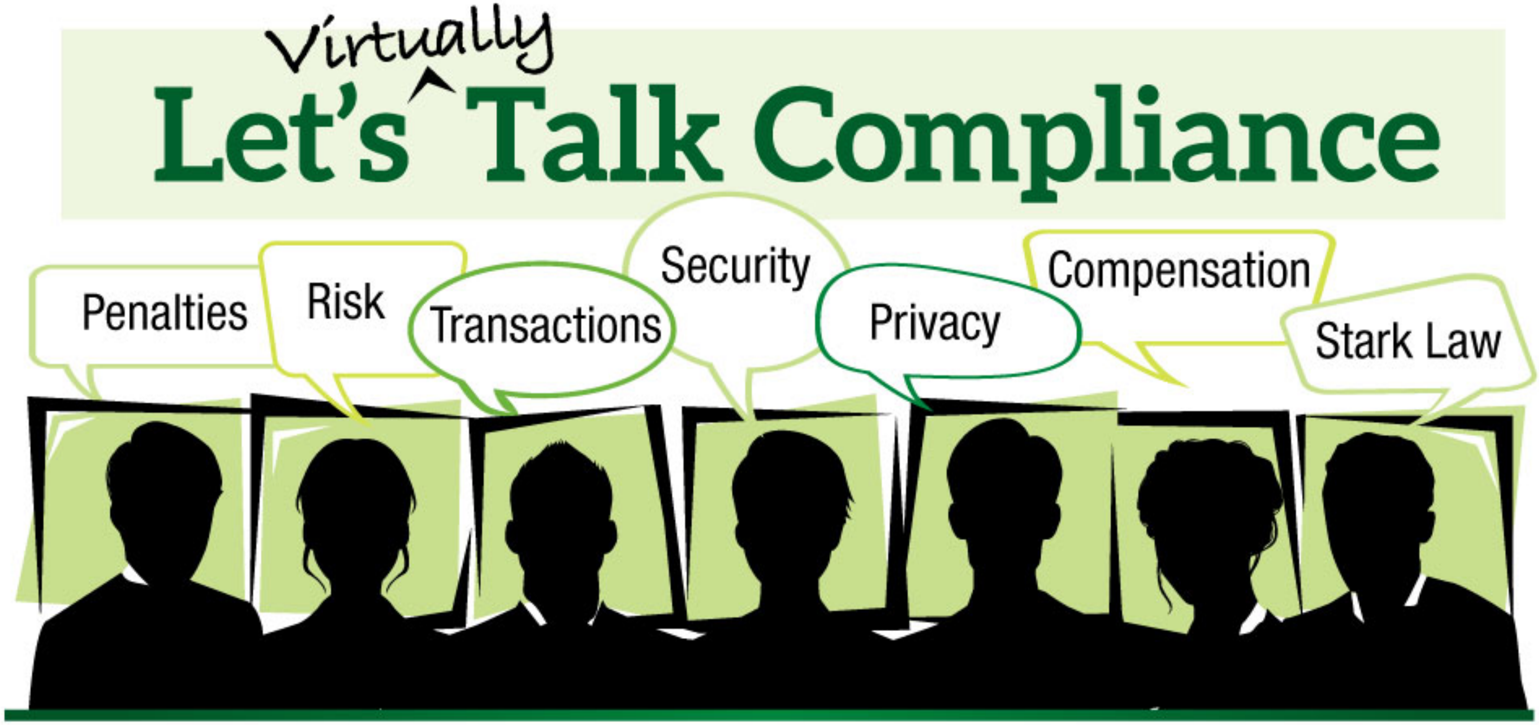
Let’s Talk Compliance

One-Day Compliance Master Class



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Let’s Talk Compliance - Agenda

