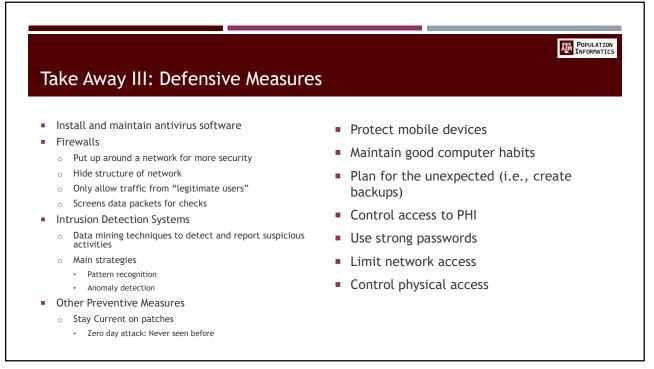
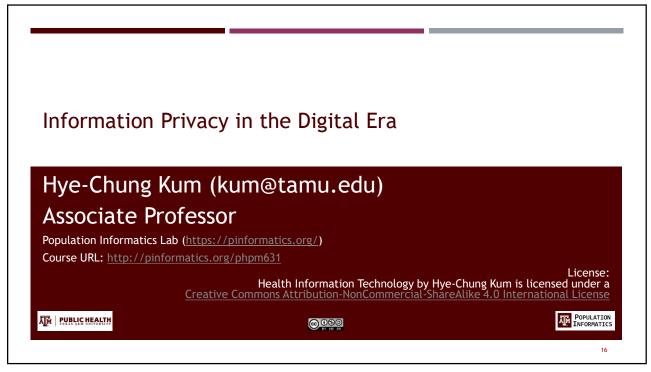


POPULATION INFORMATICS

Take Away II: Encryption

- Secret key cryptography: Based on a secret key
 - $_{\odot}~$ Same secret key used for encryption and decryption
 - Problem: How to transmit key securely on the Internet???
- Public key cryptography: Two keys used
 - $_{\odot}~$ Public key known to everybody. Used for encryption.
 - $_{\odot}~$ Private key known only to owner. Used for decryption.
 - o Reliable public key distributed
 - This is the most difficult problem!
 - Public Key Infrastructure (PKI): certification services (trusted site)

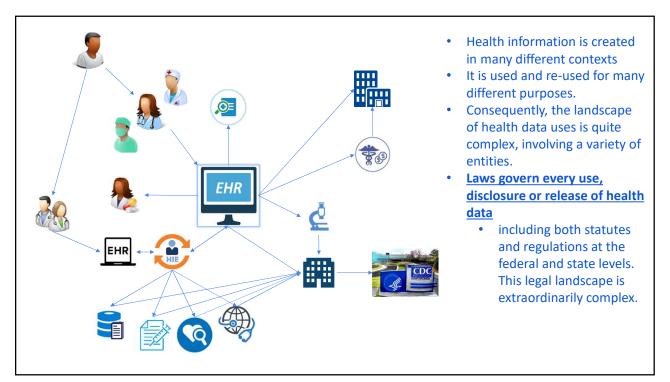






THE HEALTH DATA LANDSCAPE

How is health data used?



Objectives of This Lecture

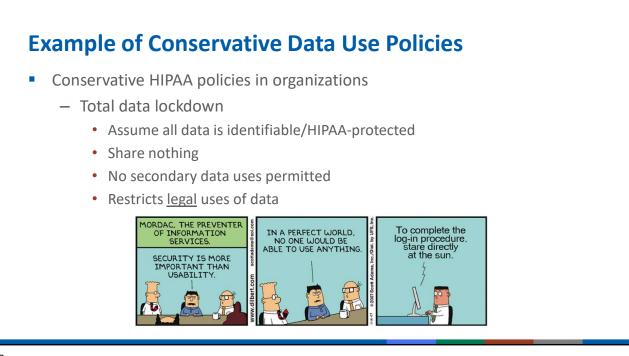
- We want to give you a basic understanding of a few legal issues that you will likely come across in your career.
- We want you to be more comfortable engaging in your legal counsel to identify legal tools that will help you accomplish your objectives
- We want to empower you to work with legal counsel to think creatively about technological solutions to legal barriers

20

Actual and Perceived Legal Barriers to Data Use and Release

- There are many "perceived" legal barriers to data use and release
 - Not all are actual legal prohibitions
- Three approaches to perceived barriers
 - Identify conservative data use policies that may need to be addressed
 - Identify legal solutions
 - Identify technological solutions

Require an understanding of underlying legal framework. Your attorney is your friend!





