

## **Looking For Will Robinson – Artificial Intelligence In Senior Care**

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## Outline Of Topics

- Artificial Intelligence (AI) in Public Health
- Legal Issues - Health Insurance Portability and Accountability Act (HIPAA) and the Wire Tap Act
- AI Innovations

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## Outline Of Topics

- 21st Century Act
- ONC Interoperability and Information Blocking
- Interoperability and Privacy
- Best Practices

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## AI - Public Health As An Example

- AI System algorithms adapt to new information learning and teaching through input and output
- Hospitals and states utilizing symptom checkers - e.g. PA DOH, CDC and Partners Healthcare (hospital conglomerate)
- Early disease detection and geographic intelligence
- Covid-greater scrutiny for LTC

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## AI - Public Health As An Example

- LTC facility residents are older, have more chronic medical problems
- Live in close proximity to each other
- LTC facility staff can introduce infectious agents to residents from the community as well as within the facility from an infected to a noninfected resident
- Delays in identifying, isolating and medically managing potentially infectious residents can lead to the spread of infection
- Visitors such as family members, volunteers and clergy can unwittingly introduce infections from the community into the nursing home

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## AI Can Address These Issues

- Screening of visitors and staff for infection - Using a combination of screening questions, biometrics and vital signs, AI systems are able to predict infections 48 hours before symptoms appear
- Early detection of infection in residents - AI has the potential to predict infections well before symptoms manifest themselves reducing the transmission risk. Particularly valuable for residents who may not be able to recognize early signs of infection because of cognitive impairment

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## AI Can Address These Issues

- Telemedicine - Telemedicine allows a clinician to make an assessment and initiate treatment. AI could also provide an algorithm, tailored specifically to nursing home residents, which would assist clinicians in accurate and early diagnosis, testing and treatment
- Companionship - LTC facility residents who are unable to have visitors are at high risk for depression, anxiety, and other mental health issues. AI systems that offer companionship have the potential to provide for residents who are isolated and unable to have contact with their families and friends

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## AI - Current Daily Technology

- Google Home, Alexa, Siri . . . and now, introducing:
  - **Orbita** – automated homecare companion engaging with a caregiver or resident care in any number of healthcare scenarios, such as medication adherence or check-ins with caregivers
  - **Pillo** – wakes up on its own to notify of time to take their medicine. A resident must verbally respond to Pillo's questions for the correct medication and the proper dose to dispense. If a patient has questions about whether to take the medication with food or at a specific time, can submit or flag for caregiver
- Are they HIPAA Compliant and what does that mean? Are BAAs in order if the facility is using a device and the related cloud storage?



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## Uses

- Turning on machines
- Playing music
- Making lists
- Setting alarms
- Accessing real-time information
- Providing health care services
  - Medicine monitoring and prompting
  - Assisting physicians in taking notes
  - Allowing patients to access their medical information
  - Allowing remote monitoring
- Collecting, compiling and manipulating data

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## How It Works

- To engage the Amazon Echo or “Alexa”, the user has to say a “wake phrase,” such as “Alexa” or “Amazon”
- The device is always passively listening for this wake phrase; once it detects the wake phrase, it begins recording the user’s question
- The question is then transmitted to Amazon’s cloud storage, where it is deciphered and a reply sent back to the user
- The device does not begin recording until it detects the wake phrase. Therefore, although the device is not recording everything that happens around it, it is listening for the wake phrase
- The user knows that his voice is being streamed to the cloud because the light ring at the top turns blue



## How It Works

- The device can also be programmed to play a “wake up sound” after it detects the wake phrase which alerts the user that it is recording and streaming
- Transmission of the voice recordings (i.e., saying the wake phrase and the subsequent question or request) to the cloud is encrypted
- Recordings are stored in the cloud and can be deleted by the user
- It is possible to turn off the device’s microphone; however, this removes the most useful functionality (i.e., hands-free operation) and likely would obviate the family’s desire to have the resident utilize the Echo, not to mention being potentially difficult for the resident to use because the button is relatively small