January 22, 2021	
10:00 a.m. – 11:00 a.m.	**Managing Cybersecurity Threats** *Barry Mathis & Chanley Howell*
11:00 a.m. – 12:00 p.m.	**The Unintended Consequences of Due Diligence** *Lori Foley & Roger Strode*
12:00 p.m. – 12:15 p.m.	**BREAK**
12:15 – 1:00 p.m.	**BROWN BAG LUNCH ROUNDTABLE**
1:00 p.m. – 2:00 p.m.	**Update on the Telemedicine Landscape** *Jackie Acosta & Valerie Rock*
2:00 p.m. – 3:00 p.m.	**Physician Compensation: Hot Topics** *Jana Kolarik & Angie Caldwell*

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SESSION #1

Managing Cybersecurity Threats

Barry Mathis & Chanley Howell

Information Blocking

PENALTY

- Effective Date – April 5, 2021
- OIG is proposing that enforcement of information blocking will not begin until 60 days after its regulation becomes final or date in final rule
- OIG refers health care providers to **appropriate agency for appropriate disincentives**
- Health IT / EHRs – **CMPs** up to $1 million for HIT providers and data networks

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Information Blocking

PENALTY

- Applies to all providers – not just federal program participants
- Future rulemaking. Medicare / federal reimbursement deductions; public “shaming”, False Claim Act liability.

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Information Blocking

21st Century Cures

- Information blocking is a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI).
- Actors
  - Health Care Providers
  - Health IT Developers
  - HINs / HIEs

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HINs / HIEs

- Entity (or has control or discretion over an entity) that
- Facilitates the exchange of EHI among two or more unaffiliated providers for
  - Treatment, payment or health care operations purpose

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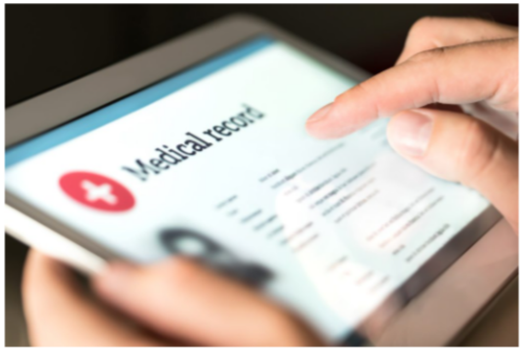
What Data - EHI?

- First 2 Years – Only USDCI Data
- Universe of EHI …
- Medical records, billing records, payment and claims records
- Health plan enrollment records
- Case management records
- Other records used, in whole or in part, by for a covered entity to make