Examples of Technological Solutions to Perceived Barriers

- Distributed database querying
 - Allows custodians to maintain custody of health data
 - Allows researchers to query distributed database network for aggregated results
 - No personally identifiable data is obtained
- Differential privacy
 - Adds random "noise" to datasets to limit re-identification of individuals
 - Maintains some aggregate query functionality
- Controlled Selective Partial Disclosure with Accountability

24

Controlled Selective Disclosure with Accountability in Patient Matching

				Privacy ris	sk: 6.9% + 39	6		
Pair	ID	FFreq	First name	Last name	LFreq	DoB(M/D/Y)	Sex	Race
1	******	(1)	~	******	1	** /** /**@@	~	() ()IFF
	***	1	~	****	1	**/**/**	~	&
Pair	ID	FFreq	First name	Last name	LFreq	DoB(M/D/Y)	Sex	Race
1	*****27**	(1)	~	******	(1)	**/**/**06	М	Q. DIFF
	****************	1	~	****	(1)	**/**/**60	М	&
Pair	ID	FFreq	First name	Last name	LFreq	DoB(M/D/Y)	Sex	Race
1	8000002767	1	JUDE	WILLIAM +	1	09/09/1906	м	W
	8000003567	(1)	JUDE	WILLIAM JR	(1)	09/09/1960	M	В

Privacy, Confidentiality, Security, and Authorization

Untangling the Legal Issues

26

Untangling the legal issues

- Four interrelated legal issues
 - Privacy
 - Confidentiality
 - Security
 - Authorization
 - AKA Consent in some circumstances (e.g., HIPAA)
- These are often incorrectly used interchangeably
 - They are <u>not</u> the same!

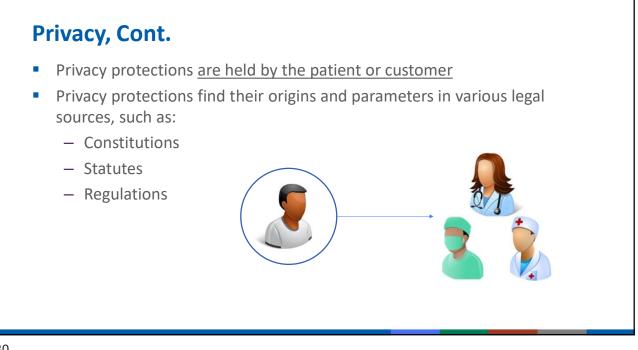
Privacy, Confidentiality, Security, & Authorization

- Each is very different in the eyes of the law
 - Different laws shape the issues for each concept
 - Examples:
 - HIPAA Privacy Rule
 - Doctor-Patient Privilege
 - HIPAA Security Rule
 - The Common Rule regulations on informed consent

28

Privacy

- "[A] set of protections against a related cluster of problems."
 - Daniel Solove, Understanding Privacy
- What sort of problems?
 - Surveillance
 - Insecurity
 - Identification
 - Secondary use
 - Exclusion
 - Aggregation
 - Disclosure



Confidentiality

- A duty or responsibility that is held by a person that receives information
- Like privacy, the origins and parameters of duties of Confidentiality are found in various legal sources, such as:
 - Constitutions
 - Statutes
 - Regulations





Confidentiality, Cont.

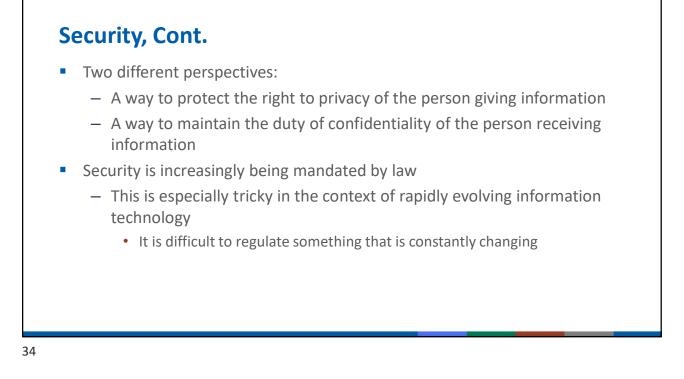
- A duty of confidentiality can apply to various entities, including:
 - Doctors
 - Nurses
 - Healthcare facility employees
 - Health department officials
 - Researchers
- A duty may not be explicit in the law
 - Ex: A statute that says information shall be held confidentially might attach a duty of confidentiality to custodians of the information.