## Issues

- In Pennsylvania the biggest concern is the Wiretapping Statute
- Advance consent would need to be obtained from anyone who will be recorded
- Risk of accidental recordings being created
- HIPAA implication
- Practical issues and difficulties in assuring compliance may outweigh the benefit of having the device

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## HIPAA And The Wiretap Act



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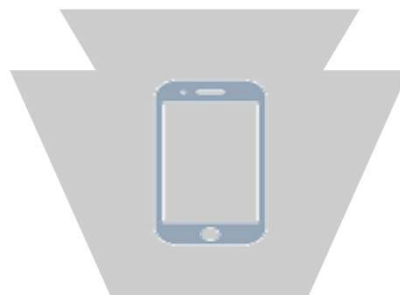
## HIPAA

- Nursing facilities are covered entities
- Resident's information, both visual and audio, is protected
- Allowing a resident to be audio recorded without consent violates HIPAA
- However, it would be prudent to include a paragraph about voice activated device use in the Notice of Privacy Practice and post signs wherever cameras are in use

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## Pennsylvania's Wiretap Act

- Prohibits intercepting/recording an electric or oral communication
- Unless all parties to the communication have given prior consent



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## Requests From Residents For Devices

- Need a policy and need to implement consistently
- Consider addressing in the NPP
- Facility is not required to accommodate these requests
- Consider Residents Rights and the new Federal Rules

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## Expectation of Privacy

- Private Cause of Action
- Pennsylvania - Is there a reasonable expectation of privacy?
- Pennsylvania common law is that an action for invasion of privacy may only be brought if there is a reasonable expectation of privacy

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## Intrusion

- Intentional interference (physical or otherwise)
- Based on the solitude or seclusion of another or his private affairs or concerns
- Must be substantial and “highly offensive” to the “ordinary, reasonable person”

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# amazon

April 5, 2019

**Amazon announces HIPAA-compliant skills for Alexa, with senior living parent companies in the mix**



Lois A. Bowers

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The Alexa-enabled Amazon Echo Dot.

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## Amazon Wants You to Use Alexa to Track Health Care Artificial-intelligence assistant meets privacy rules, giving device a potential daily role with patients



New features let Alexa schedule urgent-care appointments, check health-insurance benefits, read blood-sugar results and handle other health-care tasks. PHOTO: STEPHANIE AARONSON/THE WALL STREET JOURNAL; ISTOCK



## 'ALEXA, FIND ME A DOCTOR': AMAZON ALEXA ADDS NEW MEDICAL SKILLS

Amazon's voice assistant can now manage people's sensitive health information, which represents an important step for the company into the \$3.5 trillion health care sector. As of last Thursday, consumers will be able to use about half a dozen new Alexa health skills to ask questions such as "Alexa, pull up my blood glucose readings" or "Alexa, find me a doctor," and receive a prompt response from the voice assistant. Amazon is able to add these skills because Amazon can now sign business associate agreements with health providers under HIPAA, which means third-party health developers who follow certain guidelines can meet the rules and requirements that govern how sensitive health information is transmitted and received.

## Questions...

- What is your experience, either personally or in your organization, with these devices?
- What are the risks/benefits of these devices, and do the risks outweigh the benefits?
- Is there a difference in living setting – i.e., residential living vs. personal care/healthcare?
- How are these devices different than an iPhone/iPad in terms of privacy risk?
- How do they really work?