  decisions about individuals



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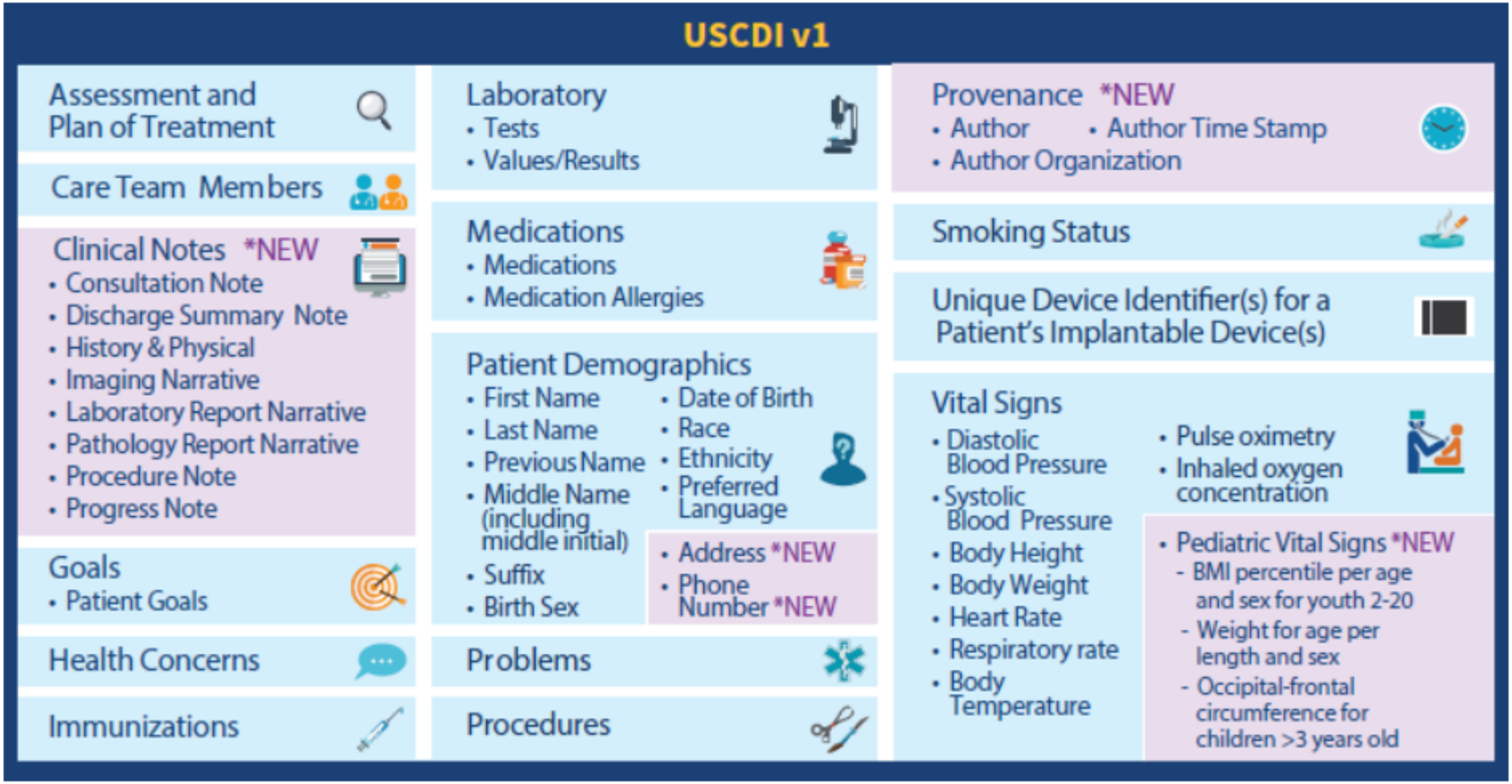
What Data - EHI?

- First two years - EHI access, exchange, and use requirements restricted to the US Core Data for Interoperability (USCDI)
- USCDI - Standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange
- A USCDI “Data Class” is an aggregation of various Data Elements by a common theme or use case



USCDI v1

Assessment and Plan of Treatment

Care Team Members

Clinical Notes *NEW
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns

Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications
- Medication Allergies

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Address *NEW
- Phone Number *NEW

Problems

Procedures

Provenance *NEW
- Author
- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory rate
- Body Temperature
- Pulse oximetry
- Inhaled oxygen concentration
- Pediatric Vital Signs *NEW
  - BMI percentile per age and sex for youth 2-20
  - Weight for age per length and sex
  - Occipital-frontal circumference for children >3 years old

