foster public trust
 - Train
 - Promote an international environment supporting AI research





Thank You

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