## Innovation

- CMS announced the Artificial Intelligence Health Outcomes Challenge on March 27, 2019, in collaboration with the American Academy of Family Physicians and Arnold Ventures, to provide an opportunity for innovators to demonstrate how AI tools, such as deep learning and neural networks, can be used to predict unplanned hospital and skilled nursing facility admissions and adverse events based on Medicare Fee-for-Service Parts A and B administrative claims data

## Innovation

- Strong, Diverse Participant Interest
  - The AI Challenge attracted applicants from across the health care and AI communities – small and large, for-profit and non-profit, traditional players and newcomers. CMS received more than 300 applications to participate in the competition
  - The 25 organizations who qualified to take part in the first round included data science specialists, health systems, diversified consultants, academics, and large U.S. multinational companies

## Innovation

- Impressive Participant Submissions
  - In the second round of the competition, the seven finalists submitted predictive algorithms for 12-month mortality of Medicare beneficiaries, and further developed their first-round forecasts of unplanned hospital and skilled nursing facility admissions, and adverse outcomes
  - The top competitors generated predictive algorithms with outstanding accuracy scores, particularly considering the limited data set used to train and test their algorithms. Accuracy metrics included industry standard measures, such as area under the ROC curve, calibration, and precision

## Innovation

- Winner
  - Participant: ClosedLoop.ai - a health care data sciences
  - Geographic Location: Austin, Texas
- Runner-Up
  - Participant: Geisinger – an integrated health system
  - Geographic Location: Danville, Pennsylvania

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## 21<sup>st</sup> Century Cures Act

- Passed in 2016 after ONC “Report on Information Blocking” indicated that market and economic conditions were creating incentives for some persons and entities to unreasonably limit access to electronic health information
- Calls for all electronically accessible health information to be accessed, exchanged, and used “without special effort on the part of the user”

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## ONC Interoperability, Information Blocking, And ONC Health IT Certification Program Final Rule (ONC Final Rule)

- Specifies a standardized core clinical data class set that must be used by certified health IT developers (U.S. Core Data for Interoperability (“USCDI”) Standard, v. 1)
- Requires that certified health IT developers adopt standardized application programming interfaces (APIs)
  - This is a type of technology that is the foundation of smartphone applications that enables seamless, user-friendly data exchange
  - The application should be free of cost for the patient and provide a secure and trusted connection with the third-party application requesting data, including authentication and authorization

## How Do APIs In Healthcare Work?



## How Do APIs In Healthcare Work?

1. A patient downloads the health app of her choice
2. The patient logs into the app and creates a username and password for the app
3. The patient uses the app to link securely to an API for the health care provider
4. The app sends a request to the provider asking for access to the patient's medical records
5. The health care provider's server validates the request coming from its API, fulfills the criteria, and sends back the patient's data in a structured format
6. The patient can now access health information from the app
7. The patient repeats steps 3-6 with other health care providers that have granted access to the app
8. Depending on the app, the patient can now merge the health information from multiple sources, to access all their health information in once place

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## CMS Interoperability And Patient Access Final Rule ("CMS Final Rule")

- Builds on the technical foundation established by the ONC Final Rule
- Implements several major policies designed to promote interoperability with respect to certain CMS-regulated payors
  - MA organizations, Medicaid, CHIP Fee-for-Service plans, CHIP managed care entities, qualified health plans on the federally facilitated exchanges, and certain health care providers



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## CMS Final Rule – Payor Requirements

- Implement and maintain secure, standards-based “Patient Access API” to provide beneficiaries with common set of data including:
  - Claims and encounter data
  - Clinical data (USCDI version 1 data set)
  - Information about formularies or preferred drug lists
  - Compliance deadline is January 1, 2021 (with enforcement discretion until July 1, 2021)

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## CMS Final Rule – Payor Requirements

- Maintain Provider Directory API
  - Compliance deadline January 1, 2021, with enforcement discretion until July 1, 2021
- Exchange clinical data (USCDI version 1 data set) with other payors at the patient’s request (“Payor to Payor Data Exchange”)
  - No specific technology specified
  - Not applicable to state Medicaid or CHIP FFS programs
  - Compliance deadline is January 1, 2022