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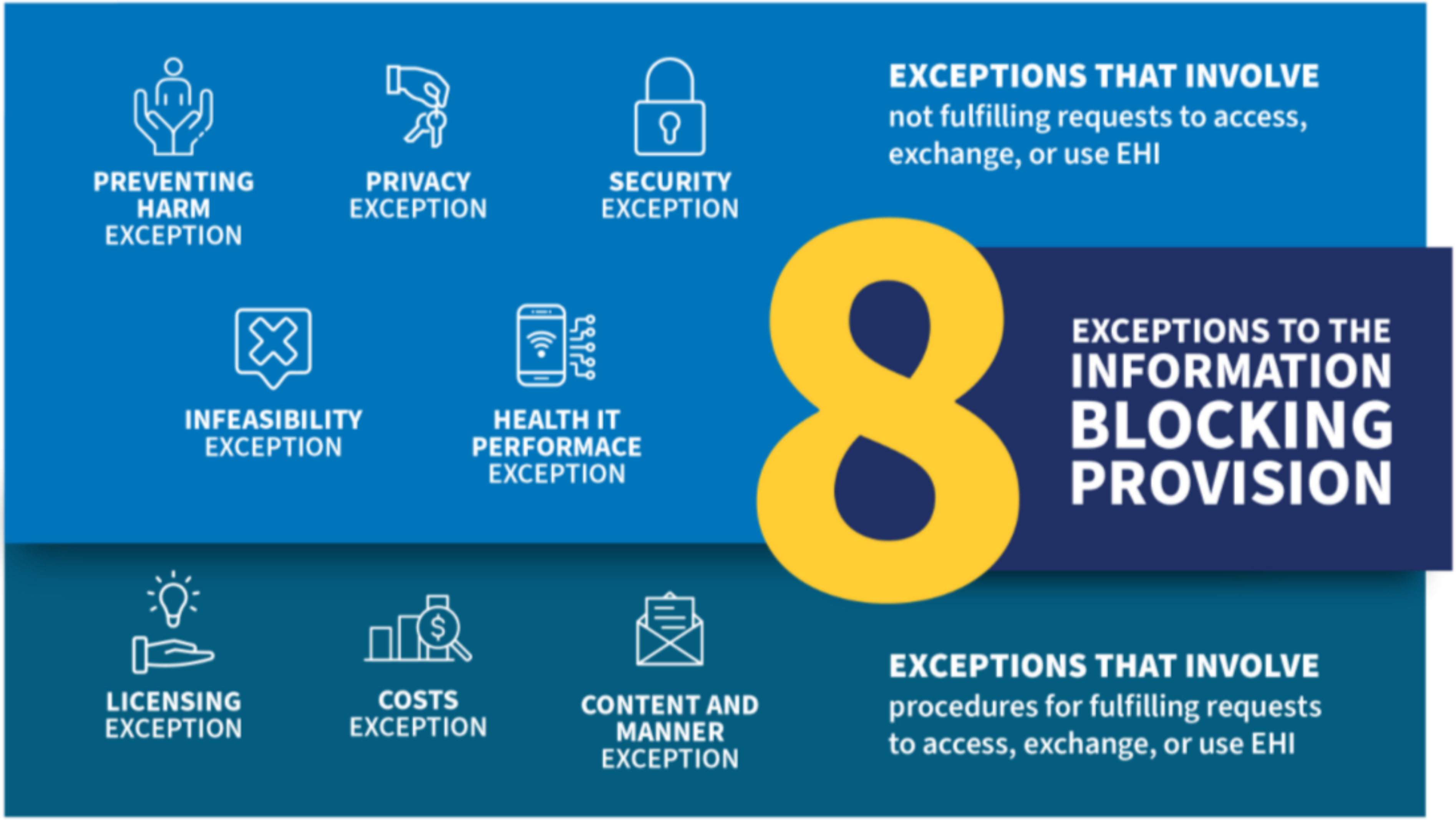

EXCEPTIONS THAT INVOLVE not fulfilling requests to access, exchange, or use EHI

- PREVENTING HARM EXCEPTION
- PRIVACY EXCEPTION
- SECURITY EXCEPTION
- INFEASIBILITY EXCEPTION
- HEALTH IT PERFORMACE EXCEPTION

8 EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION

EXCEPTIONS THAT INVOLVE procedures for fulfilling requests to access, exchange, or use EHI

- LICENSING EXCEPTION
- COSTS EXCEPTION
- CONTENT AND MANNER EXCEPTION

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Practical and Implementation Considerations

- **Turns HIPAA on its head** by requiring health-care providers and their business associates to share data in most instances where HIPAA permits, but does not require, the disclosure
- HIPAA **historically** required business associate agreements to establish permissible uses and disclosures of PHI and to prohibit uses and disclosures not permitted or required by law
- **Now,** when the law **permits** the access to or exchange of EHI, disclosure often will be **required**