32

Security

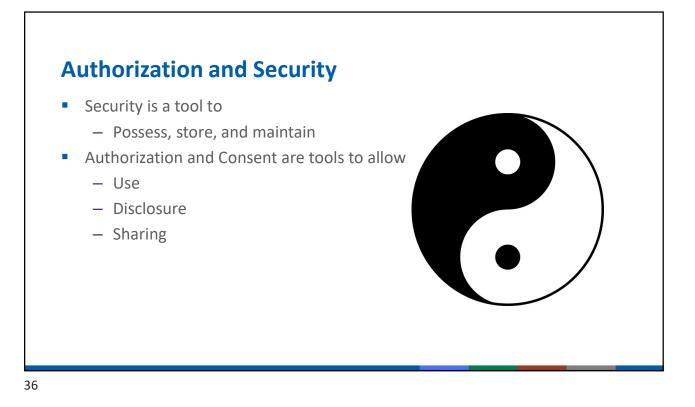
- Different from Privacy and Confidentiality
 - Privacy = A right conferred by law
 - Confidentiality = a duty of a person or entity
 - Security = <u>a TOOL</u>



Authorization and Consent

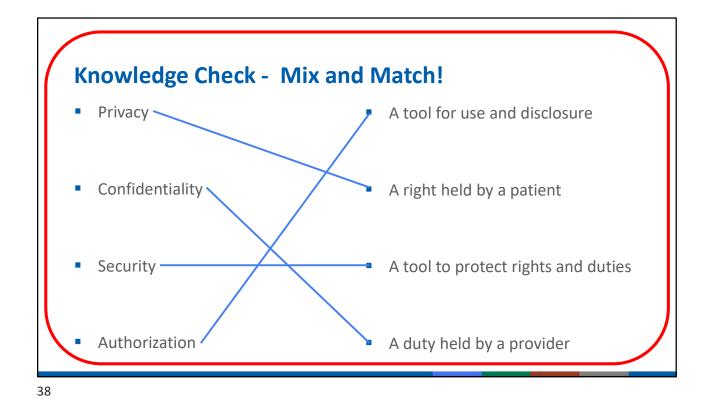
- Authorization and Consent are TOOLS like security
- Tools of
 - Use
 - Disclosure