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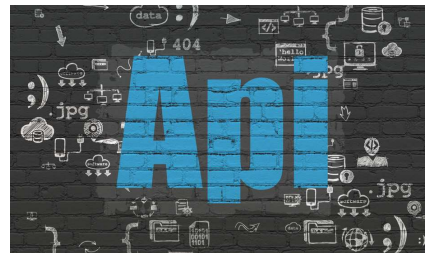
## CMS Final Rule - Provider Requirements

- Requirement that hospitals, CAHs, and psychiatric hospitals send admission, transfer, and discharge event notifications incorporated as a CoP
- Event notifications must convey patient's personal or demographic information, the name of the sending institution, and if not prohibited by law, the patient's diagnosis
- Only applicable to hospitals with the technical capacity to generate notifications (i.e., a system that uses the ADT messaging standard, HL7 2.5.1)

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## CMS Reducing Provider And Patient Burden By Improving Prior Authorization And Promoting Patients' Electronic Access To Health Information Final Rule (CMS Final Rule II)

- Patient Access APIs
  - Covered payors must make information about prior authorization decisions available to patients through Patient Access API
  - Covered payors must obtain attestation from third party apps that certain privacy provisions are included in their privacy policies when the app requests to connect with the Patient Access API
  - Covered payors must report certain metrics regarding patient use of Patient Access API to CMS
  - Effective January 1, 2023



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## CMS Final Rule II

- Provider Access API
  - Certain payors must implement a standards-based Provider Access API that makes patient data available on an individual patient basis
  - The same data that payors are required to make available to patients through the Patient Access API (i.e., claims and encounter data, USCDI v. 1 clinical data, formulary/preferred drug list, and prior authorization request information) must be made available to providers
  - Effective Jan. 1, 2023



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## CMS Final Rule II

- Payor to Payor Data Exchange
  - Extended to state Medicaid and CHIP FFS programs
  - Data exchanged must include USCDI data, claims and encounter data, and information about pending and active prior authorization requests
  - Possibilities for use with AI technologies are endless



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## Interoperability And Privacy



- Interoperability regulations will require a new orientation for providers
- For decades providers have been focused on protecting the privacy and security of EMR; now they will have to devote equal concern to ensuring access to EMR to facilitate the flow of electronic health information
- E.g., information blocking rule may require providers to provide access to PHI in circumstances where HIPAA would not
  - Generally, HIPAA permits, but does not require disclosure of PHI
  - ONC Final Rule also requires providers to take affirmative steps (e.g., making reasonable efforts to provide authorization forms)



## Best Practices – IT Investment

- Investment in IT will be necessary
  - It will be important to:
    - ▶ Standardize data collection and reporting which produces quality data imperative for successful interoperability
    - ▶ Update HIPAA policies (HIPAA permissible disclosures are now required unless an exception applies)
    - ▶ Conduct a Security Risk Assessment
    - ▶ Be proactive with EHI requests
    - ▶ Review fees associated with EHI requests
    - ▶ Revise Business Agreements and Notices of Privacy Practices
- Be sure that all EHI is remaining secure and being transmitted through secure channels

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## Best Practices – Interoperability Strategy

- Health care providers need to determine their interoperability strategy
  - Seek input from all affected stakeholders to avoid potential criticism and more formal challenges in the future
- Consider how to measure success
  - Identify key performance indicators
- Remember that interoperability is an investment in the future and an opportunity to be leaders in the provider market

*Best Practice*

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## Resources

- Medicare Learning Network, "HIPAA Privacy and Security Basics for Providers," available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurity.pdf>
- Federal Register 45 C.F.R. Part 160 and Subparts A and E of Part 16
- Office for Civil Rights ("OCR") Website: <http://www.hhs.gov/ocr/office/index.html>
- CMS AI Health Outcomes Challenge: <https://innovation.cms.gov/innovation-models/artificial-intelligence-health-outcomes-challenge>

## Resources

- HIPAA List Serve:  
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/listserv.html>
- Health Information Privacy Training Resources:  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html>
- CMS Policies and Technology for Interoperability and Burden Reduction:  
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

## Questions?

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