Practical and Implementation Considerations

- Rule requires in several places that the policies be implemented in a **consistent and non-discriminatory manner**
- If delay or denial of information may be considered interference, **compliance with an exception** may be necessary to avoid information blocking claims
- The information blocking rule will place **pressure on all actors to streamline their technology and data contracting protocols** for technology tools and data sharing projects involving EHI

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Practical and Implementation Considerations

- Data-sharing projects will be particularly reliant on the **content and manner exception** to fulfill data requests
- Particularly relevant regarding requests from **patients and third parties acting on their behalf, as well as the actor's competitors**
- To the extent the negotiation strategy instead requires reliance on the licensing or fee exceptions, **consider reasonable licensing terms and allowable fees in advance** to streamline your time frames for negotiating license conditions on non-discriminatory terms

Practical and Implementation Considerations

- Covered entities and their business associates should **update their privacy and security policies** and modify their release of information and data-sharing practices that prohibit or delay that data sharing
- In several places, the rule requires that organizational **policies be in writing (for example, in the Preventing Harm, Privacy and Security Exceptions**)

Practical and Implementation Considerations

- Although the ONC notes that the information blocking rule does not itself require actors to violate their business associate agreements and associated service level agreements, actors **cannot use these agreements to limit EHI disclosures in an arbitrary manner**
- Will take time for changes to **work their way through BAAs**
- Consider applicability of BAA language regarding **modifications to laws**

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Telehealth issues

- Remote Patient Monitoring
- Telehealth consent
- Technology platform agreements
- Employer telehealth agreements
- COVID solutions
- Contact tracing

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Telehealth issues

- State telehealth laws
- Privacy and security laws
- Electronic communications (email, text messaging, portals, apps, treatment related, telemarketing)
- COPPA (Children's Privacy)

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Telehealth issues

- Synchronous v. Asynchronous
- Good faith use - Zoom, Teams, FaceTime, etc.
- Website and App Terms of Use
- Privacy policies
- State recording laws

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Update on Cyber Threats for 2021

- **Cyber attackers are targeting the vaccine rollout:** Hacker's are leveraging the COVID-19 pandemic to distribute a series of phishing scams.
- **Plan:** Attackers will purchase domains (fake websites) and craft emails with this in mind. The amount of content, combined with the thirst for knowledge, will set the stage for a further increase in phishing attacks," he said.
- **Objective**: Identity Theft

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Update on Cyber Threats for 2021

- **Mergers, Acquisitions and Expansions targeted:** In 2021, hacker’s activity could cause disruption in operations impacting and potentially undermining deals.
- **Plan**: Attackers will use Business Email Compromise (BEC) attack vectors to embed themselves into the process and seek to ransom information or redirect funds.
- **Objective**: Extortion

Update on Cyber Threats for 2021

- **Weaponized Artificial Intelligence:** Bad actors will likely leverage machine learning (ML) to accelerate attacks on networks and systems
- **Plan**: ML engines will identify patterns in the defenses to quickly exploit vulnerabilities that have been found in similar systems and environments.
- **Objective**: Extortion & Identity Theft

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Update on Cyber Threats for 2021

- **New level of Extortion:** Numerous ransomware strains are now adopting a double-edged, blackmail model that combines extortion with theft.
- **Plan**: In addition to demanding cybercurrency for decrypting files, bad actors are threatening to upload the victims' files publicly, in circumstances of not receiving payments within a specific time frame.
- **Objective**: Extortion & Identity Theft

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Top 5 Ransomwares for 2021

- **Maze**
  - The Maze ransomware encrypts all files and demands for the ransom to recover the files. It threatens to release the information on the internet if the victim fails to pay the demanded ransom.
- **REvil**
  - REvil ransomware gang launched an auction site to sell stolen data (Source: ZDNet)
  - Victim is required to pay the requested ransom in bitcoin. If the victim fails to pay the ransom in time, the demand is doubled.