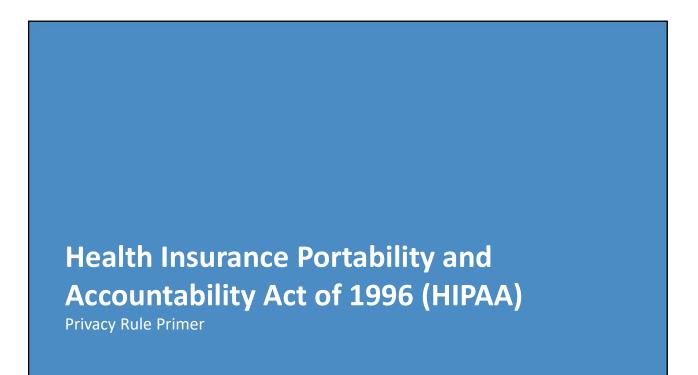


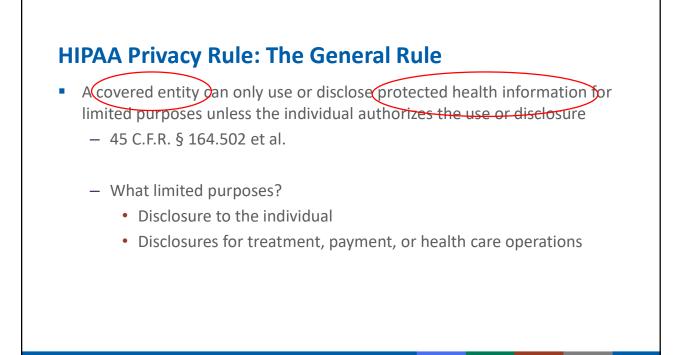


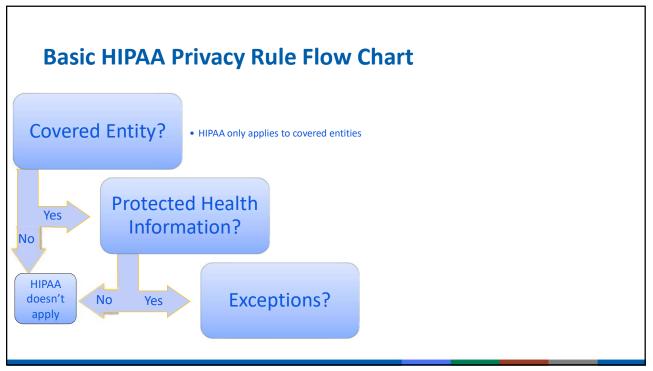
Authorization and Consent, Cont.

- Increasingly nuanced
- Contemporary authorizations often have very specific legal origins
 - May be time limited or revocable
- Important relationship with rules of privacy and confidentiality
- "Informed" consent on complicated concepts
 - Communication, language
 - Use more modern technology to better communication of dynamic information
 - Paper form vs live document via tablet
 - Avatar, simulations





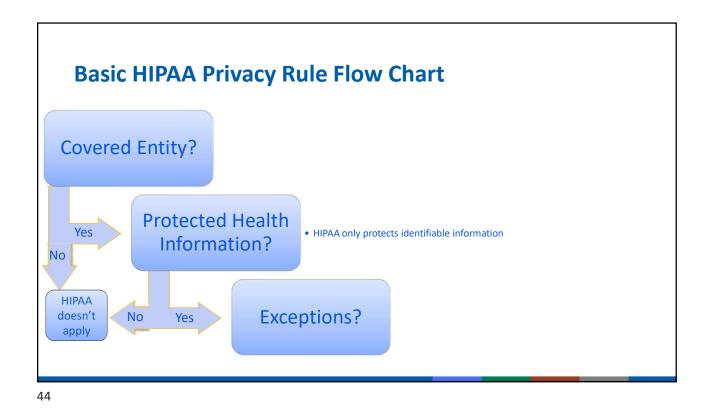


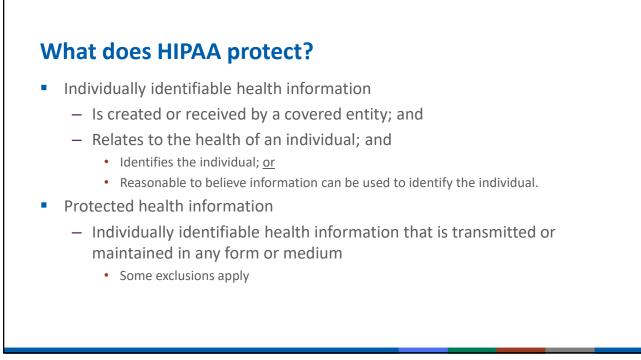


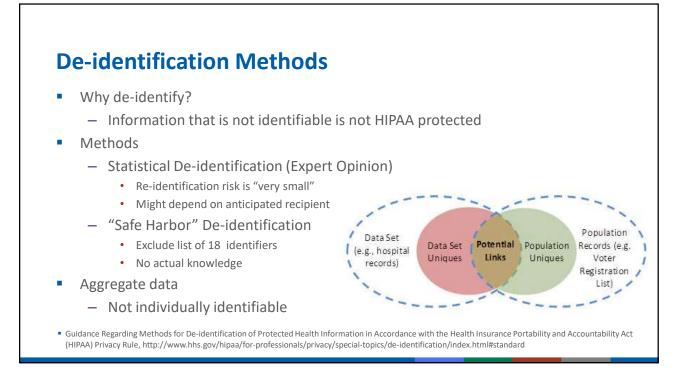
Knowledge Check

- True or False?
 - HIPAA does not apply to public health authorities unless they perform covered functions (e.g., provide healthcare services).
- TRUE!
 - Public health activities are not covered functions under HIPAA
 - However, a public health authority that performs covered functions can choose to be a hybrid entity or a covered entity

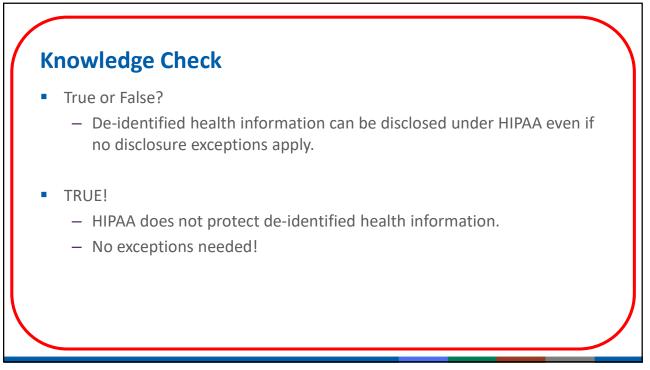
State	HIPAA Status	State	HIPAA Status	State	HIPAA Status
Alabama	L buda mi al	Leuisiana	Covered	Ohia	Lindersial
Alabama	Hybrid	Louisiana	Covered	Ohio	Hybrid
Alaska	Covered	Maine	Other	Oklahoma	Covered
Arizona	Hybrid	Maryland	Hybrid	Oregon	Covered
Arkansas	Covered	Massachusetts	Hybrid	Pennsylvania	Hybrid
California	Covered	Michigan	Hybrid	Rhode Island	Hybrid
Colorado	Other	Minnesota	Other	South Carolina	Hybrid
Connecticut	Hybrid	Mississippi	Covered	South Dakota	Hybrid
Delaware	Hybrid	Missouri	Hybrid	Tennessee	Covered
Florida	Hybrid	Montana	Covered	Texas	Hybrid
Georgia	Covered	Nebraska	Covered	Utah	Hybrid
Hawaii	Hybrid	Nevada	Hybrid	Vermont	Hybrid
Idaho	Hybrid	New Hampshire	Covered	Virginia	Hybrid
Illinois	Hybrid	New Jersey	Hybrid	Washington	Hybrid
Indiana	Hybrid	New Mexico	Covered	Wisconsin	Hybrid
lowa	Other	New York	Hybrid	West Virginia	Hybrid
Kansas	Hybrid	North Carolina	Hybrid	Wyoming	Covered

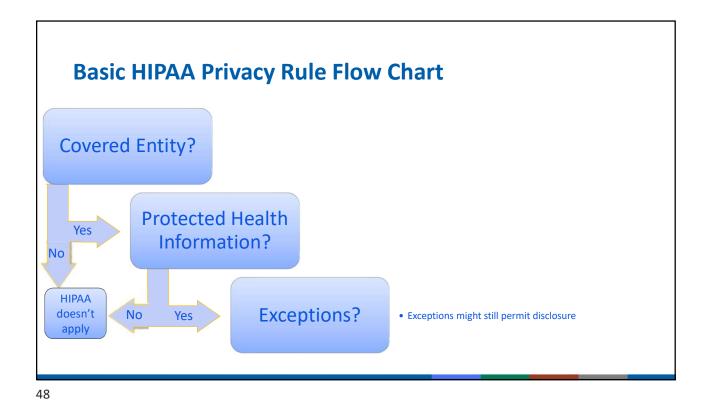
















Scope of HIPAA Disclosures

- Minimum Necessary
- Limited Data Set

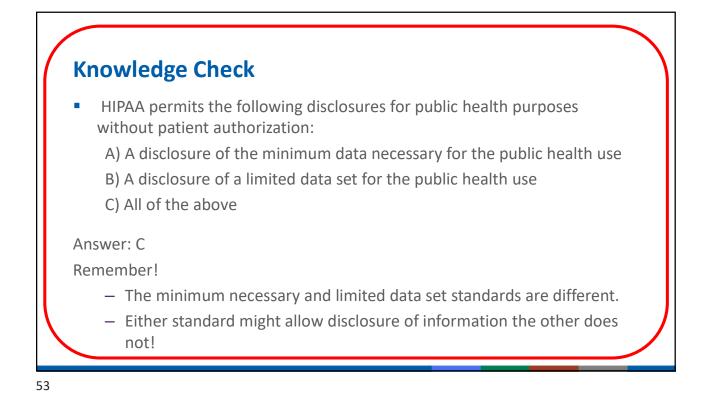
Limited Dataset v. Minimum Necessary

Limited Data set Disclosure

- A specific type of disclosure
- Specific data elements are excluded
- Permitted uses:
 - Research
 - Public health
 - Health care operations
- Requires a Data Use Agreement

Minimum Necessary Standard

- Standard for many permitted HIPAA disclosures
- Get what you need
 - Including data elements that would be excluded from a Limited Dataset disclosure
- Reasonable effort
 - Covered entity may rely (if reasonable) on PH official's representations



Prohibited Data for "Safe-harbor" De-identification	Prohibited Data in Limited Dataset
Names	Names
Telephone #	Telephone #
Fax #	Fax #
Email	Email
SSN	SSN
Medical record #	Medical record #
Health plan beneficiary #	Health plan beneficiary #
Account #	Account #
Certificate/license #	Certificate/license #
Vehicle identifiers	Vehicle identifiers
Device identifiers and serial #	Device identifiers and serial #
Web URLs	Web URLs
IP address #	IP address #
Biometric identifiers, including finger and voice prints	Biometric identifiers, including finger and voice prints
Full face photographic images	Full face photographic images
All geographic subdivisions < State	Postal Address (other than city, state, and zip)
Dates (except year)	
Other unique identifying #, characteristic, or code	
No actual knowledge information is re-identifiable	

Data Use Agreements

Legal Tool for Disclosing Health Data

Data Use Agreements (DUA)

- Formal written agreements between two or more parties
- Tools to
 - Constrain use of data after it has been disclosed
 - Constrain additional disclosure
 - Ensure rights and obligations are maintained
 - Parties (e.g., CDC, Health Departments, Healthcare providers)
 - Stakeholders (e.g., patients)

56

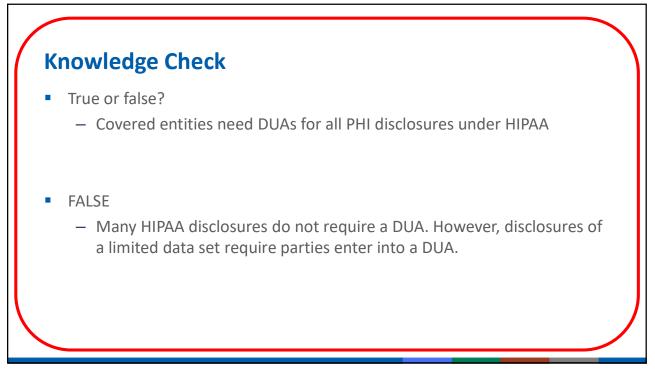
When should you consider a DUA?

- Whenever you want to disclose data, and
 - You are concerned about the future use and disclosure of your data
 - You are required by law to enter a DUA to disclose the data
 - E.g., A limited data set disclosure under HIPAA
- <u>DUA's are not required for every disclosure</u>
 - E.g., Public health disclosures for outbreak response
 - Unnecessary DUA negotiations may delay necessary response

Contents of a Limited Data Set DUA

- Establish
 - Permitted uses and disclosures of the data
 - Who is permitted to use or receive the data
- Provide that data recipient will
 - Not use or disclose data other than permitted by DUA or required by law
 - Use appropriate safeguards
 - Report unauthorized disclosures
 - Ensure any agents to whom the recipient provides the data agree to the same restrictions and conditions
 - Not identify the information or contact the individuals

45 C.F.R. § 164.514(e)(4)(ii)



Limited Data Set DUA Activity

- Task: Identify the following terms of the example DUA
 - A. Permitted uses and disclosures of the data
 - B. Who is permitted to use or receive the data
 - C. No use or disclosure other than permitted by DUA or required by law
 - D. Use of appropriate safeguards
 - E. Reporting of unauthorized disclosures
 - F. Application of DUA to other entities whom the recipient provides the data
 - G. No identification of the individuals or contact of the individuals