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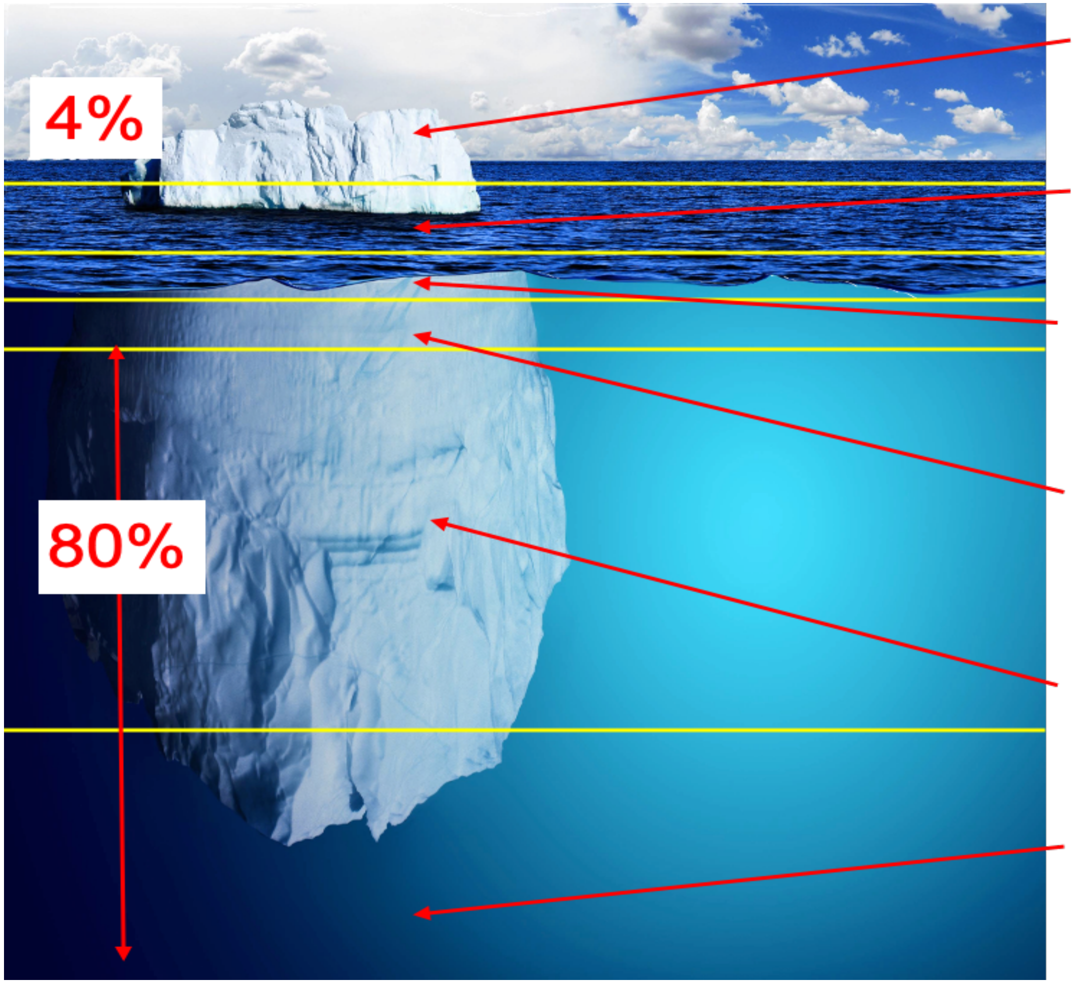
Top 5 Ransomwares for 2021

- **Ryuk**
  - Ryuk uses other malware to infect a system. It either uses TrickBot or other means like Remote Desktop Services to gain unauthorized access to a system. It uses robust military algorithms such as **RSA** and **AES** to encrypt files using a unique key for each executable.
- **Tycoon**
  - This malware is considered as an unusual one as it is deployed in a weaponized version of **Java Runtime Environment**.
  - Major threat for older unpatched systems running Java

Top 5 Ransomwares for 2021

- **NetWalker**
  - NetWalker, also known as Mailto, is one of the newest variants of the ransomware family. Various remote working individuals, enterprises, government agencies as well as healthcare organizations reported being attacked by NetWalker this year.
  - NetWalker ransomware encrypts all the Windows devices that are connected to it using a Visual Basic script attached to COVID-19 emails or an attached executable file.

Brief excursion into the DarkWeb



Level 0: Common Web - YouTube, Facebook, Wikipedia and other famous or easily accessible websites can be found here.

Level 1: -**Surface Web**
This level is still accessible through normal means, but contains "darker" websites.

Level 2: - Bergie Web
This level is the last one accessible without a proxy. Mostly sharing files and apps that violate copyright law, etc.

Level 3: - Deep Web
The first part of this level is accessible only via with proxy. It contains hacking, data for purchase and really bad stuff… Here begins the Deep Web

Level 4: - Charter Web
Things such as drug and human trafficking, banned movies and books and black markets exist there.

Level 5: - **Marianas Web**
You'll be lucky to find anyone who knows about it. Probably secret government documentation

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Reducing the threat

- Recent ransomware attacks show us that hackers aren't going anywhere. What's more, they won't hesitate to take advantage of any difficult situation, even if it's a global pandemic that affects us all.
- Behavioral based protection and Multi Factor access controls are a must.
- Vigilant education monthly if possible.
- Test scenarios and annual risk analysis.

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Reducing the threat

- According to industry predictions, almost six ransomware attacks will occur every minute in 2021.
- These projections exclude attacks on individuals and focus on businesses.
- Cyber attacks should be treated like a fire on a submarine. Organizations should plan to be attacked and learn to react decisively to minimize the damage and recover quickly.

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Thank you.

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Barry has nearly three decades of experience in the information technology (IT) and healthcare industries as a CIO, CTO, senior IT audit manager, and IT risk management consultant. He has performed and managed complicated HIPAA security reviews and audits for some of the most sophisticated hospital systems in the country. Barry is a visionary, creative, results-oriented senior-level healthcare executive with demonstrated experience in planning, developing, and implementing complex information-technology solutions to address business opportunities, while reducing IT risk and exposure. He is adept at project and crisis management, troubleshooting, problem solving, and negotiating. Barry has strong technical capabilities combined with outstanding presentation skills and professional pride. He is a prudent risk taker with proficiency in IT risk management, physician relations, strategic development, and employee team building.

Barry is a member of United States Marine Corps, Health Care Compliance Association, Association of Healthcare Internal Auditors, Healthcare Information Management Systems Society and Information Systems Audit and Control Association. He was an Honor Graduate in Systems Programming from the United States Marine Corps Computer Sciences School (MCCDC) in Quantico, VA. He is a Certified COBOL Programmer, a Certified Database Management Specialist, and a Certified Cyber Security Framework Practitioner.

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Chanley T. Howell is a partner and intellectual property lawyer with Foley & Lardner LLP, where his practice focuses on a broad range of technology law matters. He is a member of the firm's Technology Transactions & Outsourcing and Privacy, Security & Information Management Practices and the Sports, Health Care and Automotive Industry Teams.

While Chanley handles these types of engagements across all industries, he has particular expertise in the health care, telemedicine / telehealth, financial services, automotive, and hospitality industries.

In recognition of his experience, Chanley has been Peer Review Rated as AV® Preeminent™, the highest performance rating in Martindale-Hubbell's peer review rating system and in 2011-2014 and 2016, *The Legal 500* recognized Chanley for his work in technology: data protection and privacy. In 2014, he was named one of Jacksonville's "Top Lawyers" by *904 Magazine*.

Chanley is a certified information privacy professional/US (CIPP/US), certified by the International Association of Privacy Professionals.